Global Affairs Canada | Affaires mondiales Canada
125 Sussex Drive
Ottawa ON K1A 0G2

April 21, 2022

Ms. Erica Pereira
Clerk of the Committee
Standing Committee on Foreign Affairs and International Development
House of Commons
131 Queen Street, 6th Floor
Ottawa ON K1A 0A6

Dear Ms. Pereira:

Pursuant to the Committee's motion adopted on April 4, 2022, regarding the provision of documents pertaining to the study of vaccine equity and intellectual property rights, please find uploaded on the House of Commons SharePoint site the requested documents from Global Affairs Canada.

Global Affairs Canada applied limited redactions for commercially sensitive information, and personal information. As well, the department conducted third-party consultation and encouraged companies to permit the department to release to the Committee as much information as possible.

To the best of our knowledge, Global Affairs Canada has now provided all documents within the scope of the motion passed by the Committee.

Should you have any questions concerning these materials, please do not hesitate to reach out to me.

Sincerely,

Colleen Calvert
Director General and Corporate Secretary

Canada

Lackie, Kimberley -DCP

Subject: Chamber-GAC meeting re TRIPS
Location: https://us02web.zoom.us/j/83792238272

Start: Mon 2022-01-17 4:00 PM
End: Mon 2022-01-17 5:00 PM
Show Time As: Tentative

Recurrence: (none)

Organizer: [redacted]

Topic: Chamber-GAC meeting re TRIPS
Time: Jan 17, 2022 04:00 PM Eastern Time (US and Canada)

Join Zoom Meeting
https://us02web.zoom.us/j/83792238272

Meeting ID: 837 9223 8272

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: January 6, 2022 9:48 AM
To: [redacted]@chamber.ca>
Cc: David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca; [redacted]@imc-mnc.ca; [redacted]@its.jnj.com; [redacted]@pfizer.com; [redacted]@chamber.ca>; Ivana.Ivankovic@international.gc.ca
Subject: RE: TRIPS Catch-up

Hi [redacted]
Happy new year!

Hope you had a chance to recharge.

We can certainly have a catch-up meeting soon. Everything is just re-starting after the holidays so happy to have a recap on the state of play and all around update.

Please propose some times that work for you and your colleagues and we'll be able to set up a call.

Best
Loris

From: [redacted]@chamber.ca>
Sent: January 4, 2022 4:14 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca>; Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca> [redacted]@imc-mnc.ca>; [redacted]@its.jnj.com; [redacted]

[redacted]@pfizer.com>; [redacted]@chamber.ca>
Subject: TRIPS Catch-up

Hi Loris,

Happy New Year! I hope you and the GAC team had a good holiday break.

I wanted to see if you and your team would be available at some point in the near future for a catch-up re TRIPS. We're still following the issue with much interest and would appreciate a chance to catch-up on the latest state of play.

If it's agreeable to you, I would suggest that perhaps my colleague [redacted] (cc'd) coordinate schedules on the industry side and work with David in your team to find a time that works for all.

Cheers,
[redacted]

[redacted]

Canadian Chamber of Commerce | Chambre de commerce du Canada
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T: 613.238.4000 [redacted]| M:[redacted]| F: 613.238.7643
Chamber.ca | Twitter | Facebook | Instagram | LinkedIn

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: June 11, 2021 10:55 AM
To: Lesieur, Nicolas -GENEV -GVWTO
Cc: Foster, Dean -TMI; Norris, David -TMI; Moen, Martin -GENEV -GVWTO
Subject: FW: Follow-up re stakeholder engagement on TRIPS

Hi Nicolas,

I know I've mentioned this a few times, so apologies for not forwarding this to you sooner. I had mentioned that TFM was interested in having a way to provide a quick debrief of negotiating meetings relating to the waiver (I think MINT had also mentioned it). Here is the message from TFM to give some sense of it. We thought the Amb. might be best placed, if he is participating.

As it looks like negotiations could begin next week, we should start thinking about giving this some shape.

Thanks
loris

From: Verheul, Steve -TFM <Steve.Verheul@international.gc.ca>
Sent: May 13, 2021 10:47 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Melia, Shendra -TMD <Shendra.Melia@international.gc.ca>
Subject: Fwd: Follow-up re stakeholder engagement on TRIPS

See below. I've given some assurances to stakeholders that we'd set up a consultation process for once the process in Geneva becomes some kind of negotiation (assuming that happens). Welcome your thoughts on how we can best do that.

Thanks

Sent from my iPhone

Begin forwarded message:

> **From:** "Verheul, Steve -TFM" <Steve.Verheul@international.gc.ca>
> **Date:** May 13, 2021 at 10:44:27 AM EDT
> **To:** [redacted]@chamber.ca>
> **Subject: Re: Follow-up re stakeholder engagement on TRIPS**
>
> Very helpful [redacted] We'll be in touch re next steps. Thanks
>
> Sent from my iPhone
>
> > On May 12, 2021, at 7:10 AM, [redacted]@chamber.ca> wrote:
> >
> > Steve,

Thanks again for making the time to speak last week. To follow-up on your request about suggestions for business representatives to potentially bring around the table for a discussion on the TRIPS waiver, I wanted to offer the below ideas, recognizing that many of these will likely be on your radar already:

COVID-19 vaccine producer
Pfizer, **J&J**, **AZ**

Future production in Canada
Medicago

Producing COVID-19 vaccine under license or providing inputs
Merck (produces lipids), **3M** (I believe they provide filtration products that some COVID-19 vaccine producers are using but would need to double check)

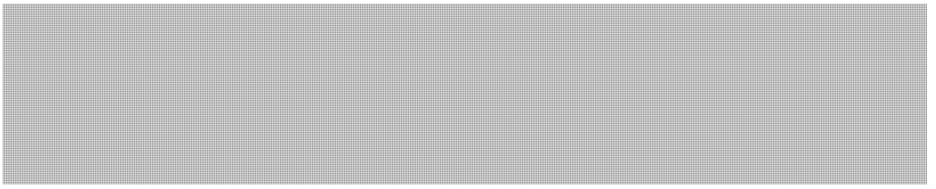
Vaccine transportation and logistics
UPS, **Kuehne+Nagel** (both active globally in distribution and would likely have global colleagues that could provide perspectives on logistics related challenges).

Associations
IMC, **Canadian Chamber**, **BIOTECanada**

The last company to flag is Providence Therapeutics. They're a Chamber member and we know their CEO Brad Sorenson. However, you'd want to know up front there is a fair amount of tension between the company and the government over vaccine procurement, which Brad has not hesitated to voice publicly (one example article here: https://www.cbc.ca/news/politics/providence-therapeutics-pulling-out-canada-1.6009068). Providence has announced it's intent to re-domicile outside of Canada due to its frustration, though the future of their planned Canadian production facility is unclear. Given the dynamics between Providence and the larger established pharma companies – they're not members of IMC and BIOTECanada – I would suggest that if GAC did want to engage them, a 1-to-1 format may be more appropriate.

I hope the above is useful. Don't hesitate to let me know if other suggestions would be helpful.

We look forward to working with you on the file.



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Lackie, Kimberley -DCP

From: [redacted]@pfizer.com>
Sent: July 21, 2021 7:30 AM
To: Mirella, Loris -TMI; Lesieur, Nicolas -GENEV -GVWTO; Norris, David -TMI; Foster, Dean -TMI
Subject: FYI only: Pfizer and BioNTech Announce Collaboration With Biovac to Manufacture and Distribute COVID-19 Vaccine Doses Within Africa
Attachments: 20.07.2021_PFE_BNT_Biovac_FINAL.pdf; AB Remarks As Written - WTO Summit 7.20.21.pdf

Good morning to you all,
As a follow up to last week's conversation, I'm please to share that this morning, Pfizer and BioNTech announced the signing of a letter of intent with The Biovac Institute, a Cape Town-based, South African biopharmaceutical company, to manufacture the Pfizer-BioNTech COVID-19 Vaccine for distribution within the African Union.

Biovac will perform manufacturing and distribution activities within Pfizer's and BioNTech's global COVID-19 vaccine supply chain and manufacturing network, which will now span three continents and include more than 20 manufacturing facilities. Pfizer and BioNTech expect that Biovac's Cape Town facility will be incorporated into the vaccine supply chain by the end of 2021. Biovac will obtain drug substance from facilities in Europe, and manufacturing of finished doses will commence in 2022. At full operational capacity, the annual production will exceed 100 million finished doses annually. All doses will exclusively be distributed within the 55 member states that make up the African Union.

Also attached, Dr Albert Bourla's remark delivered at the WTO Summit just now.

Bonne journee,
[redacted]

https://www.businesswire.com/news/home/20210721005475/en/Pfizer-and-BioNTech-Announce-Collaboration-With-Biovac-to-Manufacture-and-Distribute-COVID-19-Vaccine-Doses-Within-Africa

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PFIZER AND BIONTECH ANNOUNCE COLLABORATION WITH BIOVAC TO MANUFACTURE AND DISTRIBUTE COVID-19 VACCINE DOSES WITHIN AFRICA

NEW YORK AND MAINZ, GERMANY, July 21, 2021 — Pfizer Inc. (NYSE: PFE) and BioNTech SE (Nasdaq: BNTX) today announced the signing of a letter of intent with The Biovac Institute (Pty) Ltd, known as "Biovac", a Cape Town-based, South African biopharmaceutical company, to manufacture the Pfizer-BioNTech COVID-19 Vaccine for distribution within the African Union.

Biovac will perform manufacturing and distribution activities within Pfizer's and BioNTech's global COVID-19 vaccine supply chain and manufacturing network, which will now span three continents and include more than 20 manufacturing facilities. To facilitate Biovac's involvement in the process, technical transfer, on-site development and equipment installation activities will begin immediately.

Pfizer and BioNTech expect that Biovac's Cape Town facility will be incorporated into the vaccine supply chain by the end of 2021. Biovac will obtain drug substance from facilities in Europe, and manufacturing of finished doses will commence in 2022. At full operational capacity, the annual production will exceed 100 million finished doses annually. All doses will exclusively be distributed within the 55 member states that make up the African Union.

"From day one, our goal has been to provide fair and equitable access of the Pfizer-BioNTech COVID-19 Vaccine to everyone, everywhere," said Albert Bourla, Chairman and Chief Executive Officer, Pfizer. "Our latest collaboration with Biovac is a shining example of the tireless work being done, in this instance to benefit Africa. We will continue to explore and pursue opportunities to bring new partners into our supply chain network, including in Latin America, to further accelerate access of COVID-19 vaccines."

"We aim to enable people on all continents to manufacture and distribute our vaccine while ensuring the quality of the manufacturing process and the doses," said Ugur Sahin, M.D., CEO and Co-founder of BioNTech. "We believe that our mRNA technology can be used to develop vaccine candidates addressing other diseases as well. This is why we will continue to evaluate sustainable approaches that will support the development and production of mRNA vaccines on the African continent."

"We are thrilled to collaborate with Pfizer and BioNTech to produce and distribute the Pfizer-BioNTech COVID-19 Vaccine within Africa. This is testament of the long-standing relationship we have had with Pfizer through the Prevenar 13 vaccine," said Dr. Morena Makhoana, CEO of Biovac. "This is a critical step forward in strengthening sustainable access to a vaccine in the fight against this tragic, worldwide pandemic. We believe this collaboration will create opportunity to more broadly distribute vaccine doses to people in harder-to-reach communities, especially those on the African continent."

Pfizer and BioNTech select contract manufacturers using a rigorous selection process based on several factors: quality, compliance, safety track record, technical capability, capacity availability, highly trained workforce, project management abilities, prior working relationship, and commitment to working with flexibility through a fast-paced program. Pfizer and Biovac have worked together since 2015 on the sterile formulation, fill, finish and distribution of the Prevenar 13 vaccine.

To date, Pfizer and BioNTech have shipped more than 1 billion COVID-19 vaccine doses to more than 100 countries or territories in every region of the world. The companies are firmly committed to working towards equitable and affordable access for COVID-19 vaccines for all people around the world, actively working

with global governments as well as global health partners with the aim to provide 2 billion doses to low and middle income countries in 2021 and 2022 – 1 billion each year. This includes an agreement to supply 500 million doses to the U.S. Government at a not-for-profit price, that the government will, in turn, donate to the African Union and the COVAX 92 Advanced Market Commitment (AMC) countries, as well as a direct supply agreement with the COVAX facility for 40 million doses.

The Pfizer-BioNTech COVID-19 Vaccine, which is based on BioNTech's proprietary mRNA technology, was developed by both BioNTech and Pfizer. BioNTech is the Marketing Authorization Holder in the European Union, and the holder of emergency use authorizations or equivalent in the United States (jointly with Pfizer), Canada and other countries in advance of a planned application for full marketing authorizations in these countries.

The Pfizer-BioNTech COVID-19 Vaccine has not been approved or licensed by the U.S. Food and Drug Administration (FDA), but has been authorized for emergency use by FDA under an Emergency Use Authorization (EUA) to prevent Coronavirus Disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) for use in individuals 12 years of age and older. The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of the medical product under Section 564 (b) (1) of the FD&C Act unless the declaration is terminated or authorization revoked sooner. Please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) and Full EUA Prescribing Information available at www.cvdvaccine-us.com.

AUTHORIZED USE IN THE U.S.:
The Pfizer-BioNTech COVID19 Vaccine is authorized for use under an Emergency Use Authorization (EUA) for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.

IMPORTANT SAFETY INFORMATION FROM U.S. FDA EMERGENCY USE AUTHORIZATION PRESCRIBING INFORMATION:

- Do not administer Pfizer-BioNTech COVID-19 Vaccine to individuals with known history of a severe allergic reaction (eg, anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 Vaccine
- Appropriate medical treatment used to manage immediate allergic reactions must be immediately avai lable in the event an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 Vaccine
- Monitor Pfizer-BioNTech COVID-19 Vaccine recipients for the occurrence of immediate adverse reactions according to the Centers for Disease Control and Prevention guidelines (https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html)
- Reports of adverse events following use of the Pfizer-BioNTech COVID-19 Vaccine under EUA suggest increased risks of myocarditis and pericarditis, particularly following the second dose. The decision to administer the Pfizer-BioNTech COVID-19 Vaccine to an individual with a history of myocarditis or pericarditis should take into account the individual's clinical circumstances
- Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting
- Immunocompromised persons, including individuals receiving immunosuppressant therapy, may have a diminished immune response to the Pfizer-BioNTech COVID-19 Vaccine
- The Pfizer-BioNTech COVID-19 Vaccine may not protect all vaccine recipients
- In clinical studies, adverse reactions in participants 16 years of age and older included pain at the injection site (84.1%), fatigue (62.9%), headache (55.1%), muscle pain (38.3%), chills (31.9%), joint pain (23.6%), fever (14.2%), injection site swelling (10.5%), injection site redness (9.5%), nausea (1.1%), malaise (0.5%), and lymphadenopathy (0.3%)
- In a clinical study, adverse reactions in adolescents 12 through 15 years of age included pain at the injection site (90.5%), fatigue (77.5%), headache (75.5%), chills (49.2%), muscle pain (42.2%), fever 3 (24.3%), joint pain (20.2%), injection site swelling (9.2%), injection site redness (8.6%), lymphadenopathy (0.8%), and nausea (0.4%)

- Following administration of the Pfizer-BioNTech COVID-19 Vaccine, the following have been reported outside of clinical trials:
    - severe allergic reactions, including anaphylaxis, and other hypersensitivity reactions, diarrhea, vomiting, and pain in extremity (arm)
    - myocarditis and pericarditis
    - Additional adverse reactions, some of which may be serious, may become apparent with more widespread use of the Pfizer-BioNTech COVID-19 Vaccine
- Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy
- Data are not available to assess the effects of Pfizer-BioNTech COVID-19 Vaccine on the breastfed infant or on milk production/excretion
- There are no data available on the interchangeability of the Pfizer-BioNTech COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series
- Vaccination providers must report Adverse Events in accordance with the Fact Sheet to VAERS online at https://vaers.hhs.gov/reportevent.html. For further assistance with reporting to VAERS call 1-800-822-7967. The reports should include the words "Pfizer- BioNTech COVID-19 Vaccine EUA" in the description section of the report
- Vaccination providers should review the Fact Sheet for Information to Provide to Vaccine Recipients/Caregivers and Mandatory Requirements for Pfizer-BioNTech COVID- 19 Vaccine Administration Under Emergency Use Authorization
- Before administration of Pfizer-BioNTech COVID-19 Vaccine, please see Emergency Use Authorization (EUA) Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) including Full EUA Prescribing Information available at www.cvdvaccine-us.com

About Pfizer: Breakthroughs That Change Patients' Lives
At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us. We routinely post information that may be important to investors on our website at www.Pfizer.com. In addition, to learn more, please visit us on www.Pfizer.com and follow us on Twitter at @Pfizer and @Pfizer News, LinkedIn, YouTube and like us on Facebook at Facebook.com/Pfizer.

