APPEARANCE OF THE MINISTER OF HEALTH
OGGO
Coronavirus
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Opening Remarks for
the Honourable Patty Hajdu
Minister of Health

For an appearance before the House of Commons
Standing Committee
on Government Operations and Estimates

COVID-19

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Introduction

Mr. Chair, Honourable Members, thank you for this opportunity to speak to the Committee today about the Health Portfolio's role in the Government's response to COVID-19.

As always, our focus is on protecting the health and safety of Canadians.

During this unprecedented crisis, we must ensure that our health system is fully prepared to care for Canadians.

Purchase and distribution of equipment

To do so effectively, we are collaborating with the provinces and territories to identify their needs and purchase the required equipment, supplies and services. Canada is taking an aggressive approach to buying, especially when it comes to personal protective equipment for front-line healthcare workers.

This includes:

- ordering in bulk on behalf of provinces and territories,
- supplementing those orders by purchasing everything immediately available that meets requirements, and
- galvanizing Canadian industries to increase domestic manufacturing capacity.These measures are over and above what the provinces and territories are doing to secure their own supplies.

The Government is also coordinating shipments of supplies from other countries. Canada has established on-the-ground support in China for transportation, receiving, storage services and customs clearances.

Canada is receiving shipments, and the Government is working to rapidly allocate personal protective equipment and medical supplies to the provinces and territories, using an approach agreed to by federal-provincial-territorial (FPT) Ministers of Health.

Provinces are proactively allocated 80% of shipments on a per capita basis, while 20% is held back for the National Emergency Strategic Stockpile. This holdback is used to fulfill urgent Requests for Assistance from provinces and territories.

Supporting access to diagnostic test kits and other medical devices

Furthermore, we know that early diagnosis is essential to slowing the spread of COVID-19 in Canada.
That's why in March, I signed an Interim Order to allow expedited access to COVID-19-related medical devices, including diagnostic test kits.
An Interim Order is one of the fastest mechanisms the Government can use to help make health products available to address larger-scale, public health emergencies.

To date, we have authorized 19 tests under this Interim Order – tools that are necessary for our response to this pandemic.
The Interim Order also ensures that other COVID-19-related medical devices are available to treat, mitigate or prevent this disease.
To help do this, the Order allows Health Canada to review approvals granted by other countries when deciding whether to authorize a device for importation or sale.
It also waives all application fees for COVID-19-related medical devices, further removing impediments for manufacturers in this time of public health need.

Conclusion

Mr. Chair, the Health Portfolio, in particular through the dedication of officials at the Public Health Agency of Canada, Health Canada and the Canadian Institutes of Health Research, is committed to doing everything it can to protect the health and well-being of all Canadians.
The magnitude of this responsibility has never been more clear. It is essential that we have the medical supplies we need to fight COVID-19.

The Government will continue to do everything it can to ensure our country’s response is effective now, and that we are equipped for the future.
Thank you.

Acute Inflammatory Illness in Children Temporally Linked with COVID-19 (Kawasaki Disease)

SYNOPSIS

- Reports of multi-system inflammatory disease in children with COVID-19 have been issued in the U.K., Italy and the U.S. Alerts cite features of toxic shock syndrome and incomplete Kawasaki disease, with some children experiencing gastrointestinal symptoms and cardiac inflammation. The New York City health department has reported over 100 cases with 3 deaths (ages 5, 7 and 18). In Canada, there have been media reports of 12 children with the syndrome at Ste. Justine hospital in Montreal, Quebec.

KEY MESSAGES

- Our top priority is the health and safety of Canadians.
- Acute inflammatory illness in children is being reported in Canada and abroad, and we are working with our network of pediatricians to keep Canada's physicians informed of these cases to support detection of cases and care of children.
- We are advising Canadians to contact their healthcare provider if their child shows symptoms, such as fever and gastrointestinal illness.
- We will continue to provide Canadians with reliable information about COVID-19 to prevent the further spread and to protect Canadians from serious illnesses.

BACKGROUND

An acute inflammatory illness has recently been reported in a small number of children worldwide, temporally associated with the COVID-19 pandemic. In Canada, there have been media reports of 12 children with the syndrome at Ste. Justine hospital in Montreal, Quebec.

Symptoms

Reported symptoms include persistent fever, inflammation, poor function in one or more organs, and other clinical and laboratory features not attributable to other infections. Many affected children were hospitalized and some required intensive care. To date,

most children affected have done well and recovered. Some children have required ICU admissions.

Linkage to COVID-19

Many children with this inflammatory syndrome did not test positive for COVID-19. Globally, nasal tests for the COVID-19 virus were often negative, however blood tests for antibodies were sometimes but not always positive. While the tests themselves may have had varied accuracy, the fact that patients who tested negative for COVID-19 virus and sometimes test positive for antibodies suggests that inflammatory complications were delayed, occurring when the virus was no longer detectable on nasal swabs.

Clinicians in Canada are aware of this potential syndrome and must maintain a high index of suspicion to identify cases. Why these cases are emerging only now, and what is causing them, is unknown. It is suspected an immune response to COVID-19 activates an inflammatory process in genetically susceptible children. But other mechanisms are possible as well. The global pediatric medical community is rapidly studying this issue.

So far, children have had far less COVID-19 disease than adults. Even young people can have serious outcomes or potentially death, so it is important that everyone take precautions to prevent infection.

Surveillance

As part of the Public Health Agency of Canada's (PHAC) surveillance of COVID-19, there have been three different ways the disease activity in children have been monitored:

- the reporting of all cases to provinces, then to PHAC;
- a network of Pediatric Emergency Department physicians in Children's hospitals who report on COVID-19 cases; and
- the Canadian Pediatric Surveillance Program (CPSP), a collaboration between PHAC and the Canadian Paediatric Society.

The CPSP COVID-19 surveillance protocol is being modified to capture cases of this Kawasaki-like syndrome/multi-system inflammatory syndrome, even in the absence of a positive test for COVID-19 to increase available data concerning this emerging condition.

Federal Role

PHAC continues ongoing monitoring, intelligence gathering and international engagement to inform Canadian public health action. Canada also continues to collaborate with federal, provincial, and territorial partners to share information about COVID-19 in Canada. PHAC has a number of systems in place to monitor community spread and severe outcomes related to COVID-19 in pediatric populations.

Border Measures

SYNOPSIS

- The Public Health Agency of Canada has put in place successive border measures in response to COVID19 under the *Quarantine Act*.

POTENTIAL QUESTION

- What is the Government doing to prevent imported cases of COVID19? How are you protecting Canadians at the border?

KEY MESSAGES

- The Government of Canada is taking action at the border to limit the introduction and spread of COVID-19 and to protect the health of Canadians.

- We have enacted emergency orders under the *Quarantine Act* to restrict discretionary entry into Canada from abroad, including the U.S., and to strengthen measures to reduce the importation risk from other countries.

- All persons entering Canada, with limited exceptions – no matter their country of origin or mode of entry - are required to quarantine for 14 days.

- There are exemptions in place on mandatory quarantine so that critical infrastructure, essential services and economic supply chains continue between Canada and the U.S. Essential workers will be permitted to enter Canada, including truck drivers, firefighters and medical workers.

- Anyone not excluded from mandatory quarantine or isolation when entering Canada must have a plan and suitable location where they can isolate or quarantine for 14 days. They must wear an appropriate non-medical mask or face covering while in transit to their final destination.

IF PRESSED ON FEDERAL QUARANTINE SITES

- Individuals who do not have an appropriate isolation or self-quarantine plan will be directed to a federally designated Quarantine Facility.

- Hotels have been designated as Quarantine Facilities in a number of cities, including Vancouver, Calgary, Toronto, and Montreal.

IF PRESSED ON HOW WE SCREEN TRAVELLERS

- As travellers enter the country, they receive information on the symptoms of COVID-19. They must acknowledge that they understand the quarantine requirement and provide contact details for follow-up.

- Border Services Officers conduct preliminary screening of all travellers based on criteria and questions developed by the Public Health Agency of Canada. Those who show symptoms of COVID-19 are directed to a Quarantine Officer for further assessment.

IF PRESSED ON WORK WITH ALBERTA TO DATE

- The Public Health Agency of Canada is collaborating with provinces, including British Columbia and Alberta, towards a more integrated model at airports, minimizing duplication of effort, and streamlining information collection. PHAC is also exploring possibilities of shared quarantine space with some provinces and territories.

- As the COVID19 situation continues to evolve, supplementary health screening measures, such as those implemented by other jurisdictions, may be considered.

IF PRESSED ON COMPLIANCE AND ENFORCEMENT

- The Public Health Agency of Canada is working with the RCMP and provincial law enforcement agencies to verify compliance with the Mandatory Isolation Order.

- Penalties include a fine of up to $1 million or imprisonment for 3 years, or both, for failure to comply with this Order.

- A ticketing scheme is now in place to allow for fines for non-compliance ranging from $275 to $1000.

IF PRESSED ON BORDER PRESENCE

- We recognize the importance of having sufficient PHAC presence at Canadian Points of Entry

- Currently, PHAC has staff, including quarantine officers, on site at the four airports designated to receive international flights (Vancouver, Calgary, Toronto, and Montreal).

- PHAC is working to increase its border presence, and will staff at 12 additional points of entry by May 22, and at a total of 36 points of entry by June 30, including major land borders.

- These measures will ensure a PHAC presence at points of entry covering more than 90% of international travellers to Canada.

- All of Canada’s points of entry will continue to have 24/7 access to quarantine officer support through the remote centralized notification system (CNS).

BACKGROUND

Since February 3, the Governor in Council has made eleven Emergency Orders under the *Quarantine Act* to minimize the risk of exposure to COVID-19 in Canada – to reduce risks from other countries, to repatriate Canadians, and to strengthen measures at the border to reduce the impact of COVID-19 in Canada.

PHAC has been working with federal and provincial partners to facilitate commercial traffic to maintain the flow of essential goods and services, while continuing to protect the health of Canadians.

A travel ban is currently in place for most people entering Canada, including:

- All foreign nationals entering Canada by air;
- All travellers from the U.S., across all modes, for non-essential travel including recreation and/or tourism purposes;
- Foreign nationals entering Canada if they arrive from a foreign country other than the United States, with some exceptions, including temporary foreign workers and international students; and
- Foreign nationals entering from the U.S. with signs or symptoms of respiratory illness.

Canada has updated its temporary border agreement with the U.S. until June 21, 2020.

All persons entering Canada, with limited exceptions – no matter their country of origin or mode of entry - are REQUIRED to isolate or quarantine for 14 days in a suitable location.

Canada has 117 land border points of entry, (many of which have low volumes of travellers), 12 international airports, 4 commercial marine ports, and 3 rail stations. PHAC is increasing the presence of designated officers, including quarantine officers, at priority points of entry across Canada. Over the next 7 weeks, PHAC officers will be deployed to 36 high volume points of entry, including major land borders to cover 90% of travelers.

There are exemptions in place on mandatory quarantine/isolation which permit essential workers to enter Canada, including truck drivers, firefighters and medical workers.

Cross-border supply chains are vital to ensure the continued flow of goods, including food and medical supplies for all Canadians. As such, the Canada Border Services Agency (CBSA) is working with other federal partners to share information with commercial stakeholders to provide assurances that commercial traffic is not impeded.

<u>Enforcement:</u>
PHAC undertakes compliance and enforcement linked to ensuring that travellers are abiding by the requirement to isolate/quarantine for 14 days. In those instances, where compliance cannot be confirmed, referrals are made to the RCMP. Maximum penalties

for failing to comply with the mandatory isolation/quarantine order include a fine of up to $750,000 or imprisonment for six months, or both.

A person who causes a risk of imminent death or serious bodily harm to another person while willfully or recklessly contravening the *Quarantine Act* or the regulations could be liable for a fine of up to $1 million or imprisonment of up to three years, or both.

The *Contraventions Act* has now been changed to give law enforcement partners (including RCMP, provincial and local police) the enforcement power to issue tickets to people who do not comply with the *Quarantine Act*, with fines ranging from $275 to $1000.

Announcement from Alberta Government:
On May 20, 2020, Alberta announced new safety measures for travellers arriving at the Calgary and Edmonton international airports from outside Canada. These travellers will be required to pass through a provincial checkpoint where they will need to complete and Alberta isolation plan. Travelers will undergo a thermal scan, as elevated body temperature is a potential symptom of COVID-19.

Federal/Provincial/Territorial Special Advisory Committee:
The Government of Canada continues to work collaboratively with partners at all levels of government to respond to COVID-19 in order to protect the health of Canadians.

The Special Advisory Committee, composed of the Council of Chief Medical Officers of Health and senior public health officials from all jurisdictions, has been activated since January 2020 to focus on coordination of federal, provincial and territorial response efforts across Canada.

The Committee is co-chaired by Canada's Chief Public Health Officer, Dr. Theresa Tam, and by Dr. Saqib Shahab, Chief Medical Health Officer of Saskatchewan.

The Committee focuses on policy and technical public health aspects of the response as per the FPT Public Health Response Plan for Biological Events, informed by lessons learned from past public health responses and approved by all jurisdictions in 2017.

On May 1, 2020, the Special Advisory Committee released recommendations on next steps for Canada in a document entitled *Foundations for Living with COVID-19 in Canada: Lifting of Restrictive Public Health Measures*. One criteria for lifting of restrictive public health measures identified by the Committee is avoiding the risk of importation of cases.

The Special Advisory Committee on COVID-19 reports to the Conference of Deputy Ministers of Health and to Health Ministers from all provinces and territories.

Deputy Ministers and Health Ministers have been working closely bilaterally and through their respective multilateral table on key aspects of the pandemic response, such as the

provision of personnel protective equipment and other supplies, testing and sharing of best practices. Engagement is taking place frequently (several times a week).

Communications and Public Education on COVID-19

SYNOPSIS

- Communications and public education on COVID-19 are key to maintaining Canadians trust and confidence in the Government's response, and ensuring Canadians continue to be aware of the risks to their health and steps they can take to protect themselves, their families and their communities.

POTENTIAL QUESTION

- What is the Government of Canada doing to ensure that Canadians are informed about COVID-19 to protect themselves and stop the spread of this virus?

KEY MESSAGES

- Since the start of the COVID-19 outbreak, the Government of Canada has worked closely with provinces and territories and stakeholders to provide Canadians with the information they need to protect themselves, their families, and their communities.

- To complement online content, the Government of Canada continues to update the Canada COVID-19 mobile app, which provides users with information and resources on the disease, and allows them to track their symptoms daily.

- The Wellness Together Canada portal for mental health and substance use provides access to authoritative information and connects Canadians to peer support workers, social workers, psychologists and other professionals for confidential chat sessions or phone calls.

- We have also used a wide variety of channels to provide information and updates to Canadians.

- These include:
    - the dedicated website Canada.ca/coronavirus and other

linked pages on the COVID-19 response, which have had more than 175 million visits since their launch;
    - regular briefings to the media;
    - a toll-free information line [1-833-784-4397] with interpretation service available in 200+ languages open from 7 a.m. to midnight, 7 days a week;
    - regular public advisories to inform Canadians and the media about emerging issues and to dispel misinformation about health products [natural health products, drugs and medical devices];
    - an email notification service, which provides subscribers with links to critical information on the Government of Canada's COVID-19 website;
    - social media;
    - TV, radio, print and digital advertising; and
    - a nation-wide mail-out sent to all households across the country to reach Canadians who may not have access to or use online technology.

IF PRESSED ON INFORMATION AVAILABLE ONLINE

Through our website, Canadians can access:

- guidance and advice for travellers, healthcare professionals, essential workers, Indigenous communities and all Canadians;
- factsheets and infographics on a variety of topics, in a wide range of languages;
- a self-assessment tool to check for symptoms of COVID-19;
- a dashboard showing how the outbreak is evolving in Canada; and
- information on Health Canada's regulatory actions to support greater access to health products.