Pfizer Disclosure Notice
The information contained in this release is as of July 21, 2021. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information about Pfizer's efforts to combat COVID-19, the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine, the collaboration between BioNTech, Pfizer and Biovac to manufacture and distribute COVID-19 vaccine doses within Africa, the BNT162 mRNA vaccine program and the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2) (including qualitative assessments of available data, potential benefits, expectations for clinical trials, supply agreements and the timing of delivery of doses thereunder, efforts to help ensure global equitable access to the vaccine, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply) involving substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development,

including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as risks associated with preclinical and clinical data (including the Phase 3 data), including the possibility of unfavorable new preclinical, clinical or safety data and further analyses of existing preclinical, clinical or safety data; the ability to produce comparable clinical or other results, including the rate of vaccine effectiveness and safety and tolerability profile observed to date, in additional analyses of the Phase 3 trial and additional studies or in larger, more diverse populations following commercialization; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the risk that more widespread use of the vaccine will lead to new information about efficacy, safety, or other developments, including the risk of additional adverse reactions, some of which may be serious; the risk that preclinical and clinical trial data are subject to differing interpretations and assessments, including during the peer review/publication process, in the scientific community generally, and by regulatory authorities; whether and when additional data from the BNT162 mRNA vaccine program will be published in scientific journal publications and, if so, when and with what modifications and interpretations; whether regulatory authorities will be satisfied with the design of and results from these and any future preclinical and clinical studies; whether and when other biologics license and/or emergency use authorization applications or amendments to any such applications may be filed in particular jurisdictions for BNT162b2 or any other potential vaccines that may arise from the BNT162 program, and if obtained, whether or when such emergency use authorization or licenses will expire or terminate; whether and when any applications that may be pending or filed for BNT162b2 (including the Biologics License Application or any requested amendments to the emergency use or conditional marketing authorizations) or other vaccines that may result from the BNT162 program may be approved by particular regulatory authorities, which will depend on myriad factors, including making a determination as to whether the vaccine's benefits outweigh its known risks and determination of the vaccine's efficacy and, if approved, whether it will be commercially successful; decisions by regulatory authorities impacting labeling or marketing, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of a vaccine, including development of products or therapies by other companies; disruptions in the relationships between us and our collaboration partners, clinical trial sites or third-party suppliers; the risk that demand for any products may be reduced or no longer exist; risks related to the availability of raw materials to manufacture a vaccine; challenges related to our vaccine's ultra-low temperature formulation, two-dose schedule and attendant storage, distribution and administration requirements, including risks related to storage and handling after delivery by Pfizer; the risk that we may not be able to successfully develop other vaccine formulations, booster doses or new variant-specific vaccines; the risk that we may not be able to create or scale up manufacturing capacity on a timely basis or maintain access to logistics or supply channels commensurate with global demand for our vaccine, which would negatively impact our ability to supply the estimated numbers of doses of our vaccine within the projected time periods as previously indicated; whether and when additional supply agreements will be reached; uncertainties regarding the ability to obtain recommendations from vaccine advisory or technical committees and other public health authorities and uncertainties regarding the commercial impact of any such recommendations; challenges related to public vaccine confidence or awareness; uncertainties regarding the impact of COVID-19 on Pfizer's business, operations and financial results; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the U.S. Securities and Exchange Commission and available at www.sec.gov and www.pfizer.com.

About BioNTech

Biopharmaceutical New Technologies is a next generation immunotherapy company pioneering novel therapies for cancer and other serious diseases. The Company exploits a wide array of computational discovery and therapeutic drug platforms for the rapid development of novel biopharmaceuticals. Its broad portfolio of oncology product candidates includes individualized and off-the-shelf mRNA-based therapies, innovative chimeric antigen receptor T cells, bi-specific checkpoint immuno-modulators, targeted cancer

antibodies and small molecules. Based on its deep expertise in mRNA vaccine development and in-house manufacturing capabilities, BioNTech and its collaborators are developing multiple mRNA vaccine candidates for a range of infectious diseases alongside its diverse oncology pipeline. BioNTech has established a broad set of relationships with multiple global pharmaceutical collaborators, including Genmab, Sanofi, Bayer Animal Health, Genentech, a member of the Roche Group, Regeneron, Genevant, Fosun Pharma, and Pfizer. For more information, please visit www.BioNTech.de.

BioNTech Forward-looking Statements

This press release contains "forward-looking statements" of BioNTech within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, statements concerning: BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including a potential second booster dose of BNT162b2 and/or a potential booster dose of a variation of BNT162b2 having a modified mRNA sequence); our expectations regarding the potential characteristics of BNT162b2 in our clinical trials and/or in commercial use based on data observations to date; the ability of BNT162b2 to prevent COVID-19 caused by emerging virus variants; the expected time point for additional readouts on efficacy data of BNT162b2 in our clinical trials; the nature of the clinical data, which is subject to ongoing peer review, regulatory review and market interpretation; the timing for submission of data for, or receipt of, any marketing approval or Emergency Use Authorization; our contemplated shipping and storage plan, including our estimated product shelf life at various temperatures; and the ability of BioNTech to supply the quantities of BNT162 to support clinical development and market demand, including our production estimates for 2021. Any forward-looking statements in this press release are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: the ability to meet the pre-defined endpoints in clinical trials; competition to create a vaccine for COVID-19; the ability to produce comparable clinical or other results, including our stated rate of vaccine effectiveness and safety and tolerability profile observed to date, in the remainder of the trial or in larger, more diverse populations upon commercialization; the ability to effectively scale our productions capabilities; and other potential difficulties.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report as Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is available on the SEC's website at www.sec.gov. All information in this press release is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

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###

WTO Summit: "Expanding Equitable Access Through Increasing and Diversifying Production Capacity"
Albert Bourla's Remarks – as written
FINAL

Thank you to Dr. Ngozi and to Tedros for convening this important session.

I am confident that we agree on at least one thing: everyone - regardless of financial condition, race, religion or geography – deserves access to lifesaving COVID-19 vaccines.

To this end, the organizers have posed the following question: How do we build sufficient manufacturing capacity to meet this objective in the near term?

Thanks to unprecedented collaboration and cooperation within the industry – with governments and other stakeholders – we have made extraordinary progress to date on manufacturing vaccines.

At Pfizer, we recently announced that we will reach 3 billion doses in 2021 – doubling our initial projections – and we plan to produce up to 4 billion vaccines in 2022.

Part of our success has come from a relentless focus on efficiency that has enabled us to quickly scale up manufacturing.

When we began to supply the vaccine our average timeline from start to vial-ready was approximately 110 days. We are now approaching an average of 60 days from start to vial-ready -- an almost 50% improvement.

Early on, we determined that the best way to quickly and safely manufacture this vaccine would be to activate our extensive manufacturing network in Europe and the United States, including thousands of highly skilled workers, to prepare to produce the COVID-19 vaccine for those most in need around the world.

Pfizer and BioNTech also have relied on support from contract manufacturers to ramp up their manufacturing capabilities to produce more doses of the COVID-19 vaccine.

In fact, today, we are announcing a landmark agreement with The Biovac Institute in South Africa to manufacture the Pfizer-BioNTech COVID-19 vaccine exclusively for the 55 member states that make up the African Union. Technical transfer and related activities will begin immediately, and Biovac is expected to produce more than 100 million finished doses that will be supplied exclusively to African Union countries annually once at full operational capacity.

This collaboration is another example of our commitment, from day one, to provide fair and equitable access to the Pfizer BioNTech COVID-19 vaccine to everyone, everywhere. This commitment has been our North Star, and this agreement is just one example of the tireless work being done to expand access, in this instance to benefit Africa.

So, to Dr. Ngozi and others who have expressed concern that Africa is being left behind in part due to lack of vaccine manufacturing, I want to say that we hear you. Pfizer will continue to explore and pursue opportunities to bring new partners into its supply chain network to further accelerate access to COVID-19 vaccines.

There are two key ways that the WTO can support our efforts to expand global manufacturing:

- Maintain open trade. Open trade and efficient customs procedures become even more critical to the manufacturing and distribution of our vaccines as we bring additional partners into our network. I urge governments to address trade barriers, including export restrictions, by the end of this year. Without open trade, our efforts to accelerate manufacturing will fall short, no matter how many vaccine manufacturing plants are built around the world.

- Preserve intellectual property rules. IP rules are enabling an unprecedented amount of innovation and facilitating collaboration between biopharma innovators and partners, including our partnership with Biovac.

None of the challenges to ensuring equitable distribution of the COVID vaccine stem from the IP system.

In fact, weakening IP rules will only discourage the type of unprecedented innovation which brought vaccines forward in record time and make it harder for companies to collaborate going forward.

I thank the WTO and WHO for convening these dialogues to find practical solutions to the challenges we face, and we welcome the opportunity to support your efforts.

Thank you.

s.19(1)

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: July 12, 2021 10:38 AM
To: Foster, Dean -TMI; Norris, David -TMI
Subject: here's message to [redacted] about meeting
Attachments: RE: TRIPS Council follow-up

Hey,
As discussed, here's a draft of what I would send to [redacted] Let me know if that suits. I'll use something similar to send to [redacted]

Thanks
loris

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: June 17, 2021 10:04 AM
To: [redacted]Norris, David -TMI; Foster, Dean -TMI
Subject: RE: TRIPS Council follow-up

Hi [redacted]
Thanks for the conversation and for the additional information.

Best
loris

From: [redacted]@chamber.ca>
Sent: June 14, 2021 9:50 PM
To: Norris, David -TMI <David.Norris@international.gc.ca>; Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>; Foster, Dean -TMI <Dean.Foster@international.gc.ca>
Subject: RE: TRIPS Council follow-up

Loris, Dean, David,

Thanks again for making the time to speak. As discussed, attached is the letter that went in from several national business associations last Friday.

[redacted]

Canadian Chamber of Commerce | Chambre de commerce du Canada
1700 – 275 rue Slater Street, Ottawa ON K1P 5H9
T: 613.238.4000 ([redacted]) | M: [redacted] F: 613.238.7643
Chamber.ca | Twitter | Facebook | Instagram | LinkedIn

-----Original Appointment-----
From: David.Norris@international.gc.ca <David.Norris@international.gc.ca>
Sent: June 10, 2021 12:03 PM
To: David.Norris@international.gc.ca; [redacted]Loris.Mirella@international.gc.ca; Dean.Foster@international.gc.ca
Subject: TRIPS Council follow-up
When: June 14, 2021 3:00 PM-4:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Hi [redacted]

Please find below an MS Teams link to our meeting next Monday, June 14, to discuss the TRIPS waiver.

Best,

David

David Norris
Senior Trade Policy Officer | Agent principal de la politique commerciale
Intellectual Property Trade Policy Division | Direction de la politique commerciale sur la propriété intellectuelle (TMI)
david.norris@international.gc.ca
Telephone | Téléphone: 613-462-2826
111 Sussex Drive, Ottawa Ontario K1N 1J1

<< File: image001.png >>

Microsoft Teams meeting

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Lackie, Kimberley -DCP

Subject: Meeting with Global Affairs Canada - update on WTO TRIPS waiver discussions
Location: Microsoft Teams Meeting

Start: Wed 2021-09-15 3:30 PM
End: Wed 2021-09-15 4:30 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: Norris, David -TMI
Required Attendees: [redacted]@imc-mnc.ca>; [redacted]@pfizer.com'; '[redacted] [MEDCA]'; [redacted] Mirella, Loris -TMI; Foster, Dean -TMI

Good afternoon,

We would like to invite you to a meeting with Global Affairs Canada's Intellectual Property Trade Policy Division, this Wednesday, September 15th, from 3:30-4:30pm, for an update on the TRIPS waiver discussions at the WTO.

A Microsoft Teams link to Wednesday's meeting can be found below this message. We look forward to speaking with then.

Best,
David

David Norris
Senior Trade Policy Officer | Agent principal de la politique commerciale
Intellectual Property Trade Policy Division | Direction de la politique commerciale sur la propriété intellectuelle (TMI)
david.norris@international.gc.ca
Telephone | Téléphone: 613-462-2826
111 Sussex Drive, Ottawa Ontario K1N 1J1

Global Affairs Canada | Affaires mondiales Canada

Microsoft Teams meeting

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Lackie, Kimberley -DCP

Subject: Meeting with Global Affairs Canada on WTO TRIPS waiver discussions
Location: Microsoft Teams Meeting

Start: Thu 2021-07-15 8:30 AM
End: Thu 2021-07-15 9:30 AM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: Norris, David -TMI
Required Attendees: [redacted]@imc-mnc.ca>; [redacted]@imc-mnc.ca; [redacted]@imc-mnc.ca; [redacted]@pfizer.com; [redacted]@its.jnj.com>; [redacted]@chamber.ca>; [redacted]@imc-mnc.ca>; Moen, Martin -GENEV -GVWTO; Lesieur, Nicolas -GENEV -GVWTO; Mirella, Loris -TMI; Foster, Dean -TMI

Good morning,

We would like to invite you to a meeting with Global Affairs Canada's Intellectual Property Trade Policy Division and the Canadian Mission in Geneva, tomorrow morning (Thursday, July 15th) from 8:30-9:30am, for an update on the ongoing TRIPS waiver discussions at the WTO TRIPS Council.

The meeting will allow an opportunity to provide a state of play to this point on the TRIPS waiver discussions, as well as to share your current thinking on these discussions.

A Microsoft Teams link to tomorrow's meeting can be found below this message. We look forward to speaking with then.

Best,
David

David Norris
Senior Trade Policy Officer | Agent principal de la politique commerciale
Intellectual Property Trade Policy Division | Direction de la politique commerciale sur la propriété intellectuelle (TMI)
david.norris@international.gc.ca
Telephone | Téléphone: 613-462-2826
111 Sussex Drive, Ottawa Ontario K1N 1J1

Global Affairs Canada | Affaires mondiales Canada

Microsoft Teams meeting

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Phone Conference ID: 710 199 741#

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Lackie, Kimberley -DCP

Subject: Meeting with TMI to discuss TRIPS waiver
Location: Microsoft Teams Meeting

Start: Wed 2021-07-14 1:00 PM
End: Wed 2021-07-14 2:00 PM
Show Time As: Tentative

Recurrence: (none)

Meeting Status: Not yet responded

Organizer: Norris, David -TMI
Required Attendees: [redacted]@its.jnj.com>; Mirella, Loris -TMI; Foster, Dean -TMI

Hi [redacted]

Further to your exchange with Loris, please find below a Teams link for our meeting next Wednesday, July 14th, at 1:00pm.

Looking forward to speaking with you next week.