IF PRESSED ON RECOVERY STEPS IN CANADA

- During the reopening phase, we will continue to share

important information with all Canadians online on Canada.ca/coronavirus, as well as through the Canada COVID-19 app, email notifications, social media and regular briefings with the media.

IF PRESSED ON THE WELLNESS TOGETHER CANADA PORTAL

- During these difficult times, it is critical that Canadians have access to effective tools to support their mental health and well-being. The Wellness Together Canada portal provides Canadians with free access to a virtual network of psycho-social information services and supports in both official languages.

IF PRESSED ON THE CANADA COVID-19 APP

- The Canada COVID-19 app provides access to trusted, evidence-based information about the COVID-19 pandemic across Canada.

- The app has more than 546,000 users as of May 15. It builds on what provinces and territories are doing.

- It does not track personal information, nor is it a surveillance tool. The protection of Canadians' information is a priority for the Government of Canada, and any tool used to collect healthcare information undergoes a rigorous privacy assessment.

IF PRESSED ON PUBLIC EDUCATION FUNDING

- The $50 million in funding for the Public Health Agency of Canada is supporting ongoing communications efforts and the implementation of a comprehensive national public education campaign for COVID-19 that provides Canadians with credible information and encourages behaviours that

protect individuals and overall public health.

- The public education campaign includes advertising, social marketing, information resources, partnerships and targeted outreach to at-risk populations.

- Public education plays a critical role in our response to COVID-19 as it helps to:
    - increase awareness and understanding about symptoms and treatment;
    - provide information on preventive measures such as self-isolation; and
    - address misinformation and public concerns.

IF PRESSED ON EFFORTS TO COMMUNICATE WITH VULNERABLE POPULATIONS

- The Public Health Agency of Canada's national public education campaign includes targeted outreach to vulnerable populations, such as the elderly and those with underlying medical conditions.

- To help protect these vulnerable populations, the Government has ensured that key information on infection prevention is available to them and their caregivers, in clear and relatable terms, and in multiple formats, including having simultaneous interpretation into ASL and LSQ for all media briefings.

- Similarly, we have been supporting outreach to language minority populations by reproducing 19 communications resources, including fact sheets and infographics into 33 languages to date.

BACKGROUND

The Government of Canada is working collaboratively with partners at all levels of government to respond to COVID-19. The communications tactics outlined above aim to meet the following objectives:

- Provide Canadians with timely and accurate information about the COVID-19 situation in Canada and the risks to their health, and persuade Canadians to take specific actions to protect themselves and minimize illness and death and disruption to society.

- Communicate the actions the Government is taking in concert with the provinces and territories to prepare for and respond to the COVID-19 pandemic in Canada and its related impacts, in order to maintain public trust and confidence in the Government's response.

- Detect and address misinformation with the latest evidence and information in order to reduce fear, anxiety, stigma and other reactions that can lead to further societal, economic and other disruptions.

Key Statistics

- **More than 175 million web visits** since launch, as of May 15.
- **More than 546,000 users** of the **Canada COVID-19 App**, as of May 15.
- **More than 135,000 calls** received on the **COVID-19 toll free line** since the launch, as of May 15.
- **More than 37,000 subscribers** to the Get Updates on COVID-19 **email notification service**, as of May 15.
- National **postcard mailout** sent to **15.5 million households** across Canada.

Federal Correctional Facilities

SYNOPSIS

- The Government of Canada has taken measures to prevent introduction of COVID-19 into federal correctional institutions across Canada; as well as to strengthen their capacity to rapidly identify and contain any outbreaks that may occur; and to ensure that federal inmates have access to appropriate COVID-19 health care as all Canadians.

POTENTIAL QUESTION

- What is the federal government doing to prevent the introduction and transmission of COVID-19 in federal corrections facilities?

KEY MESSAGES

- The Public Health Agency of Canada continues to work closely with Correctional Service Canada to strengthen measures to prevent introduction and transmission of COVID-19 into federal correctional institutions across Canada.

- The Public Health Agency of Canada and Correctional Service Canada are working with local and provincial/territorial public health authorities across the country to ensure that all of the appropriate public health and infection prevention and control practices are in place to prevent or rapidly control further outbreaks.

- The National Microbiology Laboratory is working with Correctional Service Canada and provincial public health laboratories to ensure that federal correctional institutions have access to the COVID-19 laboratory testing capacity necessary to rapidly identify and manage cases.

- Correctional Service Canada is collaborating closely with local and provincial/territorial public health authorities to ensure that federal inmates have access to appropriate

COVID-19 health care, including hospital based care if it is required.

IF PRESSED ON COVID-19 OUTBREAKS AT Federal Correctional Institutions …

- The Public Health Agency of Canada is working closely with officials at Correctional Service Canada, as well as with local and provincial public health authorities to bring outbreaks at federal correctional facilities under control.

- The Public Health Agency of Canada is in daily contact with Correctional Service Canada, and has mobilized experts in epidemiology, infection prevention and control, and workplace health and safety to outbreaks at the Mission Medium Institution in British Columbia, and the Federal Training Centre Institution and Joliette Institution for Women in Quebec to support Correctional Services Canada and local public health authorities in bringing those outbreaks under control.

- In addition to reviews of Correctional Service Canada practices regarding infection prevention and control, environmental health, and workplace health and safety, the Public Health Agency of Canada has developed a suite of supporting materials including an institution self-assessment tool, standardized assessment templates and webinars for Correctional Service Canada personnel.

BACKGROUND

Correctional Service Canada (CSC) and the Public Health Agency of Canada (PHAC) are focusing on preventing and containing the spread of the virus across correctional institutions by:

- Assessing and strengthening measures to prevent and contain the transmission of the virus;
- Reviewing and auditing the infection prevention and control practices; and
- Reviewing and auditing the workplace health and safety practices.

Outbreak at Mission

CSC has been working in concert with PHAC to identify additional measures required to control outbreaks at facilities in BC and QC, and to prevent or contain outbreaks elsewhere.

Recommendations to improve infection prevention and control, environmental health, and workplace health and safety measures at federal correctional institutions are being implemented. Further reviews of these practices are planned for all federal correctional institutions across Canada.

Digital Supports and Virtual Care

SYNOPSIS

- In response to the COVID-19 pandemic, the Government of Canada is putting in place a range of digital supports to help Canadians get the information, resources and care they need. On May 3, the Prime Minister announced $240.5 million to support Canadian health systems to accelerate their efforts to meet health care needs through virtual tools and approaches. This funding will also help to support a suite of digital tools, including an online self-assessment tool, a mobile app to enhance self-assessments and provide a hub for trusted information and resources and an online portal for access to virtual psychosocial supports.

POTENTIAL QUESTION

- What has the Government of Canada done to help Canadians access the resources they need during the COVID-19 pandemic?

KEY MESSAGES

- Canadians need ready access to digital tools and resources to help during the COVID-19 pandemic, including education, information, mental health and substance use supports, alerts and screening tools.

- The Government of Canada is working closely with provinces and territories, vendors and stakeholders to make these tools widely available to Canadians and their families.

- On May 3, the Prime Minister announced that the Government of Canada is committing $240M to help Canadian health systems to accelerate their efforts to meet health care needs through virtual tools and approaches.

- This will enable Canadians to safely engage with their regular health providers through telephone, text or video-conferencing, to have their health needs met. It also means they can continue to access specialist services throughout

this time of uncertainty.

- As well, through this investment we have already implemented a suite of digital health tools, including:
    - An online self-assessment tool, which has been accessed by more than 4 million Canadians
    - A mobile app called “Canada COVID-19,” which provides reliable information and resources for Canadians. In addition, on the app, Canadians are encouraged to monitor their health on a regular basis through a daily symptom tracker.
    - *Wellness Together Canada*, a free online portal of virtual mental health and substance use supports available through the Canada COVID-19 app and Canada.ca website.
- We will continue to work with all of our partners to ensure that Canadians have access to up-to-date information, tools and resources on COVID-19.

IF PRESSED ON VIRTUAL CARE

- The Government of Canada is working with provinces and territories to support the rapid uptake and use of virtual care services.
- This means that Canadians can continue to have their regular health needs met during this unprecedented time in a safe and secure manner, through telephone, text, or video-conferencing, in addition to face-to-face visits.
- Supporting the expansion of virtual care in Canada will help

reduce the pressure on health systems and provide Canadians with needed health services and authoritative information in a safe and secure manner.

- Health Canada is already engaging in discussions with provinces and territories to identify where support is needed most.

IF PRESSED ON PRIVACY

- Privacy considerations were – and continue to be – front and centre at every stage of these initiatives.

- Vendors are bound by the privacy protective terms that are inserted in all contracts that involve personal information.

IF PRESSED ON MENTAL HEALTH AND/OR SUBSTANCE USE

- The Government of Canada recognizes that COVID-19 is creating stress and anxiety for many Canadians, particularly those who do not have ready access to their regular support networks.

- That is why the Government has launched a new online portal for mental health and substance use supports: **Wellness Together Canada.** The portal makes it easy for Canadians to access self-directed tools and find credible information on mental health and substance use issues.

- It also connects Canadians to peer support workers, social workers, psychologists and other professionals for confidential chat sessions, phone calls and online counselling.

- Use of the portal will be closely monitored to ensure that updates will best align with the needs of Canadians.

IF PRESSED ON CONTACT TRACING APPS

- Rigorous contact tracing continues to be an important part of Canada's strategy in response to COVID-19, recognizing its importance to tracking the virus and preventing future flare-ups.

- That is why the Government of Canada's national volunteer recruitment campaign included a call-out for volunteers to help provincial and territorial authorities with case tracking and contact tracing.

- In addition, mobile apps can also support these efforts by providing notifications to users of potential exposure to COVID-19.

- These apps are being explored around the world as a supplement to manual contact tracing – but we know it is not a replacement.

- Our Government believes that privacy must be a foremost consideration for the use of such apps.

- Our government is collaborating with provinces and territories, vendors and stakeholders to explore digital tools to help in the recovery phase of COVID-19.

IF PRESSED ON ADDITIONAL PLANNED ACTIVITIES IN THIS AREA

- Our government recognizes that this is an unprecedented time for Canadians, and are continuing to explore how we can best take action in innovative ways.

- We will continue to work closely with provinces and territories and other partners to evaluate needs for digital

supports.

BACKGROUND

Support for virtual care (May 3, 2020)

- On May 3, the Prime Minister announced $240.5M to support virtual care and digital tools for Canadians. This funding will support the rapid roll out of virtual care and needed supports for health systems, as the Government of Canada is working with provinces and territories to assist health services to undertake virtual care and provide health services at a distance.
- Health Canada is working with provinces and territories to begin to identify where support is needed most on virtual care and supporting infrastructure.

COVID-19 self-assessment tool (March 21, 2020)

- Developed in collaboration with Health Canada and the Public Health Agency of Canada, this tool is available to all Canadians through the Canada.ca website. The tool has been visited over 4 million times in the first month since the launch. It is intended to complement PT self-assessment tools and is empowering Canadians to make informed decisions on the appropriateness of COVID-19 testing and when to access other resources like telehealth, primary care providers and emergency departments.
- The self-assessment tool is supported through the $240.5M in funding announced on May 3.

Canada COVID-19 app (March 31, 2020)

- Accessible via mobile and web-enabled devices, this nationally available app provides an integrated platform for Canadians to receive trusted information and engage on issues related to COVID-19. It quickly became the number one medical app on both the App and Google Play Store.
- On April 11, the app launched its daily symptom tracker, which enables users to take an active role in their self-care through the daily recording of potential COVID-19 symptoms. With enough users, the symptom tracker will help to provide useful data to allow public health authorities to track the symptoms of the population as a whole, providing an indicator of how the disease is evolving in neighbourhoods, regions, and provinces.
- Canada COVID-19 is supported through the $240.5M in funding announced on May 3.

Portal for mental health and substance use supports: Wellness Together Canada (April 15, 2020)

- Through this portal, Canadians are able to access digital tools to help them monitor and manage their mental health and substance use needs, and access trained mental health professionals through digital platforms.
- Three broad types of supports are available:
    - Triage and self-monitoring tools: These are self-directed tools to guide and connect users to promotion or prevention resources. This will enable

individuals to determine their level of need, as well as self-manage their mental health and substance use.
    - Mental health promotion tools and resources: These tools and resources promote mental health and prevent poor mental health. These will focus on enhancing protective factors (e.g., resilience, coping, social support and social networks) and addressing risk factors (e.g., substance use, social isolation, discrimination and stigma).
    - Live psychosocial supports: The portal also provides confidential chat sessions, phone calls and online counselling with peer support workers, social workers, psychologists and other professionals.
- The portal is supported through the $240.5M in funding announced on May 3.

BlueDot
- Health Canada and PHAC have put in place contracts with BlueDot to enhance and expand upon existing expertise to provide further insights and understanding into the emergence, spread and public health risks of COVID-19
- This work is supported through the $240.5M in funding announced on May 3.

Get Updates on COVID-19 (April 30, 2020)
- The Government of Canada has put in place an opt-in email subscription service called “Get Updates on COVID-19.” The service provides valuable updates to those Canadians who would like to be alerted to updates on the COVID-19 situation in Canada.

Contact Awareness/Tracing Apps
- Countries around the world are looking at digital tools to help reduce the workload burden related to tracing and containing the spread of COVID-19. In Canada, many jurisdictions are also considering such tools, given their potential value to help contain the spread of disease as Canadians return to the workforce. Health Canada has been engaging with provinces and territories to understand proposed approaches.

Health Canada continues to explore other digital tools with a view to providing Canadians with the information and resources they need to stay safe and healthy during the COVID-19 pandemic. This includes resources for children to help them better understand the disease and stay safe and healthy.

Drug Shortages

SYNOPSIS

- COVID-19 is creating global supply chain challenges and increased demand for drugs used in supporting patients with the disease. Drug shortages, particularly in the context of COVID-19 critical drugs, could put the health of Canadians at risk.

- Health Canada has amplified its surveillance activities and engagement with key supply chain players. It is also taking steps to help stabilize the supply, with a focus on drugs in shortage or in high demand.

POTENTIAL QUESTION

- What action is the government taking to ensure the COVID-19 pandemic does not create drug shortages in Canada?

KEY MESSAGES

- Ensuring that Canadians have access to needed medication is a top priority for the Government of Canada. Significant efforts are being made through a whole-of-government approach to respond to drug shortages during the COVID-19 pandemic.

- We have amplified our monitoring activities. We are engaging provinces and territories, industry, healthcare and patient groups - in some cases on a daily basis. Together, we are assessing supply chain vulnerabilities to ensure action is taken to help prevent and minimize the impact of shortages.

- On March 30, 2020, I signed an Interim Order to allow for the exceptional importation of products related to COVID-19. When drugs are not available, the department has a legal pathway to bring alternate supplies of drugs to the Canadian market.

- We are also taking steps to help mitigate and prevent drug shortages. As of May 11th, Public Services and Procurement Canada has issued eight Requests for Information signaling Canada's interest in procuring and building a reserve of critical drugs in shortage.

- We are also working closely with key international regulatory partners (US, EU, UK and Australia). This has resulted in earlier risk identification and response planning.

IF PRESSED ON CURRENT DRUG SHORTAGES…

- Our government is taking proactive measures to mitigate the impact of any drug shortages related to COVID-19.

- Through this work, we have been able to secure additional supplies of needed drugs for Canada. For example, we have worked with multiple companies to facilitate access to additional supplies of drugs such as muscle relaxants (e.g. cisatracurium), inhalers (e.g. salbutamol) and sedatives (e.g. propofol) to help support COVID-19 patients.

IF PRESSED ON REQUESTS FOR INFORMATION (RFIs)…

- The RFIs were posted to identify additional supply that is not already earmarked to meet Canada's current needs.

- The initial RFIs focus on critical drugs currently in shortage – drugs that have the greatest potential impact on the health care system. These drugs include sedatives, muscle relaxants and inhalers.

- The Government will also be looking to procure other drugs, vaccines, and drugs that are showing promise in Clinical Trials.

BACKGROUND

Health Canada's role

Health Canada recognizes that drug shortages can have a significant impact on patients and health care professionals and is committed to doing its part to prevent shortages where possible and minimize their impact when they occur.

Addressing the complex issue of drug shortages is a multi-stakeholder responsibility requiring collaborative action from provinces and territories, manufacturers, distributors, practitioners, and the federal government. When national shortages occur, Health Canada works with provinces and territories and stakeholders across the drug supply chain to determine the details and status of the shortage, coordinate information-sharing, and identify mitigation strategies, which may include regulatory measures and exploring access to alternative products available in other jurisdictions.

Factors such as whether the shortage is national in scope, whether alternative supplies are available and whether the product is considered medically necessary are all considered in determining the potential impact and any necessary actions by Health Canada.

Health Canada also co-chairs the Multi-Stakeholder Steering Committee on Drug Shortages, which mobilizes provinces and territories and key stakeholder groups to play a lead role in advancing tools to address drug shortages.

Bill C-13, the *COVID-19 Emergency Response Act*

On March 25, 2020, the *COVID-19 Emergency Response Act* was brought into force to support the availability of drugs and medical devices by providing the Government with the authority to make regulations to address any future shortages of therapeutic products, including drugs and medical devices. This includes the importation of drugs and medical devices not authorized for sale in Canada to address certain shortages, such as for personal protective equipment or drugs required to treat COVID-19, and changes to the *Patent Act* to allow for compulsory licencing in health emergencies in the period up to September 30, 2020.

Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19

On March 30, 2020, the Minister of Health authorized an Interim Order which sets up a regulatory framework to help prevent and alleviate shortages of drugs, medical devices, and foods for a special dietary purpose.

It allows for the exceptional importation and sale of products that may not fully meet Canadian requirements, such as those related to licensing and labelling, but are manufactured according to comparable standards.

Health Canada designates the products eligible for importation and sale under the Interim Order. Companies with an establishment licence may import these drugs and devices after notifying Health Canada five days in advance.

The Interim Order also requires that any shortages of critical medical devices related to COVID-19, such as ventilators, be reported to Health Canada and publicly communicated. Public reporting of shortages help manufacturers and the health care system plan and react to supply disruptions, in order to mitigate the impact on patients.

These new tools allow Health Canada to address critical supply issues in an expedited manner when shortages occur and help protect the health and safety of Canadians during the pandemic.

Through this work, Health Canada has been able to secure additional supplies of needed drugs and medical devices for Canada. For example, the department has worked with multiple companies to facilitate access to additional supplies of drugs such as muscle relaxants (e.g. cisatracurium), inhalers (e.g. salbutamol) and sedatives (e.g. propofol) to help support COVID-19 patients. The issuance of medical device establishment licences related to the importation and manufacturing of PPE such as masks and gowns has also been expedited.

Engagement with Provinces and Territories

Drug shortage management requires a multi-stakeholder effort. Over the last number of years, capacity has been built up across governments leading to a more coordinated and effective approach to dealing with shortages.

Health Canada has strengthened existing mechanisms in place to manage drug shortages, including an FPT committee infrastructure to identify, report, and assess shortages in cooperation with industry and patient groups.

Health Canada has leveraged this FPT infrastructure and increased cooperation with provincial and territorial partners to identify shortage signals earlier, especially for critical drugs required for COVID-19.

Additional Collaboration

Canada has increased cooperation with international regulatory partners (US, EU, UK, Australia). This has resulted in earlier risk identification and response planning for new shortages. In addition, the government is working with key federal partners –like Global Affairs Canada, Innovation, Science and Economic Development and Public Services

and Procurement Canada – to explore ways to increase access to critical drugs. For example, Health Canada is working with Public Services and Procurement Canada to develop Requests for Information for critical drugs that are in high demand or are in shortage. The goal is to access additional supplies of critical drugs above and beyond current needs, to stabilize and build Canada's supply of these drugs for future needs as the pandemic continues to evolve.

Access to Drugs and Vaccines for COVID-19

SYNOPSIS

- The COVID-19 pandemic has created unprecedented challenges to Canada's medical system, and there is a need for drugs and vaccines to support the response.

POTENTIAL QUESTION

- What is Health Canada doing to help Canadians get access to drugs and vaccines for COVID-19?

KEY MESSAGES

- The COVID-19 pandemic is unlike anything we have seen in recent history. Health Canada is proactively doing all it can to respond to the pandemic in its role as health product regulator.

- At this time, there are no drugs or vaccines that have been proven safe and effective for the treatment or prevention of COVID-19. Several therapies are in development, and existing drugs are being assessed for this potential.

- As of May 15, 2020, Health Canada has authorized 33 clinical trials for treatments targeting COVID-19 including the first clinical trial for a vaccine specifically developed to prevent COVID-19. An up-to-date list of all these trials is available on Health Canada's website.

- Health Canada will expedite the review and approval of drugs and vaccines to address COVID-19, while

continuing to ensure that these products are safe, effective and of high quality.

IF PRESSED ON VACCINE AVAILABILITY

- Health Canada is closely monitoring global vaccine development and is in active discussions with several vaccine manufacturers and researchers to provide regulatory and scientific advice for vaccine trials that may launch in Canada.

- On May 15, 2020, Health Canada approved the first clinical trial for a vaccine targeted against the virus that causes COVID-19. The safety and optimal dose for the CanSino vaccine will be assessed before it is used in larger groups of volunteers. Health Canada will monitor the progress of this trial closely.

- Earlier this month, Health Canada also approved another clinical trial using a vaccine known as BCG vaccine, which may have a role in reducing the severity of COVID-19.

- While recognizing the urgent need for a vaccine, Health Canada will require all products to demonstrate a high level of safety, efficacy and quality before coming to the Canadian market.

IF PRESSED ON CLINICAL TRIALS

- Since no drugs have yet been proven safe and efficacious for COVID-19, Health Canada recommends that any potential treatments for this disease be investigated through clinical trials. The Department is working hard to facilitate and expedite as many of clinical trials for COVID-19 in Canada as possible, without compromising the quality standard of these trials.

- Clinical trials are conducted to determine whether new drugs are safe and effective in humans. Clinical trials ensure the quality of the study, protection of the patient, and the proper collection and retention of outcomes. It is the best mechanism to provide trial volunteers access to new drugs before they are approved.

IF PRESSED ON POTENTIAL DRUG TREATMENTS

- At present, there is insufficient evidence to recommend any specific anti-COVID-19 treatment for patients outside of clinical trials.

- Results from large, well-designed studies are needed to make any conclusions on the safety and efficacy of any drugs or vaccines.

IF PRESSED ON REMDESIVIR

- Health Canada has been closely monitoring developments for potential treatments for COVID-19, including the experimental drug remdesivir. Some early clinical trial evidence coming from the National Institute of Allergy and Infectious Diseases (NIAID) in the US suggests that it may help patients to recover sooner.

- Health Canada is aware that the U.S. Food and Drug Administration and the Japanese Ministry of Health, Labour and Welfare have given emergency authorization for remdesivir. We are working collaboratively with our international counterparts and share scientific information and align requirements for safety and efficacy where possible to expedite the review and approval process.

- Remdesivir is still considered an experimental therapy. To date, Health Canada has approved two clinical trials for remdesivir in the context of COVID-19 in Canada.

- Remdesevir has also been accessed on a case-by-case basis through Health Canada's Special Access Program (SAP), which provides emergency access to medications for serious or life-threatening conditions.

IF PRESSED ON INTERNATIONAL COLLABORATION

- Health Canada is leveraging its strong international partnerships with the US Food and Drug Administration, the European Medicines Agency, and the World Health Organization, amongst others, to share information and to raise our collective level of awareness of evidence-based approaches for vaccines and treatments. The objective is to work towards alignment on regulatory requirements and to stay informed of any potential treatments.

IF PRESSED ON STAKEHOLDER ENGAGEMENT

- Health Canada is actively engaging with stakeholders in the health product industry to proactively identify, track and provide support to sponsors of clinical trials for vaccines and treatments for COVID-19.

- Health Canada recognizes that many stakeholders, health professionals and Canadians are looking for the latest information about health products for COVID-19. The department has created a new website for the health product industry, so they know how to apply for regulatory approval and who to contact for questions. We are also making sure information relevant to health professionals and Canadians is up-to-date on our website.

IF PRESSED ON UNAPPROVED PRODUCTS

- The most appropriate way to determine what treatments may be effective for COVID-19 is through properly designed and conducted clinical trials. Health Canada is expediting the review of clinical trials so that products can be studied and made available to Canadians as quickly as possible.

BACKGROUND

New Legislative Authorities

In order to be able to take rapid action, on March 25, 2020, amendments to the *Food and Drugs Act* and the *Patent Act* were passed that will streamline processes and provide the Government with additional powers.

The amendments will:

- help prevent and mitigate shortages of drugs and medical devices;
- seek additional information from companies to confirm that products are safe for Canadians; and
- allow making, using, or selling a patented invention, such as a medication, that is needed to respond to this pandemic.

Interim measures are also improving access to products that are approved or registered in other jurisdictions with similar regulatory frameworks and quality assurances, but may not fully meet some of the regulatory requirements under the *Food and Drugs Act* — such as packaging requirements.

Mobilizing manufacturing capacity

Health Canada is working closely with stakeholders in other sectors of our economy, many of which are scaling up or re-tooling their manufacturing capacity to provide much needed tests or medical supplies. We are taking a whole-of-government approach to mobilize industry, providing them with information and support for research, market approval, manufacturing and supply.

Stakeholder Engagement

Information about health products for COVID-19 has been consolidated into a new website for the health product industry, so they know how to apply for regulatory approval and who to contact for questions. Information relevant to health professionals and Canadians is provided on the COVID-19 website.

Health Canada is actively engaging with stakeholders in the health product industry to proactively identify, track and provide support to sponsors of clinical trials, potential diagnostic tests, treatments and vaccines related to COVID-19.

Clinical Trials

Health Canada is facilitating clinical trials related to COVID-19 in Canada. Clinical trials are conducted to determine whether new drugs, diagnostics or treatments are both safe and effective in human beings. Several existing drugs have been repurposed to assess their potential in treating or preventing COVID-19, while other new drugs are under development. Since no drug treatments have been proven safe and efficacious for COVID-19, Health Canada recommends that any treatments be investigated in clinical trials.

Clinical trial applications will be reviewed and approved by Health Canada in under 15 days. As of May 15, 2020, Health Canada has authorized 33 clinical trials for treatments targeting COVID-19, most of which are repurposing existing drugs.

Until a vaccine or drug is available on the Canadian market, another option for access is Health Canada's Special Access Program. This Program is available to practitioners requiring access to unapproved drugs that could be used in the treatment of the infection. Our goal is to ensure that Canada is prepared for whatever challenges come our way.

Remdesivir

On May 1, the U.S. Food and Drug Administration (FDA) granted emergency use authorization (EUA) for the investigational antiviral remdesivir to treat COVID-19. According to their release, “the authorization is temporary and does not take the place of the formal new drug application submission, review and approval process. The EUA allows for the distribution and emergency use of remdesivir only for the treatment of COVID-19; remdesivir remains an investigational drug and has not been approved by FDA.”

On May 7, the Japanese Pharmaceutical and Medical Devices Agency (PMDA) followed the FDA’s decision and granted remdesivir a Special Approval for Emergency for treatment of COVID-19, with approval conditions to allow the access to the potential treatment of this disease. Throughout this Special Approval for Emergency, the PMDA will continue to evaluate its efficacy and safety and disseminate its information, while taking necessary actions immediately.

Health Canada is in active discussions with Gilead Sciences Canada, Inc., the manufacturer of remdesivir, to discuss an expedited regulatory pathway, including the rolling review flexibility recently made available by Health Canada, and to provide advice on how best to file an application seeking market access in Canada.

Early History (Warnings and Steps Taken) in COVID-19 Outbreak

SYNOPSIS

- Warning of a respiratory illness in Wuhan, China was received on December, 31, 2019. The Government of Canada quickly alerted provincial Chief Medical Officers of Health followed by enhanced border measures. The World Health Organization confirmed on January 12, 2020 the novel coronavirus following which the Government activated its emergency operations centre and posted signage at airports. Chief Medical Officers of Health were convened well in advance of the first Canadian presumptive case identified on January 25, 2020.

POTENTIAL QUESTION

- What warnings did the Government of Canada receive regarding COVID-19, and what steps were taken in response?

KEY MESSAGES

- Timely intelligence gathering, in collaboration with both domestic and international partners, allowed early and coordinated action by the Government of Canada.

- Canada took a number of concrete steps in advance of its first presumptive case of COVID-19 in late January, including posting signage at airports, issuing a travel alert, and convening Ministers of Health and Chief Medical Officers of Health from across the country.

- Subsequent, rapid actions were taken to mobilize Canada's national and provincial public health emergency response infrastructure as new information became available, and the risk to the health and safety of Canadians became clearer.

IF PRESSED…

- The Chief Public Health Officer of Canada informed all provincial Chief Medical Officers of Health on January 2nd, 2020 well before Canada's first presumptive case was identified on January 25th, 2020.

- On January 12th, the World Health Organization received confirmation that the respiratory illness that developed in Wuhan, China, was caused by a new coronavirus.

- Since January 24th, I have convened calls regularly with my Provincial and Territorial counterparts to ensure national coordination in the response to COVID-19.

BACKGROUND

The Public Health Agency of Canada (PHAC) operates the Global Public Health Intelligence Network (GPHIN), which is an early-warning and situational awareness system for potential public health threats worldwide—including outbreaks of infectious disease.

Canada first became aware of a respiratory illness originating in Wuhan, China through an alert through GPHIN received on December 31 2019. This information was shared by the Dr. Tam, the Chief Public Health Officer of Canada on January 2, 2020, with all provincial and territorial Chief Medical Officers of Health of Canada.

The World Health Organization (WHO) posted its first event notification on January 5, 2020, to its secure Event Information Site (EIS) for International Health Regulations (IHR) National Focal Points regarding a cluster of pneumonia of unknown etiology reported in Wuhan City, Hubei Province of China. The WHO found there was limited information to determine overall risk and advised against the application of any travel or trade restrictions against China.

Precautionary steps were taken as Canada sought additional information from the WHO. On January 7, 2020, PHAC issued a Travel Health Notice, and on January 9, 2020, PHAC issued a Public Health Alert on the Canadian Network for Public Health Intelligence, an extranet for communication with public health partners.

Confirmation of a novel coronavirus in Wuhan, China was announced by the WHO on January 12, 2020. On January 14, 2020, Dr. Tam convened a special teleconference of the Council of Chief Medical Officers of Health (CCMOH) to discuss situational updates and domestic preparedness in relation to the outbreak. PHAC activated its Health Portfolio Operations Centre on January 15, 2020 to Level 2, to actively monitor early warning signs and to prepare for possible containment and mitigation of a possible outbreak. On January 22, 2020, the Canada Border Services Agency implemented signage at major airports to raise awareness for passengers arriving from China.

Progressive escalation followed Canada's first presumptive case. Canada's first presumptive case was identified on January 25, 2020. Following this, critical public health emergency management infrastructure was mobilized for the COVID-19 response, including:

- First meeting of the Federal-Provincial-Territorial Special Advisory Committee on COVID-19 (January 28, 2020, followed by meetings on January 30 and 31, bi-weekly through February and tri-weekly since March);

- First meeting of Federal-Provincial-Territorial Ministers of Health was January 24, and have met regularly on a weekly or biweekly schedule since then; and,
- G7 Ministers of Health (weekly, starting February 3, 2020).