Best,
David

David Norris
Senior Trade Policy Officer | Agent principal de la politique commerciale
Intellectual Property Trade Policy Division | Direction de la politique commerciale sur la propriété intellectuelle (TMI)
david.norris@international.gc.ca
Telephone | Téléphone: 613-462-2826
111 Sussex Drive, Ottawa Ontario K1N 1J1

Global Affairs Canada | Affaires mondiales Canada

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Find a local number | Reset PIN

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Updated June 16, 2021

Biotechnology Innovation Organization

Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics

Vaccines

- **CureVac**
  - *Celonic* will manufacture 100 million doses of CureVac's vaccine at its plant in Heidelberg, Germany, providing bulk substance for 50 million doses by the end of 2021. (press release)
  - *Novartis* will manufacture CureVac's vaccine. (press release)
  - *GlaxoSmithKline plc* and CureVac N.V. announced a new €150m collaboration, building on their existing relationship, to jointly develop next generation mRNA vaccines for COVID-19 with the potential for a multi-valent approach to address multiple emerging variants in one vaccine. (press release)
  - *Rentschler Biopharma SE* will manufacture CureVac's vaccine. (press release)
  - *Bayer* will support the further development, supply and key territory operations of CureVac's vaccine candidate. (press release)
  - *Fareva* will dedicate a manufacturing plant in France to the fill and finish of CureVac's vaccine. (press release)
  - *Wacker Chemie AG* will manufacture CureVac's vaccine candidate at its Amsterdam site. (press release)
  - CureVac will collaborate with *Tesla Grohmann Automation* to develop an RNA printer that works like a mini-factory and can produce such drugs automatically. (press release)

- **Moderna**
  - Moderna and *Magenta* are partnering to distribute Moderna's vaccine and updated variant booster candidates in the United Arab Emirates. (press release)
  - *Tabuk Pharmaceuticals* in Saudi Arabia agreed to commercialize and distribute Moderna's vaccine and variant-specific booster candidates in Saudi Arabia. (press release)
  - *Thermo Fisher Scientific* will provide fill/finish, labeling and packaging services at a North Carolina site to support the production of hundreds of millions doses of the Moderna COVID-19 vaccine. (press release)
  - Moderna signed an agreement with *Lonza* in the Netherlands to support drug substance manufacturing for its global supply chain. (press release)
  - *Samsung Biologics* will provide large scale, commercial fill-finish manufacturing for Moderna's vaccine in South Korea. (press release)
  - *Baxter International* will provide fill/finish services and supply packaging for Moderna. (press release)
  - *Sanofi* will manufacture 200 million doses of Moderna's COVID-19 vaccine starting in September 2021. (press release)
  - *Rovi* will produce bulk substance for Moderna's COVID-19 vaccine, expanding an agreement between the companies. Rovi currently provides fill-finish for the vaccine, receiving substance from a Lonza plant in Switzerland. A new production line at Rovi's

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plant in Granada, Spain, will make ingredients for up to 100 million vaccine doses a year. (news release)
- Moderna collaborates with *Catalent* for vial filling and packaging capacity (press release)
- *Lonza*'s site in Valais, Switzerland, will manufacture Moderna's vaccine (press release)
- *Recipharm* will support formulation and fill-finish for Moderna's vaccine at their site in France. (press release)
- *Laboratorios Farmacéuticos Rovi* will support large-scale, commercial fill-finish manufacturing of Moderna's vaccine at their site in Madrid, Spain. (press release)
- *CordenPharma* will manufacture large-scale volumes of Moderna's lipid excipients to be used in the manufacture of Moderna's vaccine. (press release)
- *Takeda,* Japan's Ministry of Health, Labor and Welfare (MHLW) announced an agreement to import and distribute Moderna's vaccine. (press release)

- **Novavax**
  - Novavax partners with *SK Boiscience* of South Korea to manufacture Novavax's protein antigen, supply of Matrix MTM adjuvant, and support to SK Bioscience as needed to secure regulatory approval. (press release)
  - *Biologics Manufacturing Centre of Canada* is partnered with Novavax to produce its vaccine. (press release)
  - *FUJIFILM Diosynth Biotechnologies* will produce bulk drug substance of NVX-CoV2373, Novavax' vaccine candidate. (press release)
  - *Baxter International Inc* will provide sterile manufacturing services for NVX-CoV2373, Novavax' COVID-19 recombinant nanoparticle vaccine candidate with Matrix-M™ adjuvant. (press release)
  - Novavax collaborates with *Takeda* for local production and commercialization of Novavax' vaccine in Japan (press release)
  - *AGC Biologics* is preparing to manufacture Matrix-M™, the adjuvant component[*2] of Novavax' COVID-19 vaccine candidate, NVX-CoV2373 in its Copenhagen facility. (press release)
  - Novavax bought a Czech company (*Praha Vaccines*) to further expand COVID-19 manufacturing capacity (press release)
  - Novavax partnered with *Serum Institute of India*, increasing Novavax' global production capacity to over 2 billion doses annually. Novovax committed 1 billion doses to COVAX made possible through their partnership with the Serum Institute of India. (press release)

- **Medicago**
  - Medicago is partnering with *GlaxoSmithKline plc* to develop and evaluate a COVID-19 candidate vaccine combining Medicago's recombinant Coronavirus Virus-Like Particles (CoVLP) with GSK's pandemic adjuvant system. (press release)
  - Medicago partners with *Dynavax* to evaluate Medicago's Coronavirus Virus-Like Particle (CoVLP) with Dynavax's CpG 1018 adjuvant to support the rapid development of a

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COVID-19 vaccine candidate. (press release)

- **Providence Therapeutics**
  - India's Biological E. entered into a licensing agreement with the Canadian company, Providence Therapeutics Holdings to manufacture 1 billion doses of their mRNA COVID-19 vaccine. (Press Release)

- **Sanofi and Translate Bio**
  - Sanofi is developing a messenger RNA vaccine in partnership with Translate Bio. In March 2021, Sanofi and Translate Bio initiated a Phase 1/2 clinical trial of their mRNA COVID-19 vaccine candidate, in order to assess safety, immune response and reactogenicity, after preclinical data showed high neutralizing antibody levels. (press release)

- **Tonix Pharmaceuticals**
  - *FUJIFILM Diosynth Biotechnologies* to manufacture Tonix's vaccine. Collaboration includes development of manufacturing processes and supply of clinical trial material to support Tonix's development of TNX-1800 (press release)

- **Valneva**
  - *Dynavax* to produce adjuvant for Valneva vaccine (press release)

- **Inovio Inc**.
  - Inovio has partnered with *Kaneka Eurogentec* (Japan), *Thermo Fisher Scientific* (USA), *Richter-Helm BioLogics* (Hungary) and *Ology Biosciences* (USA) to help manufacture their vaccine candidate. (Kaneka press release) (Thermo Fischer press release) (Ology press release)
  - Inovio collaborates with *Beijing Advaccine* (Chinese company) to facilitate clinical trial translations in China (press release)

- **AstraZeneca**
  - *Siam Bioscience* in Thailand to manufacture the AstraZeneca vaccine. (press release)
  - China's *Shenzhen Kangtai Biological Products* will manufacture 400 million doses per year of AstraZeneca's COVID-19 vaccine. (news article)
  - AstraZeneca reached a licensing and technology transfer agreement with *Serum Institute of India* to supply one billion doses to low and middle-income countries (press release)
  - *CSL Behring* is manufacturing approximately 50 million doses of AstraZeneca's vaccine in Australia for supply to the country. First doses were rolled out in March 2021. (press release)
  - *Emergent BioSolutions*, *Daiichi Sankyo* to expand manufacturing of AZ's vaccine (Emergent BioSolutions press release) (Daiichi press release)
  - AstraZeneca has signed manufacturing deals with mAbxience of the INSUD Group in Argentina, Carlos Slim Foundation in Mexico, R-Pharm in Russia, Fundação Osvaldo Cruz

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(Fiocruz) in Brazil and Symbiosis Pharmaceutical in Scotland. (news release)

- **CSL Behring**
  - *Seqirus*, which is part of the CSL Group, has donated its well-established adjuvant technology – MF59® – to the vaccine efforts of multiple entities, including the University of Queensland vaccine development program. (press release)

- **Johnson & Johnson**
  - *Biological E*, in India, will make 600 million doses per year. (news article)
  - Spain's *Reig Jofre* new manufacturing plant will produce J&J vaccines starting in Q2 of 2021. (news article)
  - *Sanofi* will provide manufacturing support to Johnson & Johnson. (press release)
  - *Takeda* has made manufacturing capacity available for three months at *IDT Biologika's (IDT)* site in Dessau, Germany to manufacture J&J's vaccine. (press release)
  - J&J partnered with *Merk* to manufacture their vaccine. (press release)
  - *Catalent* will use their Anagni, Italy manufacturing facility for vial-filling, inspection, labeling and packaging services. (press release)
  - *Emergent BioSolutions* is manufacturing doses in the US. (press release)
  - J&J partnered with the *Aspen Pharmacare Ltd.* in South Africa to manufacture their vaccine. (Aspen press release)
  - *Grand River Aseptic Manufacturing* is providing fill and finish services in the US. (press release)

- **Pfizer** - **BioNtech** co-developed COVID-19 vaccine (press release)
  - *Delpharm* will start to manufacture Pfizer-BioNtech's vaccine in Normandy, France. Delpharm will also produce Johnson and Johnson and Moderna's vaccine. (news release)
  - *Thermo Fisher* is working with Pfizer and BioNtech to manufacture their COVID-19 vaccine in Italy. (news release)
  - In order to scale up manufacturing as quickly as possible, the companies have entered multiple manufacturing agreements with *Sanofi*, *Novartis*, and *Fosun Pharma*. (Sanofi press release) (Novartis press release) (Fosum press release)

- **Sanofi**
  - *Sanofi* will spend $476 million over the next five years to create a vaccine production plant in Singapore. The facility will have more flexibility than Sanofi's current sites, with the capability to produce three to four different vaccines simultaneously. (press release)

Therapeutics/Diagnostics Partnerships

- **Avacta**
  - *BBI Solutions* (based in South Wales, UK) to manufacture Avacta's saliva-based rapid SARS-CoV-2 antigen test, that is being developed by Affimer® biotherapeutics and

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reagents developer Avacta Group plc in conjunction with Cytiva (press release)

- **BeiGene**
  - BeiGene is collaborating with *Singlomics* (China) and *Peking University* for the use of monocolonal antibodies (mAbs) against COVID-19 (press release)

- **CSL Behring**
  - CSL Behring is partnering with *SAB Biotherapeutics*, a clinical-stage biopharmaceutical company, to advance and deliver a novel immunotherapy targeting COVID-19. The potential therapy would be produced without the need for blood plasma donations from recovered COVID-19 patients. (press release)
  - CSL Behring has launched a clinical trial into the use of CSL312 (garadacimab, Factor XIIa antagonist monoclonal antibody) to treat patients suffering from severe respiratory distress, a leading cause of death in patients with COVID-19 related pneumonia. (press release)

- **Eli Lilly**
  - Collaboration with *Samsung BioLogics'* to mass produce Lilly's COVID-19 antibody therapies. Lilly hopes to make up to 1 million doses this year and many more in 2021 (press release and here)
  - Manufacturing collaboration with *Amgen* for COVID-19 antibody therapies (press release)

- **Gilead**
  - Gilead signed non-exclusive voluntary licensing agreements with *nine manufacturer*s based in India, Pakistan and Egypt to expand access to generic remdesivir in 127 low and middle-income countries. (press release)
  - Gilead also forged collaborations with more than 40 trusted manufacturing partners in North America, Europe, and Asia to expand its Veklury (remdesivir) manufacturing network and meet global demand. (press release)
  - When COVID-19 cases began surging in India in April 2021, Gilead initiated efforts to expand availability of remdesivir by providing technical assistance to its seven India-based voluntary licensing partners, supporting the addition of new local manufacturing facilities, and donating API to scale up production of remdesivir. Gilead is also committed to providing support to voluntary licensees based outside of India to increase their production capacity. (press release)

- **Merck**
  - Merck announced voluntary licensing agreements with *5 Indian generic manufacturers* to accelerate and expand global access to Molnupiravir, an investigational oral therapeutic for the treatment of COVID-19. (press release)

- **Vir Biotechnology**

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- Collaboration with *GlaxoSmithKline (UK)* on monoclonal antibody (mAbs) treatment for COVID-19 (press release)

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: July 14, 2021 10:17 AM
To: [redacted]
Cc: Foster, Dean -TMI; Norris, David -TMI
Subject: RE: Meeting today

Hi [redacted]
Of course. Looking forward to speaking with you later today.

Best
loris

From: [redacted]@its.jnj.com>
Sent: July 14, 2021 10:08 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>
Subject: Re: Meeting today

Loris. Perhaps we could just briefly. As some issues I may not be able to bring fwd with the group

[redacted]

Please excuse typos and brevity
Sent from my iPhone

> On Jul 14, 2021, at 9:53 AM, Loris.Mirella@international.gc.ca wrote:
>
> Hi [redacted]
>
> Hope all is well.
>
> We are scheduled to meet today at 1:00 to discuss the TRIPS waiver.
>
> However, as we have since scheduled a call for tomorrow morning at 8:30 (invitation to be sent shortly) on the same topic with a number of the members of Innovative Medicines Canada and noting you are included in the invitation list, I just wanted to check to confirm that you would still like to meet today.
>
> Best
> loris

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: September 13, 2021 4:15 PM
To: [redacted]
Cc: Norris, David -TMI
Subject: RE: Call

Thanks, [redacted]
We will send out an invitation shortly.
loris

From: [redacted]@imc-mnc.ca>
Sent: September 13, 2021 4:09 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Subject: RE: Call

Thanks Loris. It would be myself, [redacted]

[redacted]

[redacted]

C [redacted]
innovativemedicines.ca | @innovativemeds

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: September 13, 2021 4:07 PM
To: [redacted]@imc-mnc.ca>
Subject: RE: Call

Hi [redacted]
Yes, 3:30 would work as well.
Please let me know who to include on the invitation.
Thanks
loris

From: [redacted]@imc-mnc.ca>
Sent: September 13, 2021 2:18 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Subject: RE: Call

Hi Loris. Would three thirty work for you? It seems that is better from our crew. Thanks.
[redacted]

[redacted]

C [redacted]
innovativemedicines.ca | @innovativemeds

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: September 13, 2021 10:42 AM
To: [redacted]@imc-mnc.ca>
Subject: RE: Call

Hi [redacted]
Yes, that works fine for me. I will send you an invitation on Teams. Please let me know if I should include anyone else.

loris

From: [redacted]@imc-mnc.ca>
Sent: September 13, 2021 7:12 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Subject: RE: Call

Thanks Loris. Would 2pm Wednesday work for you?

[redacted]

[redacted]

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From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: September 10, 2021 4:31 PM
To: [redacted]@imc-mnc.ca>
Subject: RE: Call

Hi [redacted]
All is well here. Hope you had a wonderful rest of the summer.

Happy to chat next week. Let's aim for Wednesday if that works for you? My day is relatively open, so will propose late morning or early afternoon, but can work to your availability.

Happy weekend to you as well!

loris

From: [redacted]@imc-mnc.ca>
Sent: September 10, 2021 4:13 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Subject: Call

Hi Loris. I hope all is well with you.

Would you have time for a quick call next week? Please let me know.

Thanks and have a good weekend.

[redacted]

innovativemedicines.ca | @innovativemeds

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: October 5, 2021 4:53 PM
To: Melia, Shendra -TMD
Cc: Foster, Dean -TMI; Norris, David -TMI
Subject: RE: J&J touchpoint re WTO Patent Waiver issue

Yes, thanks. We'll organize something with all the named divisions.
loris

From: Melia, Shendra -TMD <Shendra.Melia@international.gc.ca>
Sent: October 5, 2021 4:40 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>
Subject: RE: J&J touchpoint re WTO Patent Waiver issue

Loris,

Thanks. I don't see a need to bump it up to a higher level at our department so would suggest that you take the meeting. Depending on the results we can decide if a follow up higher level meeting is needed. Ok?

Shendra

From: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Sent: October 5, 2021 3:31 PM
To: Melia, Shendra -TMD <Shendra.Melia@international.gc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>
Subject: FW: J&J touchpoint re WTO Patent Waiver issue

Hi Shendra,

Received this invitation from J&J, and we can certainly meet on the IP and supply chain issues (and invite TPG, TCW and GVWTO to participate).