In addition, the following travel measures were implemented:

- Travel advisory against non-essential travel to China (January 29, 2020); and,
- Enhanced screening measures at major international airports including all travellers from the Province of Hubei, China (February 9, 2020)

Canada reached its 100th confirmed case on March 11, 2020.

Health Products Making False or Misleading Claims

SYNOPSIS

- Health Canada has identified health products making false or misleading claims to prevent, treat or cure COVID-19 through proactive monitoring of online sites and complaints received. This activity is illegal and Health Canada has been taking actions to stop this.

POTENTIAL QUESTION

- What is Health Canada doing about health products on the market claiming to treat, prevent or cure COVID-19?

KEY MESSAGES

- The health and safety of all Canadians is Health Canada's top priority and we are taking measures to protect consumers from illegal, false or misleading advertising of products claiming to mitigate, prevent, treat, diagnose, or cure COVID-19.

- To date, Health Canada has not authorized any product to prevent, treat or cure COVID-19. Selling health products that make false or misleading claims to prevent, treat or cure COVID-19 is illegal in Canada.

- As a result of proactive monitoring of online sites and complaints received, Health Canada has identified a wide range of health products making false or misleading claims related to COVID-19. Health Canada takes this matter very seriously and is taking action to stop this illegal activity.

- Health Canada has issued compliance letters to multiple companies directing them to immediately stop selling such products and remove references to these products from their websites. Health Canada has also been working with major online retailers to stop the posting of these products on their

sites.

- On March 27, 2020, Health Canada issued a public advisory warning Canadians about the risks of buying health products that make false or misleading claims to prevent, treat or cure COVID-19.

- To keep Canadians informed, Health Canada has posted a table which lists products and corresponding companies or advertising media found to engage in non-compliant marketing, which are currently under review or have been resolved. Health Canada took compliance and enforcement action against these organizations, as required.

- The Department is also coordinating with other government agencies, such as the Competition Bureau and the Royal Canadian Mounted Police, to address the issue of false and misleading claims related to COVID-19.

IF PRESSED

- Health Canada has followed up on hundreds of cases regarding health products making false or misleading claims related to COVID-19 identified through proactive monitoring activities or complaints received.

- Various compliance and enforcement options are available to manage the risk posed to public health and safety by false or misleading claims related to COVID-19, including on site inspections, regulatory letters, recalls, public communications or product seizures.

- In certain circumstances, when the regulatory enforcement responses are not appropriate to achieve compliance, Health

Canada may refer its findings to the Public Prosecution Service of Canada for potential prosecution.

BACKGROUND

Status of Products to Treat or Cure COVID-10
Health Canada has not approved any product to treat or cure COVID-19. Selling or advertising health products making false or misleading claims is illegal in Canada under Sections 9 (1) and 20 (1) of the *Food and Drugs Act* . Health products that have been authorized for sale by Health Canada will have an eight-digit Drug Identification Number (DIN), Natural Product Number (NPN) or Homeopathic Drug Number (DIN-HM).

Health Canada's Actions in Addressing Products Making False or Misleading Claims
Health Canada has followed up and taken action on numerous cases regarding health products making false or misleading claims related to COVID-19 identified through proactive monitoring of online sites or complaints received.

Companies have been sent compliance letters and directed to immediately stop selling such products and to remove references to these products from their websites. Health Canada has been actively monitoring websites and working with major online retailers to ensure products making false or misleading claims related to COVID-19 are removed from their sites.

On March 27, 2020, Health Canada issued a public advisory to warn Canadians about the risks associated with products making false and misleading claims related to COVID-19. Canadians were encouraged to report any information on potential false and misleading advertising or the sale of products that have not been approved by Health Canada. To keep Canadians informed, Health Canada has posted a table which lists products and corresponding companies or advertising media found to engage in non-compliant marketing, which are currently under review or have been resolved. Health Canada took compliance and enforcement actions against these organizations, as required. This list is updated bi-weekly.

When Health Canada identifies or is notified of potential non-compliance with the Food and Drugs Act or its associated regulations, it takes steps to confirm whether non-compliance has occurred and takes action based on the risk to the health of Canadians. A number of compliance and enforcement options are available to manage the risk posed to public health and safety by false or misleading claims related COVID-19 including on site inspections, regulatory letters, recalls, public communications or product seizures. Recently, Health Canada inspectors, in collaboration with the RCMP, seized over 1500 unapproved kits from a resident in British Columbia, who had acquired and sold some of them online without authorization. Health Canada determined that these kits were not authorized for sale in Canada, meaning that the Department has not evaluated their safety and effectiveness. In certain circumstances, when the regulatory

enforcement responses are not appropriate to achieve compliance Health Canada may also refer its findings to the Public Prosecution Service of Canada for potential prosecution.

The Department will continue to monitor and take action as needed to ensure that health products making false and misleading claims to diagnose, prevent, treat, or cure COVID-19 are removed from the market.

Hospital/Health Care System Impacts

SYNOPSIS

- Management of the COVID-19 pandemic has led to impacts on the health care system, such as the cancellation of elective surgeries.

POTENTIAL QUESTION

- What is the Government doing to address COVID-19's impacts on the health care system?

KEY MESSAGES

- As a result of the unprecedented efforts taken so far to implement public health measures across Canada and to free up hospital capacity, Canada's hospitals have not been overwhelmed by COVID-19 as was initially feared.

- Provinces and territories moved early to free up capacity to meet projected needs, such as cancelling elective surgeries and transferring patients into other settings.

- As provinces and territories resume health care services, such as elective surgeries, they are being cautious and taking into account the need to maintain sufficient capacity to meet demand from COVID-19 cases.

- Many provinces also continue to use publicly funded virtual care services and online screening assessments to take pressure off of emergency departments and supporting physical distancing.

- On May 3, the Prime Minister announced $240.5 million in funding to develop, expand, and launch virtual care and mental health tools to support provinces and territories in their work.

- These investments will be used to, among other things, create digital platforms and applications, improve access to virtual mental health supports, and expand capacity to deliver health care virtually, including projects to reach vulnerable Canadians.

- Data plays a key role in planning hospital capacity. We have worked with provinces and territories to model potential pressure points related to the availability of beds and ventilators, which in turn informed decisions on how to allocate resources.

- We will continue to work with provinces and territories as they implement their recovery plans to ensure health care system capacity.

IF PRESSED on how modelling is helping to inform decisions about health system capacity

- Governments continue to work collaboratively to model demands on health systems under different modelling scenarios, both at the provincial level and at the national level with support from the Canadian Institute for Health Information.

IF PRESSED on whether we will have enough capacity

- At this time, provinces and territories have indicated that they have sufficient hospital capacity to address COVID-19 for their epidemic control scenarios.

- But we know too that in our worst case scenario models, our systems would be severely stressed, despite efforts to put in place extra capacity.

- That is why governments are now thinking very carefully

about how best to de-escalate public health restrictions in a way that will avoid future spikes in demand for health services as we live with COVID-19 in the new normal.

BACKGROUND

- A committee of federal/provincial/territorial Deputy Ministers of Health is meeting regularly to address challenges in responding to the pandemic and to share best practices for the health care system response.

- This joint work builds on the work provinces and territories are already doing to put into action the pandemic plans and procedures they prepared for use in times like this, based on international experiences and guidance. Provinces and territories have taken a range of actions to increase system capacity and meet projected needs. This includes cancelling elective surgeries, physically reconfiguring spaces to fit more beds and create more isolation areas, and transferring patients to other settings.

- Many provinces have also increased use of publicly funded virtual care services and online screening assessments. This can help reduce pressure on emergency departments and is also complementing physical distancing measures. Provinces and territories are also running training exercises and simulations, and are hiring or rehiring staff to meet health system needs.

- At the same time, because the surge of COVID-19 cases has been lower than predicted by provinces to date, there is currently capacity sitting idle. Once the services cancelled to free up extra capacity are reintroduced into the system – like elective surgeries – addressing pent up demand for those services will pose its own challenges for system capacity. Governments will share best practices for when and how best to ease restrictions in a way that will best balance the needs of COVID-19 and non-COVID-19 patients.

Health Human Resource Capacity during COVID-19

SYNOPSIS

- Since early March, PTs have worked to maximize their supply of health human resources through emergency and conditional licensing mechanisms that allow experienced health care professionals who are not currently practicing to be deployed in the COVID-19 response. While health human resource (HHR) capacity to respond to acute care needs appears to be sufficient for now, the disproportionate impact of COVID-19 on long-term care facilities has created a significant HHR challenge for some jurisdictions in a vulnerable population group.

POTENTIAL QUESTION

- What is the Government of Canada doing to address shortages of healthcare providers, particularly in long-term care homes?

KEY MESSAGES

- The Government of Canada has identified over 53,000 volunteers through a national volunteer recruitment campaign. Over 6,000 of these volunteers have expertise in long-term care support work.

- More than 24,000 referrals from the inventory have been shared with provinces and territories to provide surge capacity, primarily for contact tracing and support for long-term care facilities.

- We continue to work with provinces to identify their needs and to provide surge capacity in key areas. We are also working with the Canadian Red Cross to support the coordination and training of volunteers, including in Quebec.

- When requested by provinces and territories, the Government of Canada has also sent members of the Canadian Armed Forces as surge support to long-term care facilities.

- The Government of Canada remains committed to working with provinces and territories and taking the necessary actions to protect the health and safety of Canadians during this pandemic.

BACKGROUND

Health is a shared responsibility between federal, provincial, and territorial governments. Provinces and territories (PTs) are responsible for the administration and delivery of health care and the management of their health workforces.

Provincial and Territorial Efforts to Increase HHR Supply

Since early March, PTs have worked to maximize their supply of health human resources through emergency and conditional licensing mechanisms that allow experienced health care professionals who are not currently practicing to be deployed in the COVID-19 response. This included physician and nurse retirees, students and some internationally educated health professionals.

Government of Canada National Recruitment Campaign

On April 2, as part of a comprehensive response to COVID-19, the Government of Canada created a virtual inventory for the mobilization of skilled Canadians to provide surge capacity in key areas. As needs evolve, supports will be identified for other areas requiring assistance. The Government of Canada is working the Canadian Red Cross (CRC) to respond to requests for assistance through the inventory, with CRC providing PTs with support for security and medical verifications, and training of volunteers.

To date the PSC's National Recruitment Campaign has provided contact referrals to the majority of jurisdictions who have made requests for contact tracing including; PE (183), NS (1,302 referrals), SK (992 referrals), NWT (50 referrals), QC (1,157 referrals), and ON (21, 033 referrals), while MB and NU's requests are still pending.

Some of the requests targeted specific expertise or skill sets in a particular job category. For example, QC, NS and NWT's requests sought volunteers with PSW experience, while ON has requested referrals for physicians and nurses. The majority of requests

however, were broader in scope, seeking contact lists of all volunteers available. To date, no referrals have been hired.

Impacts of COVID-19 on Long-term Care (LTC) HHR

LTC facilities are facing pre-existing HHR challenges. For example, personal support workers (PSWs) who provide the majority of hands-on care are an unregulated workforce and characterized by low pay, poor benefits, and part-time work. These challenges plus increased pressures due to the pandemic have led to difficulty in maintaining staff to resident ratios. Workers with part-time positions may also work at multiple sites; therefore, being a source of cross-infection infection.

International Issues

SYNOPSIS

- Since the beginning of the COVID-19 pandemic, Canada has engaged with international partners bilaterally, through the G7 the G20 and the World Health Organization, to help inform our domestic response and to contribute to global efforts on fighting COVID-19.

POTENTIAL QUESTION

- How is the Government of Canada working with international partners on COVID-19?

KEY MESSAGES

- With the outbreak evolving rapidly around the world, we are working closely with our international partners, including the World Health Organization, to protect the health and safety of Canadians and the global community.

- We remain committed to advancing a whole-of-government and multi-sectoral response to COVID-19. The Prime Minister and my cabinet colleagues are also engaged with their international counterparts.

- Since early February, I have been engaging my G7 counterparts on a weekly basis to share information on public health measures, to learn from others' experiences and best practices and identify possible joint actions to tackle this outbreak.

- Bilaterally, I have engaged with key international counterparts, including the United States and the United Kingdom, to discuss our respective COVID-19 responses. These discussions are valuable opportunities to learn from each other and strengthen our domestic and international responses.

- On May 4th, Canada also joined several countries in co-hosting the launch of the Coronavirus Global Response, an online pledging event to raise $8 billion US to help researchers and innovators develop solutions to test, treat and protect people and to prevent the further spread of COVID-19.

IF PRESSED on Suspension of U.S. Contributions to the WHO

- Canada has no plans to cut funding to the WHO. Canada has and will continue to be a strong supporter of the WHO. Since February 11, our government has provided $15.5 million to WHO, and a further $1.5 million to Pan American Health Organization (PAHO), the regional WHO office for the Americas, to prepare and respond to COVID-19 events.

IF PRESSED on Conducting a review of the WHO's role in the global response

- Our continued commitment to the WHO includes our interest in making it a strong, accountable, and well-governed institution.

- This includes after-action reviews, which will be important at all levels following this crisis and can provide critical insights to support necessary change

- A comprehensive post-crisis review of the global response should be undertaken when the time is right – as soon as possible, but not now.

IF PRESSED on Dr. Bruce Aylward's appearance before HESA

- Dr. Aylward is an international civil servant employed by the WHO as a Senior Advisor to the Director General; he does not represent the Government of Canada at the WHO and is not a Government of Canada employee.

- We understand that the WHO has received such requests from several different countries, and that WHO makes efforts to answer technical questions from interested parties where possible.

IF PRESSED on bilateral engagement with the U.S.

- I have engaged regularly with my U.S. counterpart, Secretary Azar, through the G7 forum. I have also held bilateral calls with him to discuss our respective COVID-19 responses, including testing, guidance for essential workers, supply chains and research.

If pressed : Interim Report of the Independent Oversight and Advisory Committee (IOAC) for the WHO Health Emergencies Programme

- The recommendations of the IOAC provide a good foundation for further post-crisis discussions as to how global responses to health emergencies can be improved.

For example, the IOAC recommends an independent assessment of the COVID-19 response, examining both Member States and the WHO Secretariat, should be undertaken “at an appropriate time”, to assess performance during the response and to identify lessons for the future. Canada has made it clear for many weeks now that it would support a comprehensive review of the global response post-crisis.

- There will many lessons that the global community will learn from this pandemic, and the IOAC has an important role to provide independent, evidence-based recommendations in this regard.

BACKGROUND

Canada has engaged with international partners to learn from the experience of others and best practices, to help inform our domestic response and to contribute to global efforts to fight against COVID-19. Since February, Canada has participated in weekly G7 Health Ministerial calls to discuss COVID-19, which has contributed to enhancing bilateral relationships with key countries such as the U.S. Given the magnitude of this

pandemic's impact across sectors, the Prime Minister and other Ministers are engaging regularly with their international counterparts, including Finance, Foreign Affairs, Agriculture and Employment.

On May 4, Canada joined the European Union, France, Germany, Norway, the United Kingdom, Japan, Saudi Arabia as the current G20 presidency and Italy as the future G20 presidency in co-hosting an international online pledging event, the Coronavirus Global Response. Canada is pledging over $850 million towards the fundraising target of $8 billion USD to support the development of rapid coronavirus diagnostics, treatments and vaccines.

As a founding member, Canada has long been a strong supporter of the World Health Organization (WHO), averaging over $70 million annually for the past 10 years in assessed and voluntary contributions to support the work of the organization. The WHO has played a valued leadership and coordination role on many aspects of the COVID-19 response and is supporting the most vulnerable countries in their preparedness and response efforts. Canada has also valued WHO's timely and evidence-based guidance during this rapidly evolving pandemic.

On April 14, U.S. President Donald Trump announced that the U.S. will temporarily suspend funding to WHO while the U.S. Administration conducts a review of the organization due to misgivings over the WHO's management of the pandemic and a perceived bias towards China.

Canada supports an independent, comprehensive review of the global response post-crisis, which would consider the actions of all actors and partners, including the WHO. However, Canada's view is that undermining the credibility of the WHO and its ability to at this point in time is not helpful. The focus should continue to be on the global pandemic response and the health of people in vulnerable situations around the world, with an emphasis on facts and evidence based approaches.

The Independent Oversight and Advisory Committee (IOAC) for the WHO Health Emergencies Programme, which provides oversight and monitoring of the development and performance of the Programme, recently published an ***Interim report on WHO's response to COVID-19: January-April 2020***.

The Interim report is a compilation of observations of how various structures and processes functioned during the early months of the pandemic. It provides an overview of the first months of the pandemic before issuing a series of recommendations on the International Health Regulations (IHR, 2005), the WHO's Health Emergencies Programme and the WHO Incident Management System, leveraging of the WHO Collaborating Centres, access to therapeutics and vaccines, ongoing public health measures support and independent review of the COVID-19 response.

Dr. Theresa Tam is a member of the IOAC. Members serve in their personal capacity and exercise their responsibilities with full regard for the paramount importance of independence.

COVID-19 Outbreak in Kearl Lake, Alberta

SYNOPSIS

- An outbreak of COVID-19 was declared at the Imperial Oil Kearl Lake, Alberta worksite on April 14, 2020. There are 108 cases linked to this worksite, 25 of which are reported in jurisdictions outside of Alberta (BC, SK, MB, NS and NL). Three cases have been hospitalized. There are no deaths reported.

POTENTIAL QUESTION

- What is the Government of Canada doing to help minimize the impact of this outbreak on Canadians?

KEY MESSAGES

- The Public Health Agency of Canada is working closely with Alberta and the other affected provinces and territories in preventing further spread associated with this outbreak.

- Industry stakeholders and Alberta Health Services have put measures in place to reduce transmission, protect their workforce and prevent further spread of COVID-19 to the community.

- The Public Health Agency of Canada is providing increased capacity for epidemiological and laboratory analysis, and we will continue to provide to our provincial and territorial colleagues.

BACKGROUND

Kearl Lake is a large oil sands worksite approximately 70 km north of Fort McMurray. Numerous companies have workers on the site, with Imperial Oil being the largest. The site also has a work camp for employees – accommodations provided by Civeo Corporation. The work camps function as a residence for workers, most of whom fly in from across the country for seven-day on, seven-day off shifts.

Cases of COVID-19 began to emerge on the site in mid-March. An outbreak was declared by Alberta Health (AH) on April 14, 2020. Of the 108 cases that have been observed:

- 25 cases are being reported from other jurisdictions (including BC, SK, MB, NS and NL);
- 88% are male;
- Cases between 24 and 68 years of age;

- Three cases have been hospitalized, two of which have been admitted to ICU; and,
- No cases have died.

Control measures

Public Health Alerts (PHA) on the outbreak have been issued to all provinces and territories by AH throughout the duration of outbreak.

As part of COVID-19 preparedness activities, the site had undertaken a number of precautionary measures prior to the outbreak (such as: closing the buffet at the camp, increasing cleaning measures, enforcing hand hygiene practices, and temperature screening) to prevent the emergence of COVID-19.

Since the outbreak was declared on April 14, further control measures were put in place by AH Services (including the masking of food service workers, and the end of communal dining). The latest illness onset was May 7, 2020. AH considers the outbreak ongoing at this time and outbreak measures will remain in place at the site.

Mass voluntary testing was undertaken for asymptomatic individuals on the site from April 19 to 23, 2020. A total of 1,888 tests were completed and 28 individuals tested positive from this mass testing.

On April 25, 2020, the government of Alberta released the COVID-19 Information Guidance for Managers and Operators of Industrial Work Camps.

Jurisdictions are providing a range of public messaging and advice to workers returning from Kearl Lake, from self-monitoring to mandatory self-isolation for 14 days.

Cases in other jurisdictions

Twenty-five of the 108 cases are being reported by BC, SK, NS, MB and NL. A cluster of cases linked to the Kearl Lake worksite have been identified in the First Nations community of La Loche, Saskatchewan. The Public Health Agency of Canada (PHAC) is working with Saskatchewan to understand the size of the cluster.

AH has shared a list of personnel who were on the site or at the work camps with affected jurisdictions to facilitate contact tracing. AH will be receiving daily line list of all people on the site moving forward. PHAC is currently working with Alberta Health and all other jurisdictions, to determine the process for notification of personnel on site moving forward.

PHAC's National Microbiology Lab is supporting with genetic sequencing of the cases to help understand transmission, and to help identify any sub-clusters of transmission among the cases.

English-Only Labelling On Certain Imported Health Products

SYNOPSIS

- The COVID-19 pandemic has created unprecedented challenges to Canada's health care system, and there is an urgent need for certain health products, such as hand sanitizers and disinfectants, to support the response.

POTENTIAL QUESTION

- Why is Health Canada temporarily allowing English-only labelling on some imported health products during the COVID-19 pandemic?

KEY MESSAGES

- Health Canada's top priority is the health and safety of Canadians, and the Department is doing everything possible to facilitate access to products needed to slow the spread of COVID-19.

- In light of the unprecedented demand and urgent need for products to help limit the spread of COVID-19, Health Canada is facilitating access, on a temporary basis, to certain imported health products labelled in only one official language to increase access to products that are in high demand.

- Many global suppliers have indicated that they are labelling products in English only to expedite production and that they will ship only to countries that will accept English-only labelling.

- Importers are now required to post bilingual label text on their websites and provide sellers with a means to inform consumers, at the point of sale, of where they can access bilingual information on the product.

- All new importers of these products through the interim

measure are required to have bilingual labelling text available to consumers. Previously authorized importers are required to have bilingual label text available on their websites and a means for sellers to inform consumers of this website at the time of sale by June 8, 2020.

- All new Canadian manufacturers of these products must use bilingual labelling. Canadian manufacturers of hand sanitizers who are currently licensed and are using unilingual labelling under the interim measure are required to move to bilingual labelling by June 8, 2020.

- Health Canada will take a risk-based approach to addressing any non-compliance identified.

- Health Canada will lift the interim measures when the regular supply stabilizes.

IF PRESSED…
Technical Grade Ethanol

- Health Canada is aware that there is a critical shortage of pharmaceutical and food-grade ethanol for use in hand sanitizers. To meet this shortage, we have temporarily authorized the use of certain sources of technical-grade ethanol in hand sanitizer products.

IF PRESSED…
Bilingual Language Requirements for Domestic and Imported Products

- Health Canada is focused on expediting review and approval of hand sanitizers and disinfectants to address the COVID-19 pandemic, while continuing to ensure that these products are safe and effective for Canadians.

- All new importers of these products through the interim measure must have bilingual labelling text available to

consumers. Importers previously authorized are required to have bilingual label text available on their websites and a means for sellers to inform consumers of this website at the time of sale by June 8, 2020.

- All new Canadian manufacturers of these products must use bilingual labelling. Canadian manufacturers of hand sanitizers who are currently licensed and are using unilingual labelling under the interim measure will be required to move to bilingual labeling by June 8, 2020.

BACKGROUND

Interim measures

In March and April 2020, Health Canada implemented a number of interim measures to facilitate expedited access to products that do not fully meet regulatory requirements (e.g., labelling) set out in regulations under the Food and Drugs Act. These measures have enabled access to the Canadian marketplace, health care settings, and commercial and industrial settings.

The interim policies include facilitating the importation of:

- hand sanitizers and disinfectants that are already authorized for sale in Canada but are not fully compliant with Health Canada requirements (e.g., English-only labelling, different packaging from what was authorized); and
- hand sanitizers and disinfectants that are not authorized for sale in Canada, but are authorized or registered in other jurisdictions with similar regulatory frameworks and quality assurances.

Some of these products may have unilingual labelling, or labelling in English or French and another language.

Importers of disinfectants and hand sanitizers are required to post bilingual labels on their website and to provide sellers with a means to inform consumers, at the time of sale, of the website where bilingual label text is posted. This could be made available through a sticker applied directly to the products, or posters or signage with take-away pamphlets at the point of sale.

Domestically, one of the specific requests from industry was a flexibility for small local distilleries that did not have the capacity for bilingual labelling to be able to use unilingual labelling in non-bilingual regions.

Given the increase in availability of hand sanitizers, domestic manufacturers of new hand sanitizers require bilingual labelling on their products. Existing product licence holders using unilingual labels under the interim measure are required to move to bilingual labelling by June 8.

Health Canada acknowledges that it may take some time before bilingual labelling or information directing consumers to the company's website for bilingual content will appear on retail shelves. Health Canada will take a risk-based approach to addressing any non-compliance identified.

Health Canada will lift the interim measures when the regular supply stabilizes.

Stakeholder Engagement

Health Canada is actively engaging with stakeholders in the natural health product and food industry to proactively identify, engage and provide support to manufactures, packagers, labelers and/or importers of hand sanitizers and disinfectants in response to the COVID-19 pandemic.

Health Canada brought together industry partners to facilitate the supply of key ingredients and to maximize the domestic production of hand sanitizers and disinfectants, and companies who do not typically operate in health product manufacturing such as distilleries, breweries and refineries producing hand sanitizers.

International Collaboration

Health Canada is leveraging its strong international partnerships and working with the United Kingdom Health and Safety Executive and the United States Food and Drug Administration to share information on best practices and evidence-based approaches for hand sanitizers and disinfectants.

Long-Term Care Homes

SYNOPSIS

- All Canadians have a role to play in helping to protect seniors and medically vulnerable people, who are at greatest risk of severe health complications from COVID-19. Many long-term care homes in Canada have been experiencing outbreaks of COVID-19 resulting in numerous deaths. The Public Health Agency of Canada has provided evidence-informed guidelines to help residents, seniors, administrators and healthcare workers in long-term care homes remain safe and healthy. These recommendations complement provincial and territorial public health efforts to prevent and control healthcare associated infections.

POTENTIAL QUESTION

- Given the severe impacts of COVID-19 on Long-Term Care facilities across Canada, what actions has the federal government taken to support provinces and territories control spread of the infection in these facilities?

KEY MESSAGES

- The Government of Canada is committed to taking the necessary action to continue to protect the health and safety of all Canadians during this pandemic.

- Residents of long-term care homes are at risk of COVID-19 infection due to shared living spaces, underlying chronic conditions and age.

- The Public Health Agency of Canada has provided infection prevention and control guidance to help prevent COVID-19 infections among residents in long-term care and assisted-living facilities.

- Following this guidance reduces the possibility of introducing COVID-19 into these facilities and helps protect workers and residents.

- To support the care of residents, the Government of Canada’s Volunteer Recruitment Campaign provides an

inventory that can be drawn upon to support staffing needs in facilities.

- The military continues to work closely with all levels of government in the fight against COVID-19, including the governments of Quebec and Ontario.

F PRESSED ON LONG-TERM CARE GUIDANCE …

- The Public Health Agency of Canada's guidance on infection prevention and control in long-term care facilities is designed to limit the possibility of introducing COVID-19 into these facilities by recommending that only those who are essential to the care of residents can enter the facility.

- Staff in long-term care facilities are encouraged to take their own steps to protect the residents by monitoring their health twice a day, following routine infection control practices and wearing a mask for the duration of their shifts.

- This guidance also recommends that staff restrict their work to only one facility in order to prevent transmitting COVID-19 between facilities.

IF PRESSED ON NATIONAL VOLUNTEER RECRUITMENT CAMPAIGN …

- The Government of Canada is supporting provinces and territories by facilitating an inventory for recruitment and mobilization of skilled Canadians to provide surge capacity in the following key areas:
    - Case tracking and contact tracing;
    - Health system surge capacity; and
    - Case data collection and reporting.

- When the recruitment campaign ended on April 24, there were 53,769 volunteers registered in the inventory from

which provincial and territorial governments can draw upon as needed.

BACKGROUND

All Canadians have a role to play in helping to protect seniors and medically vulnerable people, who are at greatest risk of severe health complications from COVID-19. Many long-term care homes in Canada have been experiencing outbreaks of COVID-19 resulting in numerous deaths. The Public Health Agency of Canada has provided evidence-informed guidelines to help residents, seniors and health care workers in long-term care homes remain safe and healthy. These recommendations complement provincial and territorial public health efforts to prevent and control healthcare associated infections.

The Government of Canada is working to ensure healthcare workers have the personal protective equipment (PPE) and medical supplies they need. We are doing this through collaborative bulk procurement with the provinces and territories, building domestic production capacity, and identifying potential alternatives and ways to extend product life.

For seniors living in long-term care homes or assisted-living facilities, there is an even greater risk of infection and transmission of the virus owing to proximity. The movement of workers from one facility to another increases the risk of spread of infection, which ultimately puts seniors more at risk of contracting the virus. Therefore, the guidelines recommend identifying staff who work in more than one location and ensuring efforts are made to mitigate this where possible.

Volunteer Recruitment

As part of the comprehensive federal, provincial and territorial response to COVID-19, the Government of Canada is supporting provinces and territories by facilitating an inventory for recruitment and mobilization of skilled Canadians to provide surge capacity in key areas.

To assist provinces and territories, the Government of Canada is working with them to identify their needs. They have identified contact tracing and case recording as areas where they require assistance. Therefore, the skills required include case management, data collection and management, public outreach and telephone interview skills. Referrals from the inventory have also been shared with a number of jurisdictions for help in long-term care facilities. Other call-outs may be issued as jurisdictions identify new areas requiring assistance. As needs evolve, support in other areas requiring assistance will be provided.

The Government of Canada is reaching out in stages. The first stage was to enlist qualified federal public servants who are currently not in roles essential to ongoing federal work to assist in those jurisdictions feeling the most pressure. The second stage includes leveraging the inventory established as part of a COVID-19 Volunteer

Recruitment campaign, and reaching out to faculties of health, public health and science across the country to disseminate a call for interested individuals to register in the inventory. A third stage will involve reaching out to all health professional and health science associations for retirees or individuals currently not engaged in the COVID-19 response.

At the end of the recruitment campaign on April 24, there were more than 53,769 volunteers registered in the inventory. To date, referrals from the inventory have been shared with a number of jurisdictions, mostly to support long term care needs:

- 919 volunteers referred to Nova Scotia
- 1,118 volunteers referred to Quebec
- 24 volunteers referred to Northwest Territories
- Saskatchewan and Ontario are also in the process of seeking referrals

COVID-19 Medical Device Authorizations

SYNOPSIS

- As an emergency public health measure, the Interim Order for Medical Devices has allowed expedited access to COVID-19-related medical devices in Canada since March 18, 2020. Health Canada has also expedited the process for issuing Medical Devices Establishment Licences in the fight against COVID-19.

POTENTIAL QUESTION

- What is Health Canada doing to ensure Canada has access to the devices needed during the COVID-19 pandemic?

KEY MESSAGES

- Health Canada will continue to leverage all regulatory tools to ensure Canadians have access to safe and effective health products to fight COVID-19.

- To date, we have authorized 165 COVID-19 medical devices including:
    - 19 testing devices; and
    - 146 devices including personal protective equipment, decontamination devices for N95 respirators, ventilators, reagents, and swabs.

- A medical device is authorized after Health Canada completes a scientific assessment, ensuring that it meets requirements for safety and effectiveness.

- Health Canada also continues to expedite applications for medical device establishment licences for products such as masks, gowns, respirators and ventilators.

IF PRESSED… on mobilizing manufacturing capacity

- Health Canada is working closely with stakeholders who are scaling up or re-tooling their manufacturing capacity to

provide much needed tests or medical supplies.