We were wondering if it would be of interest to DGs to participate (or even more senior officials if you think appropriate), since these issues are going to figure prominently in the lead up to MC12 and it may be a useful forum for developing a clearer picture.

Happy to discuss.
loris

From: [redacted]@its.jnj.com>
Sent: October 5, 2021 12:56 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Subject: J&J touchpoint re WTO Patent Waiver issue

Loris

Wondering if it might be valuable to touch base with our global trade lead at J&J, [redacted]. She can brief you on what she is hearing which she may not be able to share with the other companies.

LMK if it might be of value and if it might be possible to connect in your Geneva person.

As well if you wish – can arrange a meeting with our global government lead on supply chain, he could share with you our approach on vaccine production in developing world.

LMK what might be of interest and possible

Thx

"Stay positive…test negative"

[redacted]

Johnson & Johnson

C: [redacted]

Johnson & Johnson WORLDWIDE GOVERNMENT AFFAIRS & POLICY

Lackie, Kimberley -DCP

From: [redacted]@imc-mnc.ca>
Sent: April 1, 2022 1:00 PM
To: Mirella, Loris -TMI
Cc: Norris, David -TMI; [redacted]@pfizer.com; [redacted]@chamber.ca; [redacted] Gordon, Nicholas -TMI; Ivankovic, Ivana -TMI; Lesieur, Nicolas -GENEV -GVWTO
Subject: RE: Meeting Request

That's great Loris. Please send the invite.

Have a great weekend.

[redacted]

[redacted]

C ([redacted]
innovativemedicines.ca | @innovativemeds

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: April 1, 2022 11:22 AM
To: [redacted]@imc-mnc.ca>
Cc: David.Norris@international.gc.ca; [redacted]@pfizer.com <[redacted]@imc-mnc.ca>; [redacted]@its.jnj.com>; [redacted]@chamber.ca; [redacted]@imc-mnc.ca>; Nicholas.Gordon@international.gc.ca; Ivana.Ivankovic@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Meeting Request

Hi [redacted]

That time works on our side. We're happy to set up a call.

Please let me know if there is anyone to include other than colleagues in cc.

s.19(1)

Best
Ioris

From [redacted]@imc-mnc.ca>
Sent: April 1, 2022 9:49 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca> [redacted]@pfizer.com <[redacted]@imc-mnc.ca> [redacted]@its.jnj.com>; [redacted]@chamber.ca [redacted]@imc-mnc.ca>; Gordon, Nicholas -TMI <Nicholas.Gordon@international.gc.ca>; Ivankovic, Ivana -TMI <Ivana.Ivankovic@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>
Subject: RE: Meeting Request

Hi Loris.

Thanks for the response. We probably don't want to wait until the last week of April, so let's try for next week.

Would **noon on Wednesday 6th** work for you? Thanks.

[redacted]

C [redacted]
innovativemedicines.ca | @innovativemeds

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: March 31, 2022 11:21 AM
To: [redacted]@imc-mnc.ca>
Cc: David.Norris@international.gc.ca; [redacted]@pfizer.com [redacted]@imc-mnc.ca>; [redacted]@its.jnj.com>; [redacted]@chamber.ca; [redacted]@imc-mnc.ca>; Nicholas.Gordon@international.gc.ca; Ivana.Ivankovic@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Meeting Request

Hi

Hope all is well.

We can certainly set up a meeting to provide an update on developments relating to TRIPS.

The weeks leading into and following Easter are not proving to be workable, but we are happy to aim for a date next week (week of April 4-8) or the week of April 25-29.

Please let me know some options that would work for everyone.

Best
loris

From: @imc-mnc.ca>
Sent: March 29, 2022 3:32 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca> @pfizer.com < @imc-mnc.ca> @its.jnj.com> @chamber.ca)chamber.ca>; @imc-mnc.ca>
Subject: Meeting Request

Hi Loris.

I hope that you are doing well.

We were hoping to have an update meeting regarding TRIPS with you and your colleagues. Would you have any availabilities the week of April 11th? Please let us know.

With Kind Regards,

C
innovativemedicines.ca | @innovativemeds

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: September 15, 2021 9:51 AM
To: [redacted]
Subject: RE: Meeting Tomorrow

Hi [redacted]
That is fine for us. We'll make the first half hour count!
loris

From: [redacted]@imc-mnc.ca>
Sent: September 15, 2021 6:52 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Subject: Meeting Tomorrow

Hi Loris.

I have been called into a meeting at 4pm tomorrow. That said the rest of the members and [redacted] from my office can attend, so if it is ok with you let's proceed as planned. Sorry that I will need to sign off early.

[redacted]

[redacted]

C [redacted]
innovativemedicines.ca | @innovativemeds

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: September 22, 2021 12:37 PM
To: [redacted]
Cc: [redacted]@pfizer.com; [redacted]@chamber.ca)
Subject: RE: Summit Follow Up

Hi [redacted]
Thanks very much for following up on our discussion.

Best
loris

From: [redacted]@imc-mnc.ca>
Sent: September 22, 2021 10:23 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: [redacted]@pfizer.com <[redacted]@imc-mnc.ca>; [redacted]@gmail.com>; [redacted]@chamber.ca) <[redacted]@chamber.ca>
Subject: Summit Follow Up

Hi Loris.

Thanks for the call last week.

Regarding US developments, please see the White House background press call transcript regarding the Global Summit. The opinion of my PhRMA counterparts is that there has been no discernable change in the Administration's position.

https://www.whitehouse.gov/briefing-room/press-briefings/2021/09/22/background-press-call-by-senior-administration-officials-previewing-the-global-summit-to-end-covid-19/

[redacted]

[redacted]

[redacted]
innovativemedicines.ca | @innovativemeds

Lackie, Kimberley -DCP

From: [redacted]@chamber.ca>
Sent: January 12, 2022 11:55 AM
To: Mirella, Loris -TMI
Cc: Norris, David -TMI; Lesieur, Nicolas -GENEV -GVWTO; Ivankovic, Ivana -TMI; Gordon, Nicholas -TMI
Subject: RE: TRIPS Catch-up

Hi Loris,

Confirming that Monday, January 17 at 4:00 p.m. – 5:00 p.m. EST works well on our end and also works for our industry colleagues. I will send a meeting invite around with the zoom details shortly.

Please let me know if you have any questions or require more information.

Thank you,

[redacted]

Canadian Chamber of Commerce | Chambre de commerce du Canada
T: 613.238.4000 | M: [redacted] | F: 613.238.7643

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: January 11, 2022 4:27 PM
To: [redacted]@chamber.ca>
Cc: David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca; Ivana.Ivankovic@international.gc.ca; Nicholas.Gordon@international.gc.ca
Subject: RE: TRIPS Catch-up

Hi [redacted]
After a quick survey, it seems the most convenient time will be next Monday (January 17) from 4:00-5:00.

Thanks
loris

From: Mirella, Loris -TMI
Sent: January 10, 2022 3:21 PM
To [redacted]@chamber.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca>; Foster, Dean -TCE <Dean.Foster@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>; Ivankovic, Ivana -TMI <Ivana.Ivankovic@international.gc.ca>
Subject: RE: TRIPS Catch-up

Hi [redacted]

Thanks very much for the proposals. I'll check with my colleagues on availability and circle back to you.

In the meantime, just to let you know that Dean has moved to another assignment in the Trade branch of GAC as newly appointed director of Trade Policy and Negotiations – Europe, Middle East and Africa division.

I will remove him from further communications and add Ivana Ivankovic, a junior trade policy officer in the IP trade policy division.

Thanks
loris

From: [redacted]@chamber.ca>
Sent: January 10, 2022 3:05 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca>; Foster, Dean -TCE <Dean.Foster@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>
Subject: RE: TRIPS Catch-up

Hi Loris,

Just following up on scheduling a time for this meeting.

Could you please let me know which of the following dates and times are suitable on your end?

- January 17, 4:00 p.m. – 5:00 p.m. EST
- January 18, 11:00 a.m. – 12:00 p.m. EST
- January 18, 3:00 p.m. – 4:00 p.m. EST

Thank you,

[redacted]
Canadian Chamber of Commerce | Chambre de commerce du Canada
T: 613.238.4000 | M: [redacted] F: 613.238.7643

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: January 6, 2022 9:48 AM
To: [redacted]@chamber.ca>
Cc: David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca; [redacted]@imc-mnc.ca; [redacted]@its.jnj.com; [redacted]@pfizer.com; [redacted]@chamber.ca>; Ivana.Ivankovic@international.gc.ca
Subject: RE: TRIPS Catch-up

Hi [redacted]
Happy new year!

Hope you had a chance to recharge.

We can certainly have a catch-up meeting soon. Everything is just re-starting after the holidays so happy to have a recap on the state of play and all around update.

Please propose some times that work for you and your colleagues and we'll be able to set up a call.

Best
loris

From: [redacted]@chamber.ca>
Sent: January 4, 2022 4:14 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca>; Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>; [redacted]@imc-mnc.ca>; [redacted]@its.jnj.com; [redacted]pfizer.com>; [redacted]@chamber.ca>
Subject: TRIPS Catch-up

Hi Loris,

Happy New Year! I hope you and the GAC team had a good holiday break.

I wanted to see if you and your team would be available at some point in the near future for a catch-up re TRIPS. We're still following the issue with much interest and would appreciate a chance to catch-up on the latest state of play.

If it's agreeable to you, I would suggest that perhaps my colleague [redacted] (cc'd) coordinate schedules on the industry side and work with David in your team to find a time that works for all.

Cheers,

[redacted]

Canadian Chamber of Commerce | Chambre de commerce du Canada
1700 – 275 rue Slater Street, Ottawa ON K1P 5H9
T: 613.238.4000 [redacted] M: [redacted] F: 613.238.7643
Chamber.ca | Twitter | Facebook | Instagram | LinkedIn

Lackie, Kimberley -DCP

From: [redacted]@imc-mnc.ca>
Sent: June 2, 2021 1:03 PM
To: Norris, David -TMI
Cc: Mirella, Loris -TMI; Foster, Dean -TMI
Subject: RE: IMC call with TMI

Thanks David.

I appreciate the follow up.

With Kind Regards,

[redacted]

[redacted]

C [redacted]
innovativemedicines.ca | @innovativemeds

From: David.Norris@international.gc.ca <David.Norris@international.gc.ca>
Sent: June 2, 2021 11:48 AM
To: [redacted]@imc-mnc.ca>
Cc: Loris.Mirella@international.gc.ca; Dean.Foster@international.gc.ca
Subject: RE: IMC call with TMI

Hi [redacted]

Further to our discussion last week, we wanted to send along the contact information that you requested for colleagues in the Government of Canada.

On the work of the WTO Ottawa Group and the Trade and Health Initiative, Colin Bird, Director, Trade Negotiations Division (colin.bird@international.gc.ca) and Sarah Geddes, Deputy Director, Trade Negotiations Division (sarah.geddes@international.gc.ca), would be pleased to speak with you about these topics.

On CAMR, our Health Canada contact is Bruce Randall, Senior Executive Director, Therapeutic Products Directorate (bruce.randall@canada.ca).

Best,
David

David Norris
Senior Trade Policy Officer | Agent principal de la politique commerciale
Intellectual Property Trade Policy Division | Direction de la politique commerciale sur la propriété intellectuelle (TMI)
david.norris@international.gc.ca
Telephone | Téléphone: 613-462-2826
111 Sussex Drive, Ottawa Ontario K1N 1J1

Global Affairs Canada | Affaires mondiales Canada

-----Original Appointment-----
From: Norris, David -TMI
Sent: May 28, 2021 9:47 AM
To: '[redacted]Mirella, Loris -TMI; Foster, Dean -TMI
Subject: IMC call with TMI
When: May 28, 2021 3:30 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Hi [redacted]

Please find below an MS Teams link for our meeting this afternoon at 3:30pm.

Looking forward to meeting with then.

Best,
David

David Norris
Senior Trade Policy Officer | Agent principal de la politique commerciale
Intellectual Property Trade Policy Division | Direction de la politique commerciale sur la propriété intellectuelle (TMI)
david.norris@international.gc.ca
Telephone | Téléphone: 613-462-2826
111 Sussex Drive, Ottawa Ontario K1N 1J1

Global Affairs Canada | Affaires mondiales Canada

Microsoft Teams meeting

Join on your computer or mobile app
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Phone Conference ID: 363 437 363#

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Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: July 15, 2021 10:36 AM
To: [redacted]@pfizer.com; Lesieur, Nicolas -GENEV -GVWTO; Norris, David -TMI; Foster, Dean -TMI
Cc: [redacted]
Subject: RE: Merci and comprehensive list of Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics

Thanks, [redacted]
Appreciate everyone taking the time to participate and welcome any further insights from your collective perspective.

Best
loris

From: [redacted]@imc-mnc.ca>
Sent: July 15, 2021 10:33 AM
To: [redacted]@pfizer.com [redacted]@imc-mnc.ca>; Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>; Foster, Dean -TMI <Dean.Foster@international.gc.ca>
Cc: [redacted]@chamber.ca>; [redacted]@its.jnj.com>
Subject: RE: Merci and comprehensive list of Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics

I second [redacted] thanks for your time today. It was a very informative discussion.

We will also consider what additional input on issues related to the WTO discussions that we can provide that may be useful for GAC.

Have a good day everyone.

[redacted]

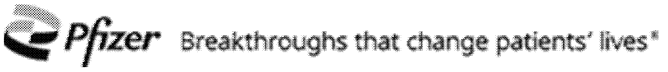
[redacted]

C [redacted]
innovativemedicines.ca | @innovativemeds

From [redacted]@pfizer.com>
Sent: July 15, 2021 10:19 AM
To: Loris Mirella (loris.mirella@international.gc.ca) <loris.mirella@international.gc.ca>; Nicolas.Lesieur@international.gc.ca; David.Norris@international.gc.ca; Dean.Foster@international.gc.ca
Cc: [redacted]@imc-mnc.ca>; [redacted]@chamber.ca>; [redacted]@its.jnj.com>
Subject: Merci and comprehensive list of Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics

Nicolas, Loris, David and Dean,
Thank you very much for taking the time to speak with our group this morning. We truly appreciate the collaboration and engagement with industry on this important topic.
If you haven't seen it yet, please find attached a comprehensive list of Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics (as of June 16th 2021). *All of these have been done without the need of a patent waiver* and I expect more partnership will emerge as well in support of increasing production of these key vaccines and therapeutics. I hope you'll find this document helpful.
Bonne fin de journée,

[redacted]
Pfizer Canada Inc.
Courriel/Email : [redacted]@pfizer.com
Cell. : [redacted]
www.pfizer.ca | www.facebook.com/Pfizer.Canada | @PfizerCA



Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: July 15, 2021 10:33 AM
To: [redacted] Lesieur, Nicolas -GENEV -GVWTO; Norris, David -TMI; Foster, Dean -TMI
Cc: [redacted]
Subject: RE: Merci and comprehensive list of Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics

Hi [redacted]

We found the conversation very helpful as well. Thank you very much for that engagement and for the additional information. I hadn't seen that list previously and we will make sure to circulate among interested colleagues.

And for everyone on this message: please feel free to get in touch if you have further questions or observations about this or other IP trade related topics of interest or concern.

Best
loris

From: [redacted]@pfizer.com>
Sent: July 15, 2021 10:19 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>; Foster, Dean -TMI <Dean.Foster@international.gc.ca>
Cc: [redacted]@imc-mnc.ca>; [redacted]@chamber.ca>; [redacted]@its.jnj.com>
Subject: Merci and comprehensive list of Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics

Nicolas, Loris, David and Dean,
Thank you very much for taking the time to speak with our group this morning. We truly appreciate the collaboration and engagement with industry on this important topic.
If you haven't seen it yet, please find attached a comprehensive list of Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics (as of June 16th 2021). *All of these have been done without the need of a patent waiver* and I expect more partnership will emerge as well in support of increasing production of these key vaccines and therapeutics. I hope you'll find this document helpful.
Bonne fin de journée,

[redacted]

[redacted]
Pfizer Canada Inc.
Courriel/Email : [redacted]@pfizer.com
Cell. [redacted]
www.pfizer.ca | www.facebook.com/Pfizer.Canada | @PfizerCA

Pfizer Breakthroughs that change patients' lives®

Lackie, Kimberley -DCP

s.19(1)

From: Mirella, Loris -TMI
Sent: January 20, 2022 4:11 PM
To: [redacted]
Cc: Lesieur, Nicolas -GENEV -GVWTO; Norris, David -TMI; Ivankovic, Ivana -TMI; Gordon, Nicholas -TMI; Hisko, Mellissa -FMNV
Subject: RE: Pfizer update on vaccine equity: We delivered 1 billion doses to 99 low and middle income countries in 2021

Hi [redacted]

Thank you again for the insightful discussion during our call Monday, and for sending us the updated Pfizer Infographic on vaccine equity.

As discussed on Monday, we recall that you would be interested in discussing in greater detail with Global Affairs Canada (GAC) other, non-IP issues relating to Canada's vaccine donation commitments.

By way of introduction, I am copying my GAC colleague, Mellissa Hisko, Deputy Director, COVID-19 Global Health Response Task Force, should you wish to discuss this topic further.

Best,
Loris

From: [redacted]@pfizer.com>
Sent: January 17, 2022 5:02 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>; Gordon, Nicholas -TMI <Nicholas.Gordon@international.gc.ca>; Ivankovic, Ivana -TMI <Ivana.Ivankovic@international.gc.ca>
Subject: FYI: Pfizer update on vaccine equity: We delivered 1 billion doses to 99 low and middle income countries in 2021

Loris, Nicolas, David, Nicholas, Ivana,
Thanks again for the discussion today. As promised, I'm pleased to share with you the updated Pfizer Infographic on Covid-19 vaccines equity (attached).

We have pledged to provide 2 billion doses of our COVID-19 vaccine to low- and middle-income countries in 2021 and 2022 – at least 1 billion doses each year.
On 29 December 2021, Pfizer and BioNTech fulfilled this pledge for 2021, having delivered more **than 1 billion doses to 99 of these countries.** We will continue to partner with governments and the global health community to supply at least another 1 billion doses to these countries in 2022.

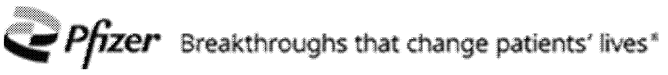
Partnering to build up scale.
The Pfizer-BioNTech global COVID-19 vaccine supply chain and manufacturing network now spans four continents and includes more than 20 facilities. This includes Contract Manufacturing Partnerships with **16 non Pfizer/BioNTech sites**. Note that all of these Contract Manufacturing Partnerships are taking place without the need of a patent waiver as proposed by some members of the WTO.

Paxlovid

Also, in case I did not share it with you last year, in November we announced an agreement enabling the Medicine Patent Pool (MPP) to facilitate additional production and distribution of our COVID therapy (Paxlovid) by granting sub-licenses to qualified generic medicine manufacturers, with the goal of facilitating greater access to the global population. Under the terms of the head license agreement between Pfizer and MPP, qualified generic medicine manufacturers worldwide that are granted sub-licenses will be able to supply PF-07321332 in combination with ritonavir to 95 countries, covering up to approximately 53% of the world's population. This includes all low- and lower-middle-income countries and some upper-middle-income countries in Sub-Saharan Africa as well as countries that have transitioned from lower-middle to upper-middle-income status in the past five years. Pfizer will not receive royalties on sales in low-income countries and will further waive royalties on sales in all countries covered by the agreement while COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization.

Further, similar to the COVID vaccine, Pfizer will offer our oral protease inhibitor therapy through a tiered pricing approach based on the income level of each country to promote equity of access across the globe. High and upper[1]middle income countries will pay more than lower income countries.

Pfizer Canada Inc.
Courriel/Email : @pfizer.com
Cell. :
www.pfizer.ca | www.facebook.com/Pfizer.Canada | @PfizerCA



Lackie, Kimberley -DCP

From: Norris, David -TMI
Sent: July 14, 2021 9:34 AM
To: Mirella, Loris -TMI; Foster, Dean -TMI
Subject: RE: Touch Base

Thanks, Loris. Will do!

David

From: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Sent: July 14, 2021 9:34 AM
To: Foster, Dean -TMI <Dean.Foster@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca>
Subject: RE: Touch Base

Thanks, Dean!

Great minds – I was drafting while your message came in.

David: could you please send out the invitation for a Teams meeting using the list provide by IMC yesterday?

Thanks
loris

From: Foster, Dean -TMI <Dean.Foster@international.gc.ca>
Sent: July 14, 2021 9:25 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca>
Subject: RE: Touch Base

Hey Loris – just noting that [redacted] from J&J is on this meeting and we are scheduled to meet with her today also. Could probably offer to cover just tomorrow but remain willing to meet separately today since already scheduled?

From: [redacted]@imc-mnc.ca>
Sent: July 13, 2021 2:59 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>
Subject: RE: Touch Base

Thanks Loris, that would be great.

Please send the invitation to the participants listed below for now. We will extend the invitation to our IPLOT Team in the mean time and I will send you the remaining participants list as soon as it is available.

[redacted]@imc-mnc.ca
[redacted]@imc-mnc.ca

[redacted]@imc-mnc.ca
[redacted]@pfizer.com
[redacted]@its.jnj.com
[redacted]@chamber.ca

Kind regards,
[redacted]

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: July 13, 2021 2:37 PM
To: [redacted]@imc-mnc.ca>
Cc: Dean.Foster@international.gc.ca; David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Touch Base

Hi [redacted]

We would be available to meet at the proposed time.

Please let us know who might participate and we can send out an invitation on MS Teams or Webex.

Best
loris

From: [redacted]@imc-mnc.ca>
Sent: July 13, 2021 9:46 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>
Subject: Touch Base

Good afternoon Loris,

I am following up on your correspondence below with [redacted] Would you and your group be available on Thursday this week from 8:30 to 9:30 a.m. (EDT).

Thanks for confirming, and I will follow up with a calendar invitation if the timing is suitable.

Lind regards,
[redacted]

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: July 12, 2021 2:00 PM
To: [redacted]@imc-mnc.ca>
Cc: Dean.Foster@international.gc.ca; David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Touch Base

Hi [redacted]

Hope you are having a pleasant summer.

Just following up on a previous conversation as you have expressed interest on behalf of IMC members of developments around waiver discussions at TRIPS Council.

If you or members would find it helpful, happy to set up a morning meeting for my team here at GAC and our colleague in Geneva to provide a state of play to this point of those discussions and for you and interested members to share your current thinking.

Please let me know some times that would be convenient in the next week or two.

best
loris

Lackie, Kimberley -DCP

From: [redacted]@imc-mnc.ca>
Sent: July 13, 2021 3:06 PM
To: Mirella, Loris -TMI
Cc: Foster, Dean -TMI; Norris, David -TMI; Lesieur, Nicolas -GENEV -GVWTO
Subject: RE: Touch Base

I forgot to mentioned Loris, via Teams would be great.

[redacted]

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: July 13, 2021 2:37 PM
To: [redacted]@imc-mnc.ca>
Cc: Dean.Foster@international.gc.ca; David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Touch Base

Hi [redacted]

We would be available to meet at the proposed time.

Please let us know who might participate and we can send out an invitation on MS Teams or Webex.

Best
loris

From: [redacted]@imc-mnc.ca>
Sent: July 13, 2021 9:46 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>
Subject: Touch Base

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Thanks for confirming, and I will follow up with a calendar invitation if the timing is suitable.

Lind regards,
[redacted]

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>

Sent: July 12, 2021 2:00 PM
To: [redacted]@imc-mnc.ca>
Cc: Dean.Foster@international.gc.ca; David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Touch Base

Hi [redacted]

Hope you are having a pleasant summer.

Just following up on a previous conversation as you have expressed interest on behalf of IMC members of developments around waiver discussions at TRIPS Council.

If you or members would find it helpful, happy to set up a morning meeting for my team here at GAC and our colleague in Geneva to provide a state of play to this point of those discussions and for you and interested members to share your current thinking.

Please let me know some times that would be convenient in the next week or two.

best
loris

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: July 12, 2021 2:00 PM
To: [redacted]
Cc: Foster, Dean -TMI; Norris, David -TMI; Lesieur, Nicolas -GENEV -GVWTO
Subject: RE: Touch Base

Hi [redacted]

Hope you are having a pleasant summer.

Just following up on a previous conversation as you have expressed interest on behalf of IMC members of developments around waiver discussions at TRIPS Council.

If you or members would find it helpful, happy to set up a morning meeting for my team here at GAC and our colleague in Geneva to provide a state of play to this point of those discussions and for you and interested members to share your current thinking.

Please let me know some times that would be convenient in the next week or two.

best
loris

From: Mirella, Loris -TMI
Sent: May 28, 2021 9:23 AM
To: [redacted]@imc-mnc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>
Subject: RE: Touch Base

Hi [redacted]

Hope all is well with you. Yes, we'd be happy to set something up for this afternoon. I can be available anytime from 3:30 onward. Please let me know a time that works for you and we'll send an invitation for a call on Teams.

Best
loris

From: [redacted]@imc-mnc.ca>
Sent: May 28, 2021 8:37 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Subject: Touch Base

Hi Loris.

It's been a while and I hope that you are doing well. Would you have a few minutes this afternoon to talk about TRIPS issues? Thanks.

With Kind Regards,

[redacted]

[redacted]

C [redacted]

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Lackie, Kimberley -DCP

From: [redacted]@imc-mnc.ca>
Sent: July 14, 2021 4:42 PM
To: Norris, David -TMI; Mirella, Loris -TMI
Cc: Foster, Dean -TMI; Lesieur, Nicolas -GENEV -GVWTO
Subject: RE: Touch Base

Good afternoon David, I did not received any further request for the meeting other than [redacted] already confirmed.

Should anyone reply to me last minute, I will forward them the invitation directly.

Kind regards,
[redacted]

From: [redacted]
Sent: July 14, 2021 10:10 AM
To: David.Norris@international.gc.ca; Loris.Mirella@international.gc.ca
Cc: Dean.Foster@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Touch Base

Thanks David, you can also add [redacted]@astrazeneca.com to the invite.

I will send you any other names by end of day today (EDT).

Kind regards,
[redacted]

From: David.Norris@international.gc.ca <David.Norris@international.gc.ca>
Sent: July 14, 2021 10:06 AM
To: [redacted]@imc-mnc.ca>; Loris.Mirella@international.gc.ca
Cc: Dean.Foster@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Touch Base

Thank you, [redacted] In terms of tracking, [redacted] and [redacted] have confirmed their attendance for tomorrow's meeting so far.

Happy to add any additional participants to the invitation as well.

Best,
David

David Norris
Senior Trade Policy Officer | Agent principal de la politique commerciale
Intellectual Property Trade Policy Division | Direction de la politique commerciale sur la propriété intellectuelle (TMI)

david.norris@international.gc.ca
Telephone | Téléphone: 613-462-2826
111 Sussex Drive, Ottawa Ontario K1N 1J1

Global Affairs Canada | Affaires mondiales Canada

From: [redacted]@imc-mnc.ca>
Sent: July 14, 2021 9:56 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>
Subject: RE: Touch Base

Good afternoon Loris, Thanks David for sending the calendar invitation. I have given our IPLOT team until 4:00 p.m. this afternoon to confirm their attendance for tomorrow morning's meeting.

I will send you the list of extra participant at the end of the day today. Thanks for adding them to the calendar invitation accordingly.

Kind regards,
[redacted]

From: Loris.Mirella@international.gc.ca <Loris.Mirella@international.gc.ca>
Sent: July 13, 2021 2:37 PM
To: [redacted]@imc-mnc.ca>
Cc: Dean.Foster@international.gc.ca; David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Touch Base

Hi [redacted]

We would be available to meet at the proposed time.

Please let us know who might participate and we can send out an invitation on MS Teams or Webex.

Best
loris

From: [redacted]@imc-mnc.ca>
Sent: July 13, 2021 9:46 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Foster, Dean -TMI <Dean.Foster@international.gc.ca>; Norris, David -TMI <David.Norris@international.gc.ca>; Lesieur, Nicolas -GENEV -GVWTO <Nicolas.Lesieur@international.gc.ca>
Subject: Touch Base

Good afternoon Loris,

I am following up on your correspondence below with [redacted] Would you and your group be available on Thursday this week from 8:30 to 9:30 a.m. (EDT).

Thanks for confirming, and I will follow up with a calendar invitation if the timing is suitable.

Lind regards,
[redacted]

From: Loris.Mirella@international.gc.ca
<Loris.Mirella@international.gc.ca>
Sent: July 12, 2021 2:00 PM
To: [redacted]@imc-mnc.ca>
Cc: Dean.Foster@international.gc.ca; David.Norris@international.gc.ca; Nicolas.Lesieur@international.gc.ca
Subject: RE: Touch Base

Hi [redacted]

Hope you are having a pleasant summer.

Just following up on a previous conversation as you have expressed interest on behalf of IMC members of developments around waiver discussions at TRIPS Council.

If you or members would find it helpful, happy to set up a morning meeting for my team here at GAC and our colleague in Geneva to provide a state of play to this point of those discussions and for you and interested members to share your current thinking.

Please let me know some times that would be convenient in the next week or two.

best
loris

Lackie, Kimberley -DCP

From: Mirella, Loris -TMI
Sent: May 28, 2021 5:24 PM
To: Bird, Colin -TCW
Cc: Norris, David -TMI; Geddes, Sarah -TCW
Subject: RE: Touch Base

Thanks, Colin. David will pass along the information to [redacted]

loris

From: Bird, Colin -TCW <Colin.Bird@international.gc.ca>
Sent: May 28, 2021 4:25 PM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca>; Geddes, Sarah -TCW <Sarah.Geddes@international.gc.ca>
Subject: RE: Touch Base

Happy to take the call or have him speak with Sarah.

Colin Bird
Directeur | Director (TCW)
T: 343-203-4430
Global Affairs Canada | Affaires mondiales Canada

From: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Sent: May 28, 2021 4:23 PM
To: Bird, Colin -TCW <Colin.Bird@international.gc.ca>
Cc: Norris, David -TMI <David.Norris@international.gc.ca>
Subject: FW: Touch Base

Hi Colin,
Hope you are surviving the week. I just spoke to [redacted] from IMC about TRIPS waiver stuff and he also had questions about Ottawa Group work. To whom should I direct him?

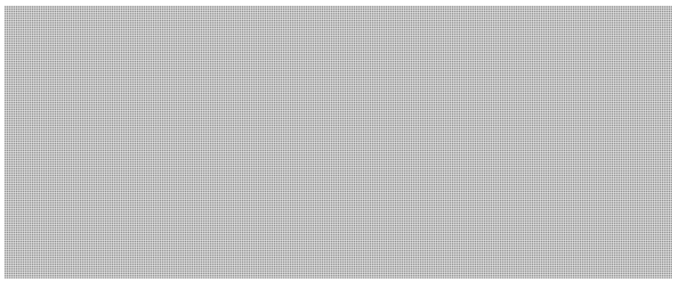
Have a great weekend.
loris

From: [redacted]@imc-mnc.ca>
Sent: May 28, 2021 8:37 AM
To: Mirella, Loris -TMI <Loris.Mirella@international.gc.ca>
Subject: Touch Base

Hi Loris.

It's been a while and I hope that you are doing well. Would you have a few minutes this afternoon to talk about TRIPS issues? Thanks.