- Across the federal government, we are mobilizing industry and providing support for research, market approval, manufacturing and supply.

- We are working closely with provinces and territories to ensure that they have the medical devices that they need.

IF PRESSED … on N95 respirators decontamination

- Extending the use of personal protective equipment through decontamination is one way of helping Canada meet supply needs.

- Health Canada is looking at ways to safely and effectively decontaminate single use N95 respirators.

- Health Canada has authorized devices to decontaminate N95 respirators under the Interim Order for Medical Devices.

IF PRESSED … on issue with KN95 respirators filtration performance and US FDA actions

- On May 7, US FDA issued a revised guidance indicating that certain respirators from China may not provide adequate respiratory protection.

- Health Canada will ensure that any companies that have distributed impacted products in Canada take appropriate action to stop selling these respirators, notify customers and relabel existing stock as “face masks” instead of “respirators”.

- Should additional safety concerns be identified, Health Canada will take appropriate action and inform Canadians,

as necessary.

IF PRESSED … on investigational testing and special access

- As of May 14, Health Canada has authorized:
  - two investigational testing authorizations, and three applications are under review; and
  - 38 Special Access Program applications for COVID-19 test kits, ultrasonic systems, endotracheal tubes and ventilators.

IF PRESSED… on exceptional import and sale of COVID-19 devices

- The Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purposes helps prevent or alleviate the effects of shortages related to COVID-19.

- Under this IO, as of May 14, Health Canada has added 51 medical devices to the List of Medical Devices for Exceptional Import and Sale.

- Importers with medical device establishment licences can import these medical devices after notifying Health Canada five days in advance.

BACKGROUND

Streamlined regulatory processes
The *Interim Order* for medical devices signed on March 18, 2020, allows expedited access to COVID-19-related medical devices, including diagnostic test kits. Health Canada can also consider approvals granted by foreign regulatory authorities in deciding whether to approve an application for the importation or sale of COVID-19-related medical devices. Use of existing devices, where the approved, intended use was not originally COVID-19-related, can also be expanded under this Interim Order.

The *Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in relation to COVID-19* helps prevent or alleviate the effects of shortages directly or indirectly related to COVID-19. Under the Interim Order, the Minister can permit the exceptional importation and sale of products that do not fully comply with Canadian requirements, but are manufactured according to comparable standards.

In recent weeks we have:

- addressed shortages by permitting the importation and sale of medical devices that are not approved in Canada, subject to certain requirements;
- facilitated access to products that may not fully meet current regulatory requirements, such as bilingual labelling, including personal protective equipment (such as masks and gowns), swabs, hand sanitizers, and hard-surface disinfectants
- amended the *Food and Drugs Act* and the *Patent Act* to support efforts to help prevent and alleviate shortages.

Health Canada continues to monitor and assess the safety, quality, and efficacy of all products allowed for import and sale under these special measures.

Decontamination of N95 respirators

Health Canada has authorized several decontamination systems: Stryker's Sterizone VP4 Sterilize,; ASP's Sterrad sterilization systems, Cleanworks's Clean Flow Healthcare Mini sterilizer; and Ecolab's Bioquell. The Department continues to evaluate new decontamination method applications submitted under the Interim Order for medical devices. A series of webinars was held with provincial and territorial healthcare partners, industry and healthcare professionals to provide information and guidance on the decontamination and re-use of N95 respirators.

COVID-19 Modelling

SYNOPSIS

- The Government of Canada models COVID-19 to look at the national picture. Modelling is used for planning purposes and is not a prediction of the future. The Government uses data and modelling to guide Canada's response to COVID-19, and to help inform public health and policy decisions to control Canada's COVID-19 epidemic. Some provincial and territorial public health authorities are also conducting their own modelling to determine the projected numbers of COVID-19 related cases and deaths to aid in their health system capacity planning.

POTENTIAL QUESTION

- Why are there differences in the COVID-19 models produced by the federal and provincial governments?

KEY MESSAGES

- Modelling is one of the tools that support planning our response to the COVID-19 epidemic. The Public Health Agency of Canada is conducting modelling studies that tell us the number of COVID-19 cases that could occur nationally depending on how effective we are in controlling the epidemic.

- Surveillance data indicate that the measures we are taking to slow the spread of COVID-19 are working but models and the experience of other countries suggest that we need to continue to be vigilant.

- The Public Health Agency of Canada works with the provinces and territories to share their data to inform the national COVID-19 model.

- We know that the COVID-19 epidemic varies across provinces and territories. There is alignment with the national level modelling results, but provincial models provide more specific projections for planning within each of the provinces.

IF PRESSED…

- Many factors contribute to regional differences in the epidemiology of COVID-19 in Canada.
- These include differences in the timing and patterns of community spread, changes in laboratory testing practices, and differing timelines for introduction of a range of public health measures.
- Notwithstanding these variables, we are observing slowed epidemic growth of COVID-19 and a levelling off of epidemic trajectories across Canada.

BACKGROUND

The COVID-19 epidemic in Canada comprises a number of different epidemics in the different provinces and territories. The Public Health Agency of Canada regularly uses data to update models for guiding public health and policy decisions.

While models are imperfect, they do allow experts to forecast infection and illness rates in the short-term, and to explore the effectiveness of different combinations and timing of public health measures to control the epidemic.

Nationally, Canada is using two modelling approaches: forecasting and dynamic models. Forecasting models use actual data on the cases being reported over time in Canada to estimate forward on how many new cases might be expected in the coming week. Dynamic models do not use actual real-life case data, yet are useful in that they permit a longer-term view based on our knowledge of how the virus behaves – this helps us to visualize potential epidemic growth scenarios and impacts of control measures that mitigate growth over time.

National Emergency Strategic Stockpile (NESS) Management

SYNOPSIS

- A recent media story highlighted the disposal of approximately 2 million expired masks and 440,000 expired gloves during the closure of the NESS warehouse in Regina in 2019. The masks and gloves had been purchased in 2009 and had passed the limit of five years for their use, as recommended by the manufacturer.

POTENTIAL QUESTIONS

- How can we be sure that the Government of Canada has the right system in place to have the necessary stockpile of health supplies to support Canada in pandemics and other emergencies? Why did the Public Health Agency of Canada dispose of N95 masks and gloves in 2019? Why did the Public Health Agency of Canada close federal stockpile locations?

KEY MESSAGES

- The Government of Canada is working closely with provinces and territories to procure the necessary health supplies to continue responding to the COVID-19 pandemic.

- The NESS was initially built on the assumption that provincial, territorial and local governments would be prepared for the most common emergencies. Consequently, it was designed to provide health emergency assets when local and provincial and territorial resources were exhausted.

- Jurisdictions have traditionally sourced Personal Protective Equipment (PPE) directly from known suppliers, and the NESS has historically only carried relatively small amounts.

- With the unprecedented nature of the current pandemic, the NESS quickly stepped into a much more active role in procurement and will continue with this expanded role as long as required. As we move forward, we will adjust, and lessons learned will inform the future of the NESS.

IF PRESSED ON INVENTORY MANAGEMENT…

- NESS reviews its stock regularly. Expired, obsolete, or unusable items are disposed of as per Treasury Board policy.

- PHAC continues to explore ways to optimize product life cycle management and minimize the disposal of expired stock.

IF PRESSED ON WAREHOUSE CLOSURES…

- A decision was made in 2013 to modernize and optimize our warehouse national footprint.

- In 2012, NESS supplies were held in 11 warehouses in 9 cities. In 2019, holdings were consolidated into 8 warehouses in 6 cities. In March 2020, an additional warehouse was leased in Ottawa, given the volume of supplies being donated to and purchased by the NESS as part of the federal government's COVID-19 response.

- When a warehouse is closed, usable supplies are moved to a new location, while obsolete and expired supplies are disposed of as per Treasury Board policy.

IF PRESSED ON FUNDING LEVEL

- Since 2012-13, the operating budget of the NESS, including salaries and operating has consistently been around $3 million annually.

- On top of the NESS core operational budget, there have been investments made for particular initiatives, stocks of supplies and medical countermeasures. Over the last 10 years, these investments have varied year over year, and have amounted to over $79 million.

BACKGROUND

Canada's National Emergency Strategic Stockpile (NESS) contains supplies that provinces and territories can request in emergencies, such as infectious disease outbreaks, natural disasters and other public health events, when their own resources are not enough. These supplies include a variety of items such as: medical equipment and supplies; pharmaceuticals; and social service supplies, such as beds and blankets.

NESS Mandate

The fundamental assumption underpinning emergency management is that provincial, territorial and local governments are prepared to a reasonable extent for the most common emergencies.

As such, the federal government's role in stockpiling emergency health assets is twofold:

- It provides surge capacity to provinces and territories at their request when their own resources are not sufficient; and
- It is the sole provider of certain assets required for rare public health emergencies, for example, costly and rarely used vaccines or antidotes.

NESS Deployments

Over the past decade, the NESS has deployed assets to assist with a range of events and emergencies, including the 2010 Olympics, 2013 Alberta Floods, Operation Syrian Refugees, the Fort McMurray wildfires, and the 2018 G7 Summit in Quebec. The NESS has also made international donations in support of the West African Ebola Outbreak, Hurricane Harvey, and to China during the current COVID-19 outbreak.

NESS Footprint

NESS facilities consist of a central depot in the National Capital Region and warehouses strategically located across Canada. In recent years, the NESS moved from nine warehouse locations across Canada to six. An independent assessment indicated that the six strategic locations would maintain the NESS' role as timely surge support. As of 2019, all NESS holdings were consolidated in eight warehouses in six locations. In March 2020, an additional warehouse was leased in Ottawa, given the volume of supplies being donated to and purchased by the NESS as part of the federal government's COVID-19 response.

Regina Closure

In 2019, approximately 2 million expired masks and 440,000 expired gloves were disposed of during the closure of the NESS warehouse in Regina. The masks and gloves had been purchased in 2009 and had surpassed the limit of five years for their use, as recommended by the manufacturer.

Modernization of the Patented Medicine Prices Review Board (PMPRB)

SYNOPSIS

- On August 9, 2019, the Government of Canada announced amendments to the *Patented Medicines Regulations* to provide the PMPRB with the tools and information needed to protect Canadians from excessive medicine prices.
- These amendments will result in lower prices for patented medicines in Canada, which are currently among the highest in the world. It is estimated that the amendments will result in savings for governments and private payers of approximately $13.2 billion over 10 years.

- The brand-name pharmaceutical industry and some patient groups have expressed concerns that the amendments could result in reduced pharmaceutical investments and reduced access to medicines. On November 21, 2019, the PMPRB launched consultations on draft guidelines to operationalize the amendments. The PMPRB is making revisions to the draft guidelines in response to the feedback it has received.

POTENTIAL QUESTION

- Will the amendments to the *Patented Medicines Regulations* reduce access to new medicines in Canada?

KEY MESSAGES

- Our Government is committed to improving Canadians' access to, and the affordability of, necessary prescription medicines.

- These regulatory amendments will help Canadians to afford the prescription medicines they need.

- Canada will continue to be an important market for new medicines. In fact, many countries with much lower medicine prices gain access to new medicines in the same time frame, or even faster than Canada.

IF PRESSED ON IMPACT ON PHARMACEUTICAL INVESTMENTS IN CANADA

- Other countries benefit from significant pharmaceutical

industry investments, while having considerably lower prices than Canada. For example, Belgium receives four times more investment dollars than Canada despite prices being 20% less.

- Our Government recognizes the importance of the life sciences sector to the Canadian economy, innovation, and quality of life. We remain committed to strengthening the innovation ecosystem in Canada.
- Our Government has also streamlined regulatory processes supporting faster access to the Canadian market for products, and significantly strengthened intellectual property protection in recent trade agreements.

If Pressed on concerns with the PMPRB Guidelines Consultation Process

- The PMPRB has published all written submissions it received during its consultation with stakeholders and the public on the draft Guidelines.

- The PMPRB is making revisions to the draft Guidelines in response to the feedback it has received.

If Pressed on Delaying the Coming-into-Force of the Regulatory Amendments

- Our Government remains committed to improving access to, and affordability Government of, necessary prescription medicines.

- Our Government will continue to assess the COVID-19 situation and will adjust the course of action, as needed.

If Pressed on Concerns with Impacts on Revenue to Industry and Drug Access

- Even with lower prices, revenues from patented drug sales are expected to continue growing over the next ten years in Canada.

- Drug companies are expected to launch their products in Canada at the same rate as they do today. In fact, industry sponsored studies have found that many countries with lower prices than Canada have faster access to new medicines, including the Netherlands, Sweden, the United Kingdom and Norway.

- Our Government has also streamlined regulatory processes supporting faster access to the Canadian market for products.

BACKGROUND

- The prices of patented medicines in Canada are regulated to be 'non-excessive' by the Patented Medicine Prices Review Board (PMPRB), a quasi-judicial federal agency created in 1987 under the *Patent Act*.

- On May 16, 2017, former Minister Philpott announced the Government of Canada's intention to modernize the PMPRB's regulatory framework through proposed amendments to the *Patented Medicines Regulations*.

- On August 9, 2019, the Government of Canada announced the final amendments which were then published on August 21, 2019 in *Canada Gazette, Part II*. The amendments are scheduled to take effect on July 1, 2020.

- The most significant reforms to the regulations since their introduction in 1987, these amendments lay the groundwork for national pharmacare by giving the PMPRB the tools to protect Canadians from excessive prices and making patented medicines more affordable.

- The amendments include three main elements:

    - Providing the PMPRB with **additional price regulatory factors** that consider the price of patented medicines relative to their value and impact on the Canadian health care system;
    - **Requiring patentees to report Canadian price information** that is net of all adjustments (e.g. rebates, discounts), so that the PMPRB is informed of actual market prices in Canada; and,
    - **Revising the "basket" of comparator countries**, to include markets with comparable consumer protection priorities, economic wealth and medicine markets as Canada. Specifically, the list of countries has been updated to remove the U.S. and Switzerland, and to add Australia, Belgium, Japan, the Netherlands, Norway, and Spain.

- The Cost Benefit Analysis that accompanies these amendments estimates 10-year savings to Canadian consumers of $13.2B ($8.8B net present value [NPV]). This amounts to about a 10.8% reduction of patented medicine revenues in Canada by year ten after implementation.

- An industry sponsored impact analysis of the PMPRB's draft Guidelines published on February 12, 2020 claims that the the draft Guideline changes will have an estimated impact to industry revenues of up to $41.8 B NPV over 10 years.

- On August 23, 2019, five brand-name pharmaceutical firms (the Canadian subsidiaries of Merck, Janssen, Bayer, Boehringer Ingelheim, and Servier) filed a constitutional challenge against the amendments in the *Superior Court of Quebec*, arguing that the federal government does not have the constitutional authority to regulate pharmaceutical pricing, claiming that this authority rests within provincial jurisdiction.

- On September 2, 2019, Innovative Medicines Canada (IMC), which represents Canada's brand-name pharmaceutical industry, and sixteen Canadian subsidiaries of brand-name pharmaceutical companies, filed an application for a judicial review of the amendments by the *Federal Court of Canada*.

- On November 21, 2019, the PMPRB launched consultations on its accompanying Guidelines, which will define operational implementation of the amendments, including specific price tests that will be applied. The PMPRB is making revisions to the draft Guidelines in response to the feedback it has received.

Guidance on the Use of Personal Protective Equipment

SYNOPSIS

- The Public Health Agency of Canada continues to work closely with Provinces and Territories to provide infection prevention and control guidance for a variety of health care settings, including long-term care facilities. The Agency has also provided advice to workplaces and businesses on how to reduce the risk of COVID-19 infections in the workplace, which may include the use of Personal Protective Equipment (PPE).

POTENTIAL QUESTION

- Why isn't the Government recommending PPE, including N-95 masks, for all front-line workers?