With Kind Regards,



C [redacted]

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Norris, David -TMI

From: Norris, David -TMI
Sent: July 15, 2021 4:01 PM
To: Campbell2, Erin (ISED/ISDE); Jenkins, Brad (IC); Hawa, Zoe -BBI; Cooper, Michelle -BBI; Blais, Pierre -MNC; Hisko, Mellissa -MNC; Lachance, Nalini -MNC; Bird, Colin -TCW; Geddes, Sarah -TCW
Cc: *TFM-Policy; de Boer, Stephen -GENEV -GVWTO -HOM/CDM; Moen, Martin -GENEV -GVWTO; O'Toole, Christopher -GENEV -GVWTO; Lesieur, Nicolas -GENEV -GVWTO; Melia, Shendra -TMD; Mirella, Loris -TMI; Foster, Dean -TMI; Ivankovic, Ivana -TMI
Subject: REPORT – TMI and GVWTO meetings with the Canadian Chamber of Commerce, Innovative Medicines Canada (IMC), and IMC members to discuss the WTO TRIPS waiver proposal (July 14 and 15, 2021)
Attachments: BIO COVID Company Partnerships 6-16-21.pdf

REPORT – TMI and GVWTO meetings with the Canadian Chamber of Commerce, Innovative Medicines Canada (IMC), and IMC members to discuss the WTO TRIPS waiver proposal (July 14 and 15, 2021)

SUMMARY

On July 15, TMI and GVWTO met with the Canadian Chamber of Commerce and Innovative Medicines Canada (IMC), as well as IMC members, to update on recent WTO TRIPS Council discussions on the proposal for a COVID-19-related waiver from the TRIPS Agreement. The meeting was attended by [redacted] Canadian Chamber of Commerce; [redacted] IMC; [redacted] IMC; [redacted] IMC; [redacted] Johnson & Johnson (J&J); [redacted] Pfizer; and [redacted] AstraZeneca Canada Inc. [redacted] Both meetings provided an opportunity for Departmental officials to provide an overview of the ongoing text-based negotiations on the TRIPS waiver, including with respect to the dynamics and themes of those discussions, and the path leading to the July 27-28 General Council meeting and MC12 in the Fall. IMC and its members expressed an interest in confirming Canada's position on the waiver and that it remains as set out in MINT's May 7 statement, as well as Canada's position on related proposals like the EU's draft declaration on existing TRIPS flexibilities, and the Trade and Health Initiative. The Chamber was also interested in knowing whether Canada will be seeking a mandate for TRIPS waiver negotiations. Participants noted appreciation for the exchange, with IMC and its members committing to providing further views on the waiver text, as well as information on voluntary licensing (attached), which GVWTO suggested could be further elaborated at the WTO Public Forum in the Fall, as well as through further engagement under the WTO Director General's "third way" initiative. Global Affairs Canada was represented by TMI/Mirella, Foster, and Norris, and GVWTO/Lesieur.

REPORT

1. TMI opened the meeting by providing an **overview of the TRIPS waiver** proposal and the current context whereby the TRIPS Council is engaged in text-based negotiations. GVWTO gave an overview of the recent meetings on the text of the waiver so far, which began on June 30, and which most recently took place on July 14 to discuss the TRIPS Council's report to the July 27-28 meeting of the General Council. GVWTO also provided a high-level overview of the dynamics in text-based negotiations so far, clarifying that waiver proposal co-sponsors and other WTO Members have not yet engaged in a substantive discussion on the text, and that recent meetings have generally dealt with thematic discussions on topics such as the scope and duration of the waiver proposal, as well as questions from

Members on implementation and the implications of the waiver for the protection of IP such as patents and trade secrets. Pfizer sought clarification on Canada's position in these discussions, and whether it has changed from MINT's May 7 statement on the waiver. Chamber/ similarly asked, "from a headquarters perspective", whether Canada is "anywhere near a point where the Government might seek a mandate" and how the Government might position itself in the waiver discussions. TMI confirmed that Canada's position has not changed, and that Canada continues to engage on the basis of the May 7 statement, adding that text-based negotiations on the waiver have largely remained static and have not yet seen substantive discussion on the text. IMC/ also asked for clarification on the positions of other WTO Members like China, which Médecins Sans Frontières has suggested supports the waiver. GVWTO confirmed that, while China has publicly noted that it is supportive of text based discussion on a waiver, it has not co-sponsored the proposal.

2. On the static nature of the **waiver discussions so far**, Pfizer/ asked whether Canada has "contributed any alternative solutions" of its own. TMI noted that, in November 2020, Canada, along with Australia, Chile, and Mexico, submitted a set of questions to waiver co-sponsors that sought clarification on specific IP barriers experienced in relation to COVID-19, but that these questions have largely gone unanswered. TMI added that, as specific IP challenges have not yet been identified, Canada has not made IP-related proposals in the TRIPS waiver context. Rather, Canada continues to engage in the waiver discussions, while also participating in parallel WTO discussions where concrete barriers have been identified, such as Canada's active engagement in the Trade and Health Initiative, and ongoing support for the WTO Director General's "third way" initiative. On **broader WTO initiatives**, Pfizer, also asked whether the WTO General Council Chair's recent selection of New Zealand Ambassador David Walker as a facilitator to lead on multilateral responses to the COVID-19 pandemic would inform the TRIPS waiver discussions. GVWTO noted that this appointment is unrelated to the TRIPS waiver discussions, and is instead focusing on a broader range of trade issues at the WTO, including those on which Canada has been at the forefront, such as topics addressed by the Trade and Health Initiative. On the EU's TRIPS Council proposal for a declaration on existing TRIPS Agreement flexibilities, IMC/ asked whether Canada has engaged on this text. GVWTO noted that, as with the waiver proposal, TRIPS Council Members, including Canada, have not actively engaged on the EU proposal, with Members largely taking the opportunity to ask questions and seek clarification from the EU. GVWTO added that, like the waiver proposal, the EU proposal still does not address broader consideration related to technology transfer for vaccines, which relies on a far broader range of know-how and technical expertise than IP (e.g. it is not simply a matter of sending the "recipe" to manufacturers in another jurisdiction).

3. On **technology transfer**, IMC/ observed that it appears that waiver co-sponsors are "deliberately skirting this fundamental issue", by assuming that tech transfer can take place solely on the basis of information contained in patents and other regulatory submissions. IMC/ suggested that there may be a "lack of understanding that, on a practical manner, it would be difficult to compel" the sharing of know-how and technical expertise absent a predictable IP framework. For instance, following the meeting, Pfizer/ circulated the Biotechnology Innovation Organization's overview of "Cross-border industry partnerships on COVID-19 vaccines and therapeutics" (attached), which contains a comprehensive list of voluntary licences conducted between vaccine developers and manufacturers. GVWTO noted that, while the leading waiver co-sponsors India and South Africa are well aware of the role played by IP in facilitating voluntary partnerships (e.g. both countries have seen notable engagement between developers and manufacturers in producing COVID-19 vaccines on this basis), other waiver co-sponsors may be under the impression that an IP waiver will facilitate collaboration along these lines. GVWTO pointed to the current situation faced by least-developed country (LDC) Members, which have long been exempt from the majority of the obligations under TRIPS, including a specific LDC exemption for pharmaceutical IP protection until 2033, but have nonetheless been unable to attract the necessary investment and voluntary licensing partnerships to produce COVID-19 vaccines, which suggests that a far broader range of factors are at play. J&J remarked that there appears to be a "lack of real knowledge" about the complexities of technology transfer, and asked whether there is a process whereby industry could clear up these misconceptions. GVWTO suggested that the WTO Public Forum, which will be held from September 28-October 1 on the theme of "Trade beyond COVID-19: Building resilience", could provide one such opportunity for stakeholders to engage on this topic. GVWTO also noted that, while the TRIPS Council meetings are not open to industry observers, engagement in the WTO Director General's "third way" discussions with industry may be a possibility, as well as through meetings at WIPO and the WHO.

4. IMC/ observed that the TRIPS waiver appears to "stem in part from view that existing mechanisms are not effective", and that "something more sweeping is needed", and asked to what extent **existing TRIPS flexibilities** have been raised in the waiver discussions. GVWTO noted that existing TRIPS flexibilities have been raised by waiver co-sponsors' in voicing longstanding concerns with these mechanisms, but have not been based in their actual experiences in making use of TRIPS flexibilities in the context of COVID-19. However, as the only country to have historical experience in using the TRIPS paragraph 6/Article 31*bis* system under CAMR, the spotlight has inevitably turned on Canada in these discussions, particularly given the CAMR request from the Canadian company Biolyse to export the J&J COVID-19 vaccine to Bolivia. GVWTO added that this issue has received attention by both waiver co-sponsors and Members like the EU, given the latter's own proposal on TRIPS flexibilities. J&J/ asked how the issue has been raised in the TRIPS Council, with GVWTO noting that Bolivia has only raised the issue to note its WTO notification on the matter, but that South Africa has regularly raised the issue in TRIPS Council meetings on the waiver.

5.

6.

. TMI clarified that there is a distinction under CAMR between the addition of a pharmaceutical product to *Schedule 1* to the *Patent Act*, which lists drugs eligible for CAMR authorization, and the subsequent steps of meeting Health Canada's regulatory approval requirements, which are ultimately necessary to receive compulsory licensing authorization. TMI again highlighted this nuance during the July 15 meeting when the discussion returned to Biolyse's request, noting that the addition of a drug to *Schedule 1* does not mean that a compulsory licence has been granted, which would still rely on meeting regulatory approval requirements in Canada.

7. Returning to the TRIPS waiver proposal, participants asked about **next steps on the waiver**, with GVWTO updating that the TRIPS Council will finalize its report to the General Council next week, which will be presented at the General Council's July 27-28 meeting. Pfizer/ asked what can be expected in the report, with TMI and GVWTO pointing to the past practice of TRIPS Council reports to the General Council in December 2020 and March 2021, whereby the Council reported that it had not reached consensus on the waiver and would continue discussions. In terms of other upcoming milestones, Chamber, pointed to MC12, and asked whether an outcome at that meeting would be "aspirational at this rate, rather than realistic". Chamber further asked where the discussions will go from here after the General Council meeting and the summer break in Geneva. GVWTO noted that the path

forward remains unclear, though that any discussion on the waiver could be less predictable heading into MC12, where it could be introduced into the mix of a broader set of issues for Ministerial consideration. Going forward, Pfizer asked what stakeholders can do to assist the Government of Canada as TRIPS waiver discussions move ahead, noting that they would like to "supportive in any way [that they] can". TMI suggested that any questions from industry on the waiver proposal, including issues that may give rise to concerns and areas that Canada should gather information on, would be worth conveying. TMI committed to reaching out to stakeholders again as the discussions proceed. IMC expressed appreciation for the meeting on behalf of participants, noting that while they routinely receive updates through the International Federation of Pharmaceutical Manufacturers and Associations, it was "helpful to have the Canadian lens" on these discussions. Participants agreed to remain in contact, and to share further information going forward.

Drafted: TMI/Norris
Consulted: TMI/Mirella, Foster; GVWTO/Lesieur

Updated June 16, 2021

Biotechnology Innovation Organization

Cross-Border Industry Partnerships on COVID-19 Vaccines and Therapeutics

Vaccines

- **CureVac**
  - *Celonic* will manufacture 100 million doses of CureVac's vaccine at its plant in Heidelberg, Germany, providing bulk substance for 50 million doses by the end of 2021. (press release)
  - *Novartis* will manufacture CureVac's vaccine. (press release)
  - *GlaxoSmithKline plc* and CureVac N.V. announced a new €150m collaboration, building on their existing relationship, to jointly develop next generation mRNA vaccines for COVID-19 with the potential for a multi-valent approach to address multiple emerging variants in one vaccine. (press release)
  - *Rentschler Biopharma SE* will manufacture CureVac's vaccine. (press release)
  - *Bayer* will support the further development, supply and key territory operations of CureVac's vaccine candidate. (press release)
  - *Fareva* will dedicate a manufacturing plant in France to the fill and finish of CureVac's vaccine. (press release)
  - *Wacker Chemie AG* will manufacture CureVac's vaccine candidate at its Amsterdam site. (press release)
  - CureVac will collaborate with *Tesla Grohmann Automation* to develop an RNA printer that works like a mini-factory and can produce such drugs automatically. (press release)

- **Moderna**
  - Moderna and *Magenta* are partnering to distribute Moderna's vaccine and updated variant booster candidates in the United Arab Emirates. (press release)
  - *Tabuk Pharmaceuticals* in Saudi Arabia agreed to commercialize and distribute Moderna's vaccine and variant-specific booster candidates in Saudi Arabia. (press release)
  - *Thermo Fisher Scientific* will provide fill/finish, labeling and packaging services at a North Carolina site to support the production of hundreds of millions doses of the Moderna COVID-19 vaccine. (press release)
  - Moderna signed an agreement with *Lonza* in the Netherlands to support drug substance manufacturing for its global supply chain. (press release)
  - *Samsung Biologics* will provide large scale, commercial fill-finish manufacturing for Moderna's vaccine in South Korea. (press release)
  - *Baxter International* will provide fill/finish services and supply packaging for Moderna. (press release)
  - *Sanofi* will manufacture 200 million doses of Moderna's COVID-19 vaccine starting in September 2021. (press release)
  - *Rovi* will produce bulk substance for Moderna's COVID-19 vaccine, expanding an agreement between the companies. Rovi currently provides fill-finish for the vaccine, receiving substance from a Lonza plant in Switzerland. A new production line at Rovi's

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plant in Granada, Spain, will make ingredients for up to 100 million vaccine doses a year. (news release)
- Moderna collaborates with *Catalent* for vial filling and packaging capacity (press release)
- *Lonza*'s site in Valais, Switzerland, will manufacture Moderna's vaccine (press release)
- *Recipharm* will support formulation and fill-finish for Moderna's vaccine at their site in France. (press release)
- *Laboratorios Farmacéuticos Rovi* will support large-scale, commercial fill-finish manufacturing of Moderna's vaccine at their site in Madrid, Spain. (press release)
- *CordenPharma* will manufacture large-scale volumes of Moderna's lipid excipients to be used in the manufacture of Moderna's vaccine. (press release)
- *Takeda,* Japan's Ministry of Health, Labor and Welfare (MHLW) announced an agreement to import and distribute Moderna's vaccine. (press release)

- **Novavax**
  - Novavax partners with *SK Boiscience* of South Korea to manufacture Novavax's protein antigen, supply of Matrix MTM adjuvant, and support to SK Bioscience as needed to secure regulatory approval. (press release)
  - *Biologics Manufacturing Centre of Canada* is partnered with Novavax to produce its vaccine. (press release)
  - *FUJIFILM Diosynth Biotechnologies* will produce bulk drug substance of NVX-CoV2373, Novavax' vaccine candidate. (press release)
  - *Baxter International Inc* will provide sterile manufacturing services for NVX-CoV2373, Novavax' COVID-19 recombinant nanoparticle vaccine candidate with Matrix-M™ adjuvant. (press release)
  - Novavax collaborates with *Takeda* for local production and commercialization of Novavax' vaccine in Japan (press release)
  - *AGC Biologics* is preparing to manufacture Matrix-M™, the adjuvant component[*2] of Novavax' COVID-19 vaccine candidate, NVX-CoV2373 in its Copenhagen facility. (press release)
  - Novavax bought a Czech company (*Praha Vaccines*) to further expand COVID-19 manufacturing capacity (press release)
  - Novavax partnered with *Serum Institute of India*, increasing Novavax' global production capacity to over 2 billion doses annually. Novovax committed 1 billion doses to COVAX made possible through their partnership with the Serum Institute of India. (press release)

- **Medicago**
  - Medicago is partnering with *GlaxoSmithKline plc* to develop and evaluate a COVID-19 candidate vaccine combining Medicago's recombinant Coronavirus Virus-Like Particles (CoVLP) with GSK's pandemic adjuvant system. (press release)
  - Medicago partners with *Dynavax* to evaluate Medicago's Coronavirus Virus-Like Particle (CoVLP) with Dynavax's CpG 1018 adjuvant to support the rapid development of a

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COVID-19 vaccine candidate. (press release)