KEY MESSAGES

- The appropriate use of personal protective equipment or PPE is one component of infection prevention and control.

- Working closely with provinces and territories, the Public Health Agency of Canada has developed evidence-based guidance on infection prevention and control for acute care and long-term care settings, as well as home care settings, including the appropriate use of PPE.

- The Agency has also provided advice to workplaces and businesses outside the health sector on how to reduce the risk of COVID-19 infections in the workplace, which may include the use of PPE in some workplaces.

- The Government of Canada continues to emphasize that, physical distancing, hand hygiene and coughing or sneezing into your arm or sleeve are the most effective ways to prevent transmission of the COVID-19 virus.

- Wearing a non-medical mask or face covering when you cannot maintain a 2-metre physical distance from others, is

recommended as an additional measure you can take to prevent further transmission of the virus to others.

- Non-medical masks for face coverings are not PPE, but they are a way to prevent spread of the COVID-19 virus to others.

IF PRESSED ON USE ON NON-MEDICAL MASKS FOR HEALTHCARE WORKERS:

- Healthcare workers need medical masks, including surgical, medical procedure masks and respirators such as N95 masks.

IF PRESSED ON WHY POSITION ON MASK USE BY THE GENERAL PUBLIC HAS CHANGED:

- Canadian public health guidance related to COVID-19 has been changing as the evidence base and our understanding of COVID-19 rapidly evolves. We are continually looking at the evidence as it is being produced and working with our partners across the country and around the world to learn more.

- Wearing a non-medical mask is an additional measure we can take to protect others, particularly when physical distancing is not possible in public settings (e.g., grocery shopping, in close settings such as public transit).

BACKGROUND

Canadian public health guidance related to COVID-19 has been adjusted as the evidence base and our understanding of COVID-19 evolves.

Healthcare workers need medical masks, including surgical, medical procedure masks and respirators such as N95 respirators. It is extremely important that we have enough supply of medical masks for healthcare workers where it is urgently needed for medical procedures and to care for individuals who have COVID-19.

Personal Protective Equipment (*PPE) in healthcare settings*

The Public Health Agency of Canada's (PHAC) interim guidance on infection prevention and control in acute healthcare settings was updated to ensure we provide comprehensive recommendations based on the best available evidence. The guidance emphasizes the need for environmental and administrative controls in facilities to protect healthcare workers and patients, as well as the fundamental importance of training in the use of PPE. It indicates that droplet and contact precautions are appropriate for most patient care. Aerosol-generating medical procedures require N95 respirators along with other PPE. The guidance remains interim as it is subject to revision based on new scientific evidence.

In new technical guidance, PHAC recommends that all healthcare workers in acute care hospitals wear medical masks and eye protection/face shields for the full duration of a shift in acute healthcare settings. Wearing a medical mask throughout the duration of a shift is an important measure to help reduce the risk of transmission from a healthcare worker to a patient. This recommendation applies to healthcare workers who are in direct contact with patients, as well as environmental services staff working in patient care areas. In addition, any healthcare workers who have COVID-19-related symptoms should immediately go home and only return to work following the advice of their local public health units.

Healthcare workers should refer to their province or territory's guidance, as well as facility policies on the use of masks, eye protection, and other PPE, including any PPE conservation strategies that are in place.

Public use of non-medical face coverings

Wearing a non-medical mask or face covering in the community has not been proven to protect the person wearing it. However, with the emerging information regarding pre-symptomatic and asymptomatic transmission, and the goal to stop the spread of COVID-19, wearing a non-medical mask is recommended to protect others when physical distancing is not possible in public settings (e.g., grocery shopping, in close settings such as public transit).

Wearing a non-medical mask in the community does not mean you should stop practicing the public health measures that are known to work, such as physical distancing. All of the recommendations regarding physical distancing, and hand hygiene are based on what is known to work best to protect from infection. Non-medical masks will not prevent COVID-19 spread without consistent and strict adherence to good hygiene and public health measures, including frequent handwashing and physical distancing.

PPE may be an important component of infection prevention efforts in non-healthcare workplaces. However, the choice and use of PPE is based on occupational health and safety advice specific to the job and workplace. PHAC provides information to help employers and employees determine what infection prevention and control measures, which might include PPE, are necessary in their workplaces.

Procurement of Personal Protective Equipment

SYNOPSIS

- The global COVID-19 pandemic has resulted in an unprecedented shortage in personal protective equipment (PPE) and other medical supplies. To support the needs of Canada's frontline healthcare response, the Government of Canada, in coordination with the provinces and territories, launched a significant bulk procurement, engaging a diverse number of new suppliers and manufacturers both internationally and through the Government of Canada's domestic "Call to Action" to increase domestic production.

POTENTIAL QUESTIONS

- What is the Government of Canada doing to address shortages of PPE and other medical supplies?
- How is the Public Health Agency of Canada equipping frontline healthcare workers with the PPE required to protect their health and mitigate the spread of COVID-19?

KEY MESSAGES

- The Government of Canada is continuously working to secure critical personal protective equipment (PPE) supplies and medical equipment, and to expedite delivery of supplies to our frontline healthcare workers.

- Canada is receiving PPE shipments, and is working rapidly to allocate the supplies to the provinces and territories as per an approach agreed upon by federal-provincial-territorial Ministers of Health.

- The Public Health Agency of Canada is also deploying PPE and ventilators from its National Emergency Strategic Stockpile in response to urgent requests for assistance from provinces and territories.

- In addition, the Government of Canada is also receiving offers of donations from international and domestic organizations via the donations portal on the Government of

Canada COVID-19 website.

IF PRESSED ON HOW THE GOVERNMENT OF CANADA IS ADDRESSING THE GLOBAL SHORTAGE OF PPE SUPPLIES …

- The Government of Canada, through the leadership of Public Services and Procurement Canada (PSPC), and Innovation Science and Economic Development Canada, has galvanized Canadian industry to increase domestic manufacturing capacity, including re-tooling facilities to produce PPE and medical equipment and supplies, including ventilators and rapid testing kits.

- PSPC has confirmed contracts for a variety of PPE and other medical supplies including over 130 million N95 respirators and equivalents (e.g., KN95 respirators), 315 million surgical masks, 130 million protective gowns, and 30 thousand ventilators.

- The Public Health Agency of Canada is receiving staggered delivery of shipments, and to date, has allocated approximately 2 million N95 respirators and equivalents (e.g., KN95 respirators), 30 million surgical masks, 11 million pairs of nitrile gloves, and 4 million face shields to provinces and territories, and more is expected to arrive and be distributed in the coming days.

- Additionally, the Public Health Agency of Canada has also distributed to provinces and territories donations of over 450 thousand N95 and equivalent respirators, 450 thousand surgical masks, and 400 thousand pairs of gloves.

IF PRESSED ON HOW THE GOVERNMENT OF CANADA IS ENSURING THE QUALITY OF PPE SUPPLIES …

- Due to intense global competition for PPE and other medical supplies, countries have needed to engage with a diverse number of new suppliers and manufacturers.

- As a result, PPE and medical supplies received by the Public Health Agency of Canada, whether procured internationally or domestically, are verified to meet the technical specifications for healthcare settings for COVID-19 prior to distribution to provinces and territories. The process is the same for donations.

- For example, a KN95 respirator undergoes visual inspection to verify for defects in design and construction, and is tested to confirm performance expectations. Surgical masks undergo a fluid resistance and a breathing resistance test.

- Supplies that do not meet specifications are subsequently assessed for potential use in non-healthcare settings.

- To date, a large majority of the products received by the Government of Canada have met the technical specifications for healthcare settings for COVID-19 response; however, as a result the Public Health Agency of Canada's stringent review process, approximately 9.9 million KN95 respirators were assessed as not meeting the technical specifications.

IF PRESSED ON THE SUPPLIER OF KN95 RESPIRATORS SOURCED FROM CHINA….

- Due to ongoing quality issues, the Government of Canada has suspended shipments from this specific supplier and is pursuing the appropriate recourse actions.

IF PRESSED ON THE USE OF KN95 RESPIRATORS….

- Health Canada, as the regulator for medical devices in Canada, traditionally accepts the U.S. National Institute for Occupational Safety and Health (NIOSH) certification as an appropriate quality standard for N95 respirators used by health care providers.

- In support of COVID-19 response, to expand the availability of these types of respirators for sale or import in Canada, Health Canada is also accepting equivalent alternate standards used in other countries such as the KN95 and FFP2 respirators (including those with head straps or ear loops).

- This is in alignment with the United States Food and Drug Administration's guidance that was recently revised on May 7, 2020.

IF PRESSED ON REUSE AND STERILIZATION OF N95 RESPIRATORS….

- Health Canada has already authorized certain machines to decontaminate N95 respirators under the Interim Order for Medical Devices.

- The Public Health Agency of Canada has procured 82 sterilization devices with Stryker Canada. Of these, 81 units have been allocated to provinces and territories based on their needs, and one unit allocated to the National Research Council.

- These units will provide a total additional national capacity to reprocess approximately 275 thousand N95 respirators a week.

IF PRESSED ON HOW THE GOVERNMENT OF CANADA IS ADDRESSING THE EXPEDITED DELIVERIES OF PPE SUPPLIES TO PROVINCES AND TERRITORIES…

- The Government of Canada awarded a contract to Amazon to facilitate the logistics of distributing PPE and supplies to support the COVID-19 response.

- Amazon is working directly with the Canadian Armed Forces and Canada Post to manage warehousing, and Purolator, to deliver the products to provincial and territorial health authorities, across the country, for the frontline healthcare response.

- In addition to the Amazon contract, the Government of Canada has solicited interest from companies to provide logistic services to help receive and distribute the extraordinary volume of orders of PPE across Canada in a timely manner. We are in the process of reviewing proposals.

IF PRESSED ON UNDERSTANDING THE DEMAND FOR PPE TO SUPPORT THE REOPENING OF THE ECONOMY

- Workplace health and safety measures to support the economic reopening will include a range of practices and protocols based on public health advice, which may not necessarily include the use of PPE.

- The **Canadian Centre for Occupations Health and Safety,** governed by federal, provincial and territorial governments, as well as employers and unions, is working with sectors and partners to develop tailored occupational health and safety guidelines for various economic sectors based on public health guidance.

- The federal government is engaging regularly with provinces and territories, business stakeholders and industry associations in all sectors of the economy to better understand their needs and reopening strategies. We are also working with experts to better understand and assess the PPE needs of Canada's society and economy, based on the most up-to-date public health advice.

BACKGROUND

To address the procurement and distribution needs in support of frontline health care response to COVID-19, the Government of Canada deployed a multi-pronged approach of interdepartmental coordination that includes the Public Health Agency of Canada (PHAC), Health Canada, National Research Council (NRC), Global Affairs Canada, the Department of National Defense, Public Services and Procurement Canada (PSPC), and Innovation, Science and Economic Development Canada (ISED).

Federal/Provincial/Territorial (F/P/T) Bulk Procurement

ISED and PSPC continue to galvanize Canadian industries to increase domestic manufacturing capacity, including re-tooling facilities to produce equipment and supplies including portable ventilators, surgical masks, and rapid testing kits.

Throughout this process, PHAC, Health Canada and the NRC are playing a critical role, conducting technical reviews to verify that the products meet the Government of Canada technical specifications for COVID-19 as available on the PSPC's buy and sell website.

Urgent need is further facilitated by Health Canada, expediting regulatory approvals of product reviews and licenses through the Interim Order for Medical Devices signed by the Minister of Health on March 18, 2020. As the regulatory authority, Health Canada also continues to monitor the safety, quality, and efficacy of all medical devices for use in the diagnosis, treatment, mitigation and prevention of COVID-19.

Health Canada also continues to actively engage the medical device industry as well as provinces and territories to monitor for any signals of supply disruptions in Canada. Manufacturers and importers are also now required to notify the Minister of Health of medical device shortages of devices considered critical. Health Canada is closely monitoring the supply of any potential treatments for COVID-19 and working with companies to help ensure continued supply in Canada.

PPE Testing and Quality Assessments

Sourcing PPE from new suppliers (both domestically and abroad) is challenging. Once products are delivered to PHAC they must undergo quality verification before

distribution to provinces and territories (P/Ts). This process is supported by testing capacity within the NRC.

Test results are also used to inform future procurements. PSPC and PHAC work with suppliers to address issues at the source or avoid purchasing from unreliable suppliers in the future once issues are identified.

KN95 Respirators

On May 7, the United States Food and Drug Administration (FDA) issued revised guidance, indicating that certain filtering facepiece respirators from China may not provide adequate respiratory protection. The FDA still considers KN95 respirators medical devices equivalent to N95s, but authorization for KN95 respirators will require additional validation and review by FDA.

Health Canada Medical Devices has subsequently updated its regulatory guidance, *Optimizing the use of masks and respirators during the COVID-19 outbreak*, and issued a recall for over 60 companies as identified on the U.S. National Institute for Occupational Safety and Health (NIOSH) website. Similar to the FDA, Health Canada will continue to authorize KN95 medical respirators in Canada through the Interim Order for Medical Devices pathway but as of May 7, Health Canada will request test results from independent testing facilities to validate the effectiveness of these respirators.

On May 8, CBC reported that of the approximately 11 million KN95 respirators received by the Government of Canada and sourced by a Montreal-based supplier out of China, 8 million did not meet the Government of Canada's technical specifications for healthcare settings for COVID-19 response, 1 million met specifications, and 1.6 million were pending testing results. This number not meeting specifications has since increased to approximately 9.9 million as results are received for the remaining 80 thousand. PSPC has suspended shipments from this supplier and is pursuing the appropriate recourse on behalf of the Public Health Agency of Canada.

Reuse and sterilization

Due to increased demand of N95 respirators, PHAC has also been working closely with Health Canada, the NRC, and ISED on identifying companies with experience manufacturing the equipment used in reprocessing in order to authorize these technologies to safely and effectively reprocess N95 respirators.

Health Canada issued its first authorization under the Interim Order for Medical Devices to Stryker for its Sterizone VP4 on April 5, 2020, and has since authorized additional devices including Sterrad and Steris sterilizers that are widely available and distributed across Canadian hospitals.

F/P/T Allocation and Distribution

As agreed to by F/P/T Ministers of Health, PHAC is allocating procured PPE using an 80/20 formula—80% is distributed to P/Ts on a per capita basis and the remaining 20% replenishes the inventory of the National Emergency Strategic Stockpile (NESS),

including a 2% allocation to Indigenous Services Canada. The purpose of the NESS is to provide surge capacity to P/Ts when their own resources are not sufficient.

To support distribution, PSPC awarded a contract with Amazon valued at up to $5 million. This contract is primarily for use of the Amazon interface to push out the allocation of supplies to P/Ts. Amazon is working with the Canadian Armed Forces, Canada Post and Purolator.

On May 4, to facilitate the intake and distribution of large volumes of PPE and medical supplies, PSPC posted a Request for Proposal (RFP) notice on the PSPC Buy and Sell website to solicit interest from major logistics service providers. This new expression of interest relates to a multimodal logistics solution, going beyond distribution and includes warehousing, customs documentation and brokerage, and inventory management. The RFP closed on May 11, and the review of the expressions of interest is now underway.

Canadian Food Inspection Agency (CFIA) Inspectors and COVID-19

SYNOPSIS

- "The union representing Canada's food inspectors says that Ottawa is threatening disciplinary action against employees who refuse to be reassigned to work at COVID-19-infected meat plants." *(CBC News, May 11, 2020)*

POTENTIAL QUESTION

- Why is this Government standing by while its food inspectors are being infected with COVID-19? Why is this Government not protecting its employees from unsafe working conditions?

KEY MESSAGES

- The Canadian Food Inspection Agency is committed to protecting the health and safety of its employees while maintaining critical inspection services.

- Canadian Food Inspection Agency employees follow the health and safety guidance issued by the Public Health Agency of Canada, Health Canada, and local public health authorities. They also follow protocols put in place at the establishments in which they work.