- **Providence Therapeutics**
  - India's Biological E. entered into a licensing agreement with the Canadian company, Providence Therapeutics Holdings to manufacture 1 billion doses of their mRNA COVID-19 vaccine. (Press Release)

- **Sanofi and Translate Bio**
  - Sanofi is developing a messenger RNA vaccine in partnership with Translate Bio. In March 2021, Sanofi and Translate Bio initiated a Phase 1/2 clinical trial of their mRNA COVID-19 vaccine candidate, in order to assess safety, immune response and reactogenicity, after preclinical data showed high neutralizing antibody levels. (press release)

- **Tonix Pharmaceuticals**
  - *FUJIFILM Diosynth Biotechnologies* to manufacture Tonix's vaccine. Collaboration includes development of manufacturing processes and supply of clinical trial material to support Tonix's development of TNX-1800 (press release)

- **Valneva**
  - *Dynavax* to produce adjuvant for Valneva vaccine (press release)

- **Inovio Inc**.
  - Inovio has partnered with *Kaneka Eurogentec* (Japan), *Thermo Fisher Scientific* (USA), *Richter-Helm BioLogics* (Hungary) and *Ology Biosciences* (USA) to help manufacture their vaccine candidate. (Kaneka press release) (Thermo Fischer press release) (Ology press release)
  - Inovio collaborates with *Beijing Advaccine* (Chinese company) to facilitate clinical trial translations in China (press release)

- **AstraZeneca**
  - *Siam Bioscience* in Thailand to manufacture the AstraZeneca vaccine. (press release)
  - China's *Shenzhen Kangtai Biological Products* will manufacture 400 million doses per year of AstraZeneca's COVID-19 vaccine. (news article)
  - AstraZeneca reached a licensing and technology transfer agreement with *Serum Institute of India* to supply one billion doses to low and middle-income countries (press release)
  - *CSL Behring* is manufacturing approximately 50 million doses of AstraZeneca's vaccine in Australia for supply to the country. First doses were rolled out in March 2021. (press release)
  - *Emergent BioSolutions*, *Daiichi Sankyo* to expand manufacturing of AZ's vaccine (Emergent BioSolutions press release) (Daiichi press release)
  - AstraZeneca has signed manufacturing deals with mAbxience of the INSUD Group in Argentina, Carlos Slim Foundation in Mexico, R-Pharm in Russia, Fundação Osvaldo Cruz

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(Fiocruz) in Brazil and Symbiosis Pharmaceutical in Scotland. (news release)

- **CSL Behring**
  - *Seqirus*, which is part of the CSL Group, has donated its well-established adjuvant technology – MF59® – to the vaccine efforts of multiple entities, including the University of Queensland vaccine development program. (press release)

- **Johnson & Johnson**
  - *Biological E*, in India, will make 600 million doses per year. (news article)
  - Spain's *Reig Jofre* new manufacturing plant will produce J&J vaccines starting in Q2 of 2021. (news article)
  - *Sanofi* will provide manufacturing support to Johnson & Johnson. (press release)
  - *Takeda* has made manufacturing capacity available for three months at *IDT Biologika's (IDT)* site in Dessau, Germany to manufacture J&J's vaccine. (press release)
  - J&J partnered with *Merk* to manufacture their vaccine. (press release)
  - *Catalent* will use their Anagni, Italy manufacturing facility for vial-filling, inspection, labeling and packaging services. (press release)
  - *Emergent BioSolutions* is manufacturing doses in the US. (press release)
  - J&J partnered with the *Aspen Pharmacare Ltd.* in South Africa to manufacture their vaccine. (Aspen press release)
  - *Grand River Aseptic Manufacturing* is providing fill and finish services in the US. (press release)

- **Pfizer** - **BioNtech** co-developed COVID-19 vaccine (press release)
  - *Delpharm* will start to manufacture Pfizer-BioNtech's vaccine in Normandy, France. Delpharm will also produce Johnson and Johnson and Moderna's vaccine. (news release)
  - *Thermo Fisher* is working with Pfizer and BioNtech to manufacture their COVID-19 vaccine in Italy. (news release)
  - In order to scale up manufacturing as quickly as possible, the companies have entered multiple manufacturing agreements with *Sanofi*, *Novartis*, and *Fosun Pharma*. (Sanofi press release) (Novartis press release) (Fosum press release)

- **Sanofi**
  - *Sanofi* will spend $476 million over the next five years to create a vaccine production plant in Singapore. The facility will have more flexibility than Sanofi's current sites, with the capability to produce three to four different vaccines simultaneously. (press release)

Therapeutics/Diagnostics Partnerships

- **Avacta**
  - *BBI Solutions* (based in South Wales, UK) to manufacture Avacta's saliva-based rapid SARS-CoV-2 antigen test, that is being developed by Affimer® biotherapeutics and

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reagents developer Avacta Group plc in conjunction with Cytiva (press release)

- **BeiGene**
  - BeiGene is collaborating with *Singlomics* (China) and *Peking University* for the use of monocolonal antibodies (mAbs) against COVID-19 (press release)

- **CSL Behring**
  - CSL Behring is partnering with *SAB Biotherapeutics*, a clinical-stage biopharmaceutical company, to advance and deliver a novel immunotherapy targeting COVID-19. The potential therapy would be produced without the need for blood plasma donations from recovered COVID-19 patients. (press release)
  - CSL Behring has launched a clinical trial into the use of CSL312 (garadacimab, Factor XIIa antagonist monoclonal antibody) to treat patients suffering from severe respiratory distress, a leading cause of death in patients with COVID-19 related pneumonia. (press release)

- **Eli Lilly**
  - Collaboration with *Samsung BioLogics'* to mass produce Lilly's COVID-19 antibody therapies. Lilly hopes to make up to 1 million doses this year and many more in 2021 (press release and here)
  - Manufacturing collaboration with *Amgen* for COVID-19 antibody therapies (press release)

- **Gilead**
  - Gilead signed non-exclusive voluntary licensing agreements with *nine manufacturer*s based in India, Pakistan and Egypt to expand access to generic remdesivir in 127 low and middle-income countries. (press release)
  - Gilead also forged collaborations with more than 40 trusted manufacturing partners in North America, Europe, and Asia to expand its Veklury (remdesivir) manufacturing network and meet global demand. (press release)
  - When COVID-19 cases began surging in India in April 2021, Gilead initiated efforts to expand availability of remdesivir by providing technical assistance to its seven India-based voluntary licensing partners, supporting the addition of new local manufacturing facilities, and donating API to scale up production of remdesivir. Gilead is also committed to providing support to voluntary licensees based outside of India to increase their production capacity. (press release)

- **Merck**
  - Merck announced voluntary licensing agreements with *5 Indian generic manufacturers* to accelerate and expand global access to Molnupiravir, an investigational oral therapeutic for the treatment of COVID-19. (press release)

- **Vir Biotechnology**

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- Collaboration with *GlaxoSmithKline (UK)* on monoclonal antibody (mAbs) treatment for COVID-19 (press release)

Lackie, Kimberley -DCP

From: Norris, David -TMI
Sent: September 16, 2021 1:30 PM
To: Campbell2, Erin (ISED/ISDE); Jenkins, Brad (ISED/ISDE); Hawa, Zoe -BBI; Cooper, Michelle -BBI; Blais, Pierre -MNC; Hisko, Mellissa -FMNV; Lachance, Nalini -MNG; Bird, Colin -TCW; Geddes, Sarah -TCW; Lesieur, Nicolas -GENEV -GVWTO; O'Toole, Christopher -GENEV -GVWTO; Larose, Sylvie -WSHDC -TD
Cc: *TFM-Policy; de Boer, Stephen -GENEV -GVWTO -HOM/CDM; Moen, Martin -GENEV -GVWTO; Melia, Shendra -TMD; Mirella, Loris -TMI; Foster, Dean -TMI
Subject: REPORT – TMI meeting with the Canadian Chamber of Commerce, Innovative Medicines Canada (IMC), and IMC members to update on the WTO TRIPS waiver proposal (September 15, 2021)

REPORT – TMI meeting with the Canadian Chamber of Commerce, Innovative Medicines Canada (IMC), and IMC members to update on the WTO TRIPS waiver proposal (September 15, 2021)

SUMMARY

On September 15, TMI met with the Canadian Chamber of Commerce and Innovative Medicines Canada (IMC), as well as IMC members, to update on the most recent WTO TRIPS Council discussions on the proposed COVID-19-related waiver from the TRIPS Agreement, as well as to discuss the next steps in these discussions at the WTO. The meeting followed from TMI's previous meeting with industry in mid-July, and provided an opportunity to update on the TRIPS Council's July 27 report to the WTO General Council, as well as on the most recent TRIPS Council meeting on September 14, which largely saw a restatement of positions by waiver co-sponsors and other Members. Industry expressed interest in the prospects for a decision on the waiver ahead of, or at, the twelfth WTO Ministerial Conference (MC12) in November-December, as well as how it may inform, or be informed by, parallel work by the Ottawa Group on the Trade and Health Initiative and the WTO response to COVID-19 more broadly. Industry reiterated its interest in addressing topics covered by the Trade and Health Initiative, such as export restrictions and trade facilitation, and expressed concerns regarding the potential further extension of the EU transparency and authorisation mechanism for exports of COVID-19 vaccines. The meeting was attended by [redacted] Canadian Chamber of Commerce [redacted] IMC; [redacted] MC; [redacted] Johnson & Johnson (J&J); and [redacted] Pfizer. Global Affairs Canada was represented by TMI/Mirella, Foster, and Norris.

REPORT

1. IMC/[redacted] opened the meeting by recalling the last update in July, and noted participants' interest in news on recent developments since the August break at the WTO. As the last meeting took place before the WTO TRIPS Council's July 27 report to the General Council, TMI provided a brief update on that process (that the TRIPS Council had not reached consensus on the waiver, and would continue discussions in the Fall, with the first such meeting taking place on September 14). TMI also provided an update on those discussions, noting that waiver co-sponsors and other WTO Members continue to repeat longstanding positions on the waiver, and that Members have not yet engaged on the substance of the waiver text. Given the lack of progress in text-based discussions on the waiver since July, J&J/[redacted] asked about what can be expected going into MC12, and whether the TRIPS waiver and IP will factor into the Ministerial Conference. TMI noted that a range of trade and health topics can be expected to be raised at MC12, and that waiver co-sponsors are advocating for the completion of text-based negotiations either before or after that meeting. In addition, TMI noted the parallel WTO process on the response to COVID-19 led by Ambassador David Walker (New Zealand) as facilitator, which currently covers all elements except for IP and the waiver discussion, and that India and

South Africa have proposed that the waiver discussions be integrated with this process. J&J also asked whether there might be strong advocacy on the part of waiver co-sponsors to add the waiver to the MC12 agenda; TMI also noted that waiver co-sponsors could potentially seek a vote either at the General Council or at MC12, though voting is relatively rare at the WTO and poses considerable procedural uncertainty.

2. With respect to MC12, Chamber/ noted that the International Chamber of Commerce has reported on the possibility of an MC12 outcome on trade and health, and in particular, on vaccine supply chains. Pfizer, took note of the most recent meeting of the WTO-WHO-IMF-World Bank Task Force on COVID-19, where Pfizer's global CEO noted the importance of addressing "roadblocks" to the distribution of COVID-19 vaccines and other medical products. Pfizer, noted that these roadblocks do not pertain to IP, but rather issues related to export restrictions and trade facilitation, as well as regulatory processes and procurement. While noting the ongoing context of the Canadian federal election and the caretaker convention, Pfizer/ signalled that industry remains interested in discussing these topics going forward. Pfizer, also noted concern with reporting on the possible extension of the EU transparency and authorisation mechanism for exports of COVID-19 vaccines. On the Trade and Health Initiative at the WTO, J&J, asked whether other WTO Members will be supporting this work, with TMI noting that Ottawa Group Members are undertaking outreach on the initiative. TMI also noted the July General Council communication on trade and health, as circulated by the Ottawa Group and other WTO Members.

3. Returning to the TRIPS waiver discussion, Pfizer/ asked whether co-sponsors have responded to questions raised by other Members, and whether any new arguments have been articulated, with TMI noting that recent meetings have largely seen a restatement of positions around the table. Chamber similarly asked whether the U.S. position has shifted. TMI noted that WTO Member positions largely remain the same, including the U.S., but drew attention to the planned U.S.-led global vaccine summit, which is expected to take place next week on the margins of the UN General Assembly. TMI asked if industry has any intel on the summit, and whether it may include discussions on the waiver. Chamber/ Pfizer , and IMC, all noted recent media reporting that South Africa may use the opportunity to press on the waiver issue, and suggested that even if the waiver is not on the official agenda, it will likely form part of the "hallway" discussions at the summit next week.

4. Finally, Pfizer asked if industry can provide any further information on these topics, with TMI taking note of information circulated by Pfizer after the previous meeting on voluntary licensing arrangements between vaccine developers and contract manufacturing organizations. TMI added that officials are closely following announcements on voluntary licencing arrangements, including in view of the attention to this topic in recent TRIPS waiver discussions, and welcomed further sharing of information on the part of industry moving forward. Finally, Chamber, noted that he would be speaking on a panel on the waiver the following day, during the McDonald Laurier Institute's event on "Considering the global impact of waiving patent rights for COVID vaccines" (webcast available here). Participants agreed to remain in contact and to share information and developments on the waiver, as well as on broader WTO discussions, in the coming months.

Drafted: TMI/Norris
Consulted: TMI/Mirella, Foster

Norris, David -TMI

From: Norris, David -TMI
Sent: May 13, 2021 11:38 AM
To: Bird, Colin -TCW; Geddes, Sarah -TCW; Niarchos, Joanna -TCW; Thiessen, Kari -TCW; Bourns, Laura -TCW; Osborn, Kathleen -TCW; Lesieur, Nicolas -GENEV -GVWTO; O'Toole, Christopher -GENEV -GVWTO; Nadon, Jean-Sébastien -TPG; del Castillo, Ricardo -TPG; Tanguay, Rosalind -TPG; Villeneuve, Francis -TPB; Magnus, Benjamin -TPB
Cc: *DMT-Policy; *TFM-Policy; Melia, Shendra -TMD; Hembroff, Kendal -TCD; Moen, Martin -GENEV -GVWTO; Mirella, Loris -TMI; Foster, Dean -TMI
Subject: REPORT: MINT meeting with Innovative Medicines Canada, Pfizer Canada, and Hoffman La Roche regarding the WTO TRIPS waiver proposal (Wednesday, May 12)

REPORT: MINT meeting with Innovative Medicines Canada, Pfizer Canada, and Hoffman La Roche regarding the WTO TRIPS waiver proposal (Wednesday, May 12)

SUMMARY

On Wednesday, May 12, MINT met with Innovative Medicines Canada (IMC); Communications and Government Affairs, IMC; Pfizer Canada; and IMC (Roche Pharma Canada), to discuss the WTO TRIPS waiver proposal. The meeting provided for a generally positive exchange, with interlocutors appreciating the "delicate political situation" faced by the Government of Canada in addressing the pandemic, and underscoring the importance of further collaboration with industry. On the TRIPS waiver, IMC and Pfizer reiterated that their global research and development (R&D) and production models are "anchored" by IP, and questioned the "simplistic" view of removing IP when the industry is faced with more immediate supply chain and goods trade challenges, as well as in the area of regulatory harmonization. On these points, MINT highlighted Canada's active role in the Ottawa Group and the Trade and Health Initiative, as well as Canada's encouragement for the WTO Director General's "third way" engagement with industry. MINT also noted Canada's interest in seeking consensus-based solutions on the TRIPS waiver, and assured that, while Canada "will absolutely be at the table when we see the text", the Government will discuss with industry as negotiations proceed, reminding that Canada is "not committing ourselves until we see text in front of us". On MINT's recent statement on the waiver, IMC and Pfizer noted that the statement was "highly appropriate" and "very well received" by the industry, and thanked MINT for the "meaningful" commitment to discuss these issues with industry going forward.

REPORT

1. MINT began the meeting by highlighting the important collaborative relationship between the pharmaceutical industry and the Government of Canada, and the important role of vaccine R&D and distribution in addressing the pandemic. Noting that "this won't be the last pandemic in our lifetime", Pfizer/ added that the industry is focused on the path forward for Canada, and is working with ISED and PSPC on what that path "will look like, either post pandemic or post election". Turning to the TRIPS waiver discussion, IMC/ noted that the industry "appreciates the pressure the government is under internationally", but that now is "not the time to pit one stakeholder group against another", suggesting that the industry is more interested in exploring "third way" options to get vaccines around the world. As part of these efforts, Pfizer, added that Pfizer has reached out to low- and middle-income countries (LMICs) to offer its vaccine at "what would be deemed a more than fair price". Rather, LMIC's have generally pointed to concerns with the transfer of mRNA technology and know-how, as well as challenges in incorporating this innovative technology into their own manufacturing capacity.

2. In reiterating the importance of IP to the industry's R&D and production models, Pfizer/ reminded that Pfizer currently has a capacity to produce 1.3 billion vaccine doses annually, and is on track to expanding this capacity to 3 billion doses by end of year, which is "anchored on expectations of IP and the return on investment that comes from having IP protection". He also noted that much of this R&D relies on "upstream" IP that does not necessarily find itself in a finished product. In order to ramp up global production, Pfizer/ added that, rather than claimed IP barriers, global supply chain bottlenecks are the main area of concern, suggesting that "lots of existing carefully laid infrastructure breaks down if we change the rules under which we're operating". Pfizer/ also noted that Pfizer continues to innovate on new versions of its vaccine, such as a refrigerated version that can be stored at room temperature for use in developing countries lacking cold chain technology, all of which is "anchored" on IP. With respect to global access, Pfizer also reminded that advance purchase agreements with governments around the world include clauses allowing for the donation of surplus doses to other countries. In addition, Pfizer/ pointed to the importance of ensuring high regulatory standards and good manufacturing practices (GMP) for vaccine production, noting that certain unnamed but "well-vaccinated countries that would not have met Health Canada's regulatory and GMP standards" are now seeing up to a "60% relapse" in COVID-19 recurrence.

3. Interlocutors also challenged the assumption that an IP waiver will necessarily facilitate global collaboration, reminding that voluntary collaboration has been essential to the production and distribution of vaccine doses so far. For instance, Roche/ noted that yesterday, Roche donated 10,000 doses of an unnamed COVID-19 therapeutic (presumably the arthritis treatment Tocilizumab) to India, in collaboration with the U.S.-based firm Genentech. Noting the importance of ensuring high-quality production that meets regulatory standards, Roche, added that, "if we're going to partner, we partner with our peers". Noting the oft-cited industry figure that vaccine production relies on "280 components from 86 suppliers in 19 countries", IMC/ questioned the assumption that "anyone [can] just pop up" and produce a vaccine. IMC cited data from the International Federation of Pharmaceutical Researchers and Manufacturers which reports that there are currently 245 COVID-19 vaccines and therapeutics in discovery processes, with 217 already involving collaboration between companies, noting that "what some are saying isn't happening is already happening across the board".

4. Taking note of interlocutors' focus on supply chain challenges, MINT reiterated that, in taking a leadership role in the WTO Ottawa Group, Canada has sought to address these challenges from the outset of the pandemic, including through the Trade and Health Initiative. MINT underscored the importance of taking a pragmatic approach to these issues, in concretely understanding the challenges facing WTO Members and finding consensus on "actual impediments" to vaccine and medical product distribution and access. IMC/ reiterated the industry's support for ongoing work on the Trade and Health initiative and efforts to address supply chain challenges, as noted in IMC's recent testimony to CIIT. In addition to supply chains, IMC/ suggested that Canada and other WTO Members also need to address regulatory considerations, noting that regulatory differences across countries remain an "important barrier". MINT committed to following up with GAC officials on how regulatory issues may be dealt with in the context of the Trade and Health Initiative. IMC/ also briefly noted the domestic regulatory uncertainty of the forthcoming amendments to the Patented Medicine Prices Review Board (PMPRB "in a number of weeks" (recall that the PMPRB reforms will enter into force on July 1),

5. Returning to the TRIPS waiver, IMC/ took note of MINT's recent statement on the waiver, noting that the industry was "very pleased" and that it was "well received" in committing Canada to a balanced approach going forward. Pfizer/ noted that the statement was "highly appropriate", particularly in acknowledging the importance of IP and industry's role in vaccine R&D. MINT noted that Canada is "very committed to working on reducing and eliminating all barriers" reminding that "IP is just one part" of this discussion, and that WTO Members will need to reach consensus on these issues. MINT added that Canada will need to be a part of building a consensus-based solution, and "will absolutely be at the table when we see the text", but that "we don't know what's there yet". In the meantime, MINT also drew attention to the WTO Director General's continued "third way" engagement with originators and manufacturers of COVID-19 vaccines and medical products as part of the range of initiatives at the WTO to leverage the multilateral trading system to address the pandemic. As text-based discussions on a TRIPS waiver proposal have not yet started, MINT added that Canada is "not committing ourselves until we see text in front of us", and that Canada will be

engaging with industry as discussions move forward. MINT again underscored that any waiver would require consensus, which is "how the WTO works". IMC/[redacted]k thanked MINT for the "finesse that you've brought to this very pressured situation", and committed to further discussion on these matters, including in respect of supply chain issues. MINT agreed that it will be important to provide "good factual information" on the challenges created by the pandemic, such that concrete and consensus-based solutions can be found.

Minister of Small Business, Export Promotion and International Trade
Video call with Innovative Medicines Canada, Hoffman La Roche (Roche Pharma Canada), and Pfizer Canada regarding the WTO TRIPS waiver proposal
Wednesday, May 12, 2012, 13:00

OBJECTIVES

- Clarify Canada's position on the TRIPS waiver discussions, whereby Canada has recently expressed readiness to discuss proposals in this area, in particular for COVID-19 vaccines.
- Address Innovative Medicines Canada (IMC, with Hoffman La Roche and Pfizer) expected strong opposition to Canada's consideration of any proposed COVID-19-related waiver from the WTO *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS).
- Reaffirm Canada's recognition of the broader supply chain challenges informing the production and distribution of COVID-19 vaccines and other medical products, and Canada's active support for addressing these challenges through the WTO Trade and Health Initiative, which IMC supports.

KEY MESSAGES

Introduction

- Thank representatives from IMC, Pfizer, and Hoffman LaRoche for their ongoing engagement and expertise on issues related to the production and distribution of COVID-19 vaccines and other medical products, including recent TRIPS waiver discussions.
- We take note of IMC's recent testimony on the TRIPS waiver to the House of Commons Standing Committee on International Trade on April 14, as well as IMC's recent press release expressing concern with the proposed waiver.

Scripted Key Messages

- The Government of Canada firmly believes in the importance of protecting intellectual property (IP), and recognizes the integral role that industry has played in innovating to develop and deliver life-saving COVID-19 vaccines.
- The Government of Canada has confirmed that it is ready to discuss proposals for an IP waiver, in particular for COVID-19 vaccines, under the WTO TRIPS Agreement, and to seek a consensus-based outcome on this basis.

- Since the introduction of the TRIPS waiver proposal in October 2020, Canada has actively worked with other WTO Members and international partners to identify barriers to vaccine access – many of which are unrelated to IP, such as supply chain constraints.
- In addressing these supply chain challenges, Canada remains actively committed to the work of the WTO Trade and Health Initiative to strengthen global supply chains and support timely, open trade and the delivery of essential medicines and medical supplies, including vaccines, around the world.
- Canada also supports the “third way” engagement of the WTO Director General in facilitating voluntary licensing and transfer of technology between developers and manufacturers of COVID-19 vaccines and other medical products.
- With respect to the proposed TRIPS waiver, Canada remains committed to finding consensus-based solutions in the WTO and reaching an agreement that accelerates global vaccine production and does not negatively impact public health.
- I understand that co-sponsors will be circulating a revised TRIPS waiver proposal in the second half of May; the Government of Canada will need to further assess any proposal or proposals received, in order to inform our engagement on this matter.
- Given the complex challenges of arriving at consensus within the WTO membership, any negotiation on a proposed waiver would take time, and would then need to be implemented by individual WTO Members.
- The Government of Canada will continue to ensure open lines of communication and consultation with industry and all stakeholders, to inform our engagement on any WTO negotiations as they move forward.

Responsive – Will Canada support text-based negotiations on the TRIPS waiver proposal?

- *At this point, the Government of Canada is ready to discuss proposals for an IP waiver, in particular for COVID-19 vaccines, under the TRIPS Agreement.*
- *As the original co-sponsors of the TRIPS waiver have indicated that they will be circulating a revised proposal later this month, we would need to assess any proposal in detail.*
- *We also await any proposals from other WTO Members that have recently announced support for a TRIPS waiver, such as from the United States, and would similarly need to assess any text proposed.*
- *Canada remains committed to seeking consensus-based outcomes on the TRIPS waiver proposal.*

Responsive – Why is Canada supporting discussions on a proposed TRIPS waiver when stakeholders have identified more immediate challenges like supply chain barriers?

- *Canada remains interested in finding consensus-based solutions to the range of complex challenges raised by the COVID-19 pandemic, and in leveraging the entire multilateral trading system to address obstacles identified by WTO Members.*
- *This includes continued support for the WTO Trade and Health Initiative, as well as the WTO Director General's "third way" engagement between vaccine developers and manufacturers.*
- *We remain of the view that all of these challenges can be addressed in parallel, and that the WTO can continue to play an important role in this regard.*
- *While WTO Members have identified concrete challenges in respect of supply chains, we remain open to hearing the views of the WTO membership in respect of IP, and to finding consensus-based solutions to any challenges identified.*

Responsive – Modernization of the Patented Medicine Prices Review Board (PMPRB) and claims of investment uncertainty

- *Canada has committed to improving the accessibility, affordability, and appropriate use of prescription medicines.*

- *Understand that the coming into force date of the PMPRB amendments has been delayed until July 1, 2021.*
- *I would invite you to share any views you might have on the PMPRB with the Minister of Health.*

Questions

- *Given last week's U.S. announcement on the TRIPS waiver, we would be interested in any reactions from the brand-name pharmaceutical industry, including any views that you may have heard from your U.S. industry counterparts.*

MEETING CONTEXT

- **Previous interactions with the interlocutor:** IMC and its membership regularly engage with GAC officials on a range of pharmaceutical policy issues related to Canada's trade agenda, as well as on domestic policy developments. In recent interactions with IMC, the industry has expressed strong concern with the ongoing modernization of the Patented Medicine Prices Review Board (PMPRB), alleging that forthcoming reforms in this area will have a "destabilizing impact" on the industry. Most recently, IMC testified before the House of Commons Standing Committee on International Trade (CIIT), as part of its study on the WTO TRIPS waiver proposal, where it expressed strong concern for the TRIPS waiver and indicated that the waiver could contribute to an already-uncertain investment climate, in view of the existing uncertainty in the context of the PMPRB reforms.
- **Political Climate:** IMC has stressed the continued importance of ongoing collaboration between the innovative pharmaceutical sector and the Government of Canada in addressing the ongoing challenges presented by the COVID-19 pandemic. In addition to the Government of Canada's agreement with Pfizer on the procurement of COVID-19 vaccine doses through to 2024, IMC has pointed to the investment of its membership towards the development of more than 500 new products and medicines in Canada.
- **Key Issues:**
- TRIPS waiver proposal: IMC strongly opposes the TRIPS waiver, and has urged Canada and other WTO Members to "ensure that any negotiated agreement effectively addresses the problem of global vaccine access and does not undermine vaccine production or negatively impact public health". IMC has instead pointed to more immediate concerns for COVID-19 vaccine production and distribution, such as supply chain bottlenecks and goods-trade shortages and scarcity of raw materials (see Annex for background).
- Supply chain challenges: While opposing the TRIPS waiver proposal, IMC continues to support Canada's engagement in the WTO Trade and Health Initiative.
- PMPRB modernization: The PMPRB is a quasi-judicial body that protects Canadians by ensuring that the prices of patented medicines sold in Canada are not excessive. IMC has expressed strong concern with the ongoing modernization of the PMPRB, and has in recent months linked these concerns to Canada's trade policy agenda, including in the context of recent CIIT testimony on the TRIPS waiver.
- **Key Statistics:** IMC consists of 47 companies that support 100,000 jobs in Canada, contributing Can$15 billion to the Canadian economy and Can$2 billion in research and development.

BIOGRAPHIES

[redacted] **Innovative Medicines Canada (IMC)**

[redacted]

[redacted] **(Roche Pharma Canada)**

[redacted]

([redacted] **Pfizer Canada**

[redacted]

Annex: Background – WTO TRIPS waiver proposal

The India/South Africa waiver proposal was tabled in October 2020, and seeks a waiver from certain sections of the WTO *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), namely copyright, industrial designs, patents and undisclosed information, in respect of access to COVID-19-related diagnostics, treatments, vaccines, and equipment. In recent months, waiver co-sponsors, which also include Members of the African Group and LDC Group, have pushed for text-based negotiations on the proposal, and have committed to circulating a revised proposal in the second half of May 2021.

While the U.S. initially expressed opposition to the proposal, on May 5, 2021, the United States Trade Representative (USTR) announced the U.S. Administration's support for the waiver, signalling that the U.S. will "actively participate in text-based negotiations" on the proposed waiver in respect of IP protections for "COVID-19 vaccines". Thus far, the U.S. has not clarified whether it envisions limiting the scope of any waiver to COVID-19 vaccines, as opposed to the broader waiver proposal tabled by India and South Africa. On May 7, MINT issued a statement confirming that Canada is ready to discuss proposals on an IP waiver, in particular for COVID-19 vaccines, under TRIPS, and remains committed to finding solutions and reaching an agreement that accelerates global vaccine production and does not negatively impact public health. Canada has consistently expressed its support for consensus-based outcomes, and can proceed on the basis of any consensus that emerges at TRIPS Council. Canada's position on the current waiver proposal has not been in opposition, but rather to pose questions to waiver proponents on evidence of impediments to the production and supply of COVID-19 vaccines and medical products that are caused by WTO IP rules.

The next formal TRIPS Council meeting is scheduled to take place on June 8-9; however, in view of the USTR announcement and the impending revised proposal from co-sponsors, an informal meeting or meetings could be called in the coming weeks.

IMC statement on the WTO TRIPS waiver proposal" "Innovative Medicines Canada cautions against COVID-19 TRIPS IP waiver" (May 6, 2021)

"The extraordinary development of the COVID-19 vaccines now being deployed globally is a testament to collaboration and innovation by governments, industry, and other stakeholders.

"Waiving TRIPS Intellectual Property (IP) protections will not address the real issues of trade barriers, global supply chain bottlenecks, and scarcity of raw materials that are impacting the supply of COVID-19 vaccines. IP protection is a crucial element for a thriving life sciences sector and therefore we urge Canada and other nations to ensure that any negotiated agreement effectively addresses the problem of global vaccine access and does not undermine vaccine production or negatively impact public health.

"Ongoing collaboration between the innovative pharmaceutical sector and the Government of Canada is needed to ensure the health and safety of all Canadians and citizens globally. Canadian officials should be commended for their work at the World Trade Organization (WTO) such as the Ottawa Group Trade and Health Initiative to assess measures to strengthen and facilitate the flow of essential medicines and medical supplies between nations. Such measures are targeted at the substantive issues impacting global supply chains during the pandemic.

"Since it will not address the real issues afflicting vaccine supply and distribution, Innovative Medicines Canada does not support the proposed TRIPS IP waiver for COVID-19 vaccines at the WTO. The proposed waiver of TRIPS IP protections would be a disappointing step that will create greater uncertainty and unpredictability in the production, quality, and availability of COVID-19 vaccines worldwide."