- Masks and face shields are made available to all Canadian Food Inspection Agency meat inspectors.

- When cases of COVID-19 occur in a food processing establishment, the Canadian Food Inspection Agency works with local public health authorities to determine the level of risk of exposure for CFIA employees, and their need for self-isolation and/or referral to health services for testing.

IF PRESSED ON THE PRESSURES PUT ON THE WORKFORCE

- The Canadian Food Inspection Agency (CFIA) is hiring new inspectors and veterinarians and temporarily bringing back

CFIA employees who have recently retired. To date, CFIA has hired 70 inspectors and 20 veterinarians.

- The Canadian Food Inspection Agency is exploring work agreements with provincial and territorial inspection authorities. Resource-sharing agreements are already in place with Ontario and Alberta, and others are in progress.

- The Canadian Food Inspection Agency is reassigning staff to areas of high priority and providing them with necessary training and tools to properly execute food safety inspections.

IF PRESSED ON EMPLOYEE MENTAL HEALTH

- Employees are encouraged to consult numerous resources available to them and their families, such as the Employee and Family Assistance Program, the HOPE Peer Support Program, and the Centre of Expertise on Mental Health in the Workplace.

BACKGROUND

In any establishment where there is a COVID-positive case, Canadian Food Inspection Agency (CFIA) employees are asked to immediately 1) notify their manager, 2) prepare to leave the workplace, and 3) self-isolate and self-monitor for symptoms while they wait on the provincial/local public health authorities to assess the situation and provide additional instructions.

Only in cases where a CFIA employee's risk of exposure is determined to have been low by provincial/local public health authorities (example: CFIA employees were not present in the part of the plant where the COVID-positive employees were working) will they be permitted to safely return to work at the establishment.

CFIA looks to provincial/local public health authorities to perform a contact investigation and provide a risk assessment of any employees that should move to (continue to) self-isolate.

CFIA has issued guidance and instructions to its employees relating to prevention and wellness. Employees have been instructed to self-assess their own condition on a daily

basis before reporting to work and to be diligent in monitoring their own personal condition in order to minimize any risks to their health and that of others in the establishments they report to.

CFIA employees (including inspectors) who are exhibiting any signs or symptoms of illness have been advised to contact their managers and stay home.

To further protect the health and safety of its employees, CFIA has also provided specific written guidance and instructions (posted online) to meat slaughter and processing establishments across the country on prevention measures and response protocols when there are suspected and confirmed cases of the virus amongst plant employees.

CFIA has asked all establishments to be prepared to share their response plans in the case of confirmed or suspected positive cases of COVID-19 in an effort to trace back exposure risks and determine needed next steps.

CFIA expects that each third party establishment operator is complying with the advice and guidance provided by the Public Health Agency of Canada (PHAC), as well as that from local Public Health Authorities in addressing the COVID-19 outbreak.

The decision to suspend operations is the result of an establishment’s cooperation with directions or recommendations from local and provincial health authorities, and CFIA does not have jurisdiction in that area. This includes the assessment of mitigation and control measures the determination on workplace conditions (presenting a high risk for infection) or the assessment.

COVID-19 Testing Reagent Procurement

SYNOPSIS

- The Public Health Agency of Canada works closely with provincial and territorial laboratories to conduct laboratory testing for the virus that causes COVID-19. As of May 17, 2020, 1,296,000 people in Canada were tested for COVID-19. Over the last week, an average of 28,451 individuals were tested a day in Canada. Global shortages of testing reagents have resulted in the Government of Canada implementing an aggressive procurement strategy to supply reagent to meet current and future demand.

POTENTIAL QUESTION

- Has the Government of Canada procured a sufficient supply of reagents to meet current and future demand for COVID-19 testing?

KEY MESSAGES

- The Government of Canada is taking action on all fronts to mitigate the impact of the global shortage of testing reagent on Canada's testing capacity.

- We are procuring testing supplies both domestically and abroad. We are investing to build sustainable capacity in Canada.

- Public-private collaborations are helping us meet reagent needs. For example, a testing reagent developed by the National Microbiology Laboratory is being produced by LuminUltra, a New Brunswick-based company that will supply extraction reagent for 500,000 tests a week for the next year.

- These efforts will help ensure Canadians have access to the laboratory testing they need in response to the serious health threat posed by COVID-19.

IF PRESSED ON CAPACITY TO TEST MORE CANADIANS …

- Canada has and will continue to test symptomatic individuals, as part of our evidence-based approach, while considering the evolving science on other testing scenarios. As the science evolves, our approach will keep pace, and policies and protocols will be updated accordingly.

- As new products or platforms become available and approved for use in Canada, the Public Health Agency of Canada will work with provincial public health laboratories to acquire new products and platforms to augment existing testing capacity.

IF PRESSED ON WHAT OTHER STEPS CANADA HAS TAKEN TO ENSURE THERE IS SUFFICENT REAGENTS FOR TESTING…

- The Public Health Agency of Canada has also worked closely with provincial public health laboratories to provide access to different test platforms. This enables provincial public health laboratories to leverage other platforms to mitigate reagent shortages.

- The Government of Canada is investigating other in-Canada options for the production of reagents for testing purposes.

BACKGROUND

The Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) is working in close collaboration with provincial and territorial public health laboratories to perform diagnostic testing for the virus that causes COVID-19.

As of May 17, 2020, 1,296,000 patients in Canada were tested for COVID-19. Testing in Canada is focused on people who present with symptoms consistent with COVID-19. Canada's testing strategies continue to evolve as the outbreak of COVID-19 spreads. PHAC works with provincial and territorial partners on a national testing strategy that will help us maximize the impact of our testing resources and delay the spread of COVID-19 in high-risk settings, such as hospitals and long-term care facilities.

Reagents are chemicals that are used to extract, amplify, and/or detect the virus. Internationally, there has been a shortage of reagents to support laboratory testing.

Cancellation of CIHR Spring Grant Competition

SYNOPSIS

- COVID-19 continues to draw public, political and media attention with most recent scrutiny on funding decisions for non-COVID-19 and COVID-19 research, notably CIHR's Rapid Research Response and the Spring 2020 Project Grant Competition.

POTENTIAL QUESTIONS

- Why did CIHR cancel its Spring 2020 Project Grant Competition?
- How were Covid-19 research grants selected and approved for funding?

KEY MESSAGES

Spring 2020 Project Grant Competition

- I want to assure you that CIHR did not take the decision lightly to postpone the Spring 2020 Project Grant competition and consulted closely with the research community when considering options in the face of the COVID-19 pandemic.
- In March, it became clear that asking hundreds of researchers to travel to Ottawa to review thousands of applications was not the right thing to do. Physical distancing had to be respected and researchers were preoccupied with the closing of their labs across Canada.
- This is why, instead of launching the Spring Competition, CIHR decided to act quickly to support the research community in this difficult time and granted extensions to researchers who currently hold a CIHR grant.
- No funding from the Spring Competition was used in the funding of research related to COVID-19; all remaining funds will be reinvested in future Project Grant Competitions.

Rapid Research Response to COVID-19

- As you know, research is a critical component of both domestic and international efforts to address COVID-19- and the Canadian research community has risen to the challenge.

- With respect to CIHR's COVID-19 Rapid Research Response, standard processes were expedited though, as per usual, each application was subjected to rigorous peer review.
- And I want to thank the research community for responding in record time to identify the most promising research projects to fight this virus. To keep the COVID-19 funding competition moving quickly, many researchers volunteered their time and effort to peer review the applications CIHR received.
- As such, I have confidence that the research funded through CIHR's Rapid Research Response to COVID-19 represents projects that have the greatest potential to help Canada address this public health crisis.

BACKGROUND

Why did CIHR cancel the Spring 2020 Grant Competition?

CIHR made the decision to cancel the spring competition following consultations with its partners at the U-15, Universities Canada, HealthCareCAN, and the University Delegates Network, among others. CIHR made this decision for the following key reasons:

- Virtual review is currently not feasible. With the situation continuing to evolve, we could not be certain about the reliability of the critical infrastructure required to deliver a high-quality competition.
- Many of our peer reviewers are clinician scientists and health professionals who have heeded the call to lend a hand as resources are stretched thin on the ground. It would have been irresponsible for CIHR to divert their attention at this critical time of need.
- With researchers following public health advice to curtail travel and self-isolate, carrying out face-to-face peer review for the Spring 2020 Project Grant competition would have been contrary to all public health advice.
- Our pool of peer reviewers is made up of many professors who are now faced with the task of modifying their courses and final exams to switch to delivering them in an online format. This shift will entail a great deal of work, and we do not want to add to their burden.
- Finally, we know that, just as we all are, the researchers who would normally peer review for this competition are occupied with looking after the health and safety of their families and loved ones, as well as additional care-giving roles, which need to be their top priority.

How will the funds from the Spring 2020 Project Grant competition be redistributed to the research community?

CIHR had planned to invest $275M in this competition and, as with all competitions, this investment would have been made over multiple fiscal years. Similar to the measures taken when the Spring 2017 Project Grant competition was delayed, CIHR will use some of the funds that were planned for the Spring 2020 competition to financially extend all existing investigator-initiated research grants scheduled to expire between June 30, 2020 and March 30, 2021, for one year. This extension applies only to Nominated Principal Applicants (NPAs) with a grant expiring within the date range who applied to the Spring 2020 competition, as these applicants were applying for a grant to replace one that was expiring. Additionally, CIHR will financially extend all bridge grants provided to NPAs in the Fall 2019 Project Grant competition who also applied to the Spring 2020 Project Grant competition.

These measures are anticipated to cost $31M and will be taken from the $275M that was planned for the Spring 2020 Project Grant competition. The remaining amount (approximately $244M) will be allocated to the Project Grants program to help mitigate the effects of increased application pressures for future competitions. In addition, CIHR's emergency funding for COVID-19 research was not taken from the Project Grant envelope. It is specifically a component of the Government of Canada response to this crisis and is new money to CIHR (i.e., not from our base budget). The specific budgets available for those future Project Grant competitions will be announced when the next funding opportunity launches this summer.

COVID-19 Rapid Research Response at a glance:
Canada's research community is contributing to the global response to COVID-19 and is well-poised for significant discoveries.

The Canadian Institutes of Health Research (CIHR), as Canada's health research funding agency, has moved at an unprecedented pace to mobilize the research community and deliver programs while maintaining rigour in funding the most outstanding research.

Canadians will benefit from this research through enhanced prevention, detection, and treatment options for COVID-19 as well as an evidence base on which to inform effective social and public health policy responses.

To mobilize Canada's research community, CIHR and its federal and provincial partners accelerated their timelines to launch the initial two COVID-19 Rapid Research Response competitions, totaling $54.3M that translated into 99 research grants.

The medical countermeasures funding accounts for 52 of the 99 projects funded for a total of $36.5M, including research into vaccines, diagnostics, transmission dynamics, therapeutics and clinical management. The social and policy countermeasures funding

accounts for 47 of the 99 projects funded for a total of $17.7M, including research into coordination, governance, and logistics; public health response and its impact; social dynamics, communications, and trust; and, transmission dynamics.

- CIHR used the priorities identified by the WHO and GloPID-R to inform this initiative.
- Hundreds of researchers volunteered their expertise to peer review the applications received so that the funding competition could be completed in record time.
- Grants funded for two-year terms and with an agreement that data and findings would be openly shared.

On April 23, 2020, CIHR was approved for an additional $114.9M in funding through the Prime Minister's announcement of new support for countermeasures against COVID-19. Building on the initial investment of $54.3M to support 99 research projects on COVID-19, the majority of the new investment of will enable researchers to accelerate the development, testing and implementation of medical and social countermeasures to mitigate the rapid spread of COVID-19 and its negative consequences on people, communities, and health systems.

COVID-19 Immunity Task Force

SYNOPSIS

- The Government of Canada has established a COVID-19 Immunity Task Force to oversee the coordination of a series of country-wide blood test surveys that will tell us how widely the virus has spread in Canada and provide reliable estimates of potential immunity and vulnerabilities in Canadian populations. Over the next two years, at least one million blood samples will be collected and tested for the presence of SARS-CoV-2 antibodies. Knowledge of the level of immunity in the general population, and in vulnerable populations such as the elderly and healthcare workers, will guide important public health decisions and immunization strategies once a vaccine becomes available.

POTENTIAL QUESTIONS

- Who will be part of the COVID-19 Immunity Task Force Leadership Group?
- How will privacy and confidentiality concerns regarding the results of these blood tests be addressed?

KEY MESSAGES

- The COVID-19 Immunity Task Force will mobilize Canada's top public health professionals and scientists to undertake coordinated studies on the extent of COVID-19 infection in the population.

- The Government of Canada has approved funding of the COVID-19 Immunity Taskforce and serological surveillance for $300 million over 2 years.

- Understanding the potential immunity to COVID-19 in specific high-risk groups like the elderly or health-care workers will give us information on the best strategies to re-open the economy while guarding against a second wave of infection.

- It will contribute to global data collection on immunity to COVID-19 to accelerate efforts to understand this virus and how to fight it.

IF PRESSED ON COVID-19 IMMUNITY TASK FORCE

- The composition of the COVID-19 Immunity Task Force will reflect key agencies of the Government of Canada and include representation from several provincial Ministries of Health as well as experts from across Canada in matters related to serologic surveillance, immunology, virology, infectious diseases, public health, and clinical medicine.

- The COVID-19 Immunity Task Force will operate under the direction of a Leadership Group composed of experts who are recognized for their scientific leadership, international public health experience in knowledge translation and networks, and experience leading complex initiatives.

- The Leadership Group, which includes Canada's Chief Public Health Officer and Canada's Chief Science Advisor, had its first meeting on April 28th, 2020, where the initial roles and priority areas of work and processes were established.

- The COVID-19 Immunity Task Force will put in place the necessary mechanisms to ensure that privacy, confidentiality and ethical considerations are guiding the direction and implementation of this initiative.

- Online activities of the COVID-19 Immunity Task Force include their new website, as well as engaging with scientists through the CanCOVID Network, a platform mandated by Canada's Chief Science Advisor to expedite communication and collaboration between the scientific, healthcare and policy communities during the COVID-19 crisis.

BACKGROUND

As the first wave of COVID-19 begins to peak in Canada, it is important not only to marshal all available resources to manage the immediate surge of patients needing care, but also to anticipate what lies beyond the peak. In Canada, we do not know the degree of immunity to COVID-19 in the population.

Serology testing (collecting and testing blood samples for antibodies to SARS-CoV-2) of large numbers of people will provide the data needed to understand the scale of infection in the Canadian population. This approach will help us capture not only symptomatic individuals, but also asymptomatic or mildly symptomatic people who we are not aware of as they did not seek healthcare. The importance of coordinated, rapid and representative national surveys cannot be understated. They provide critical information on the current spread of COVID-19, and help us prepare for possible future waves of infection, both in the general population or vulnerable groups.

Targeted sero-surveys on the levels and trends in immune status amongst specific groups such as public-facing workers or among children and youth can inform the best timing of decisions for safe return to work and to school. They can help to direct proactive preventive efforts with vaccines and disease-modifying or even disease-preventing therapies should they become available. And they inform targeted surveillance efforts to contain and stop further outbreaks before they become epidemics.

The COVID-19 Immunity Task Force, a pan-Canadian consortium for COVID-19 serology surveillance, is being established to catalyze, support, and harmonize the design and rapid implementation of population-based studies that will generate reliable first estimates of SARS-CoV-2 immunity, overall and in vulnerable populations across Canada. This work will also contribute to what is happening globally. For example, as part of the World Health Organization global initiatives that provide standardized protocols: Solidarity II (pool findings from large-scale antibody studies around the world); and Unity Studies (population based sero-prevalence, household transmission).

Spartan Biosciences

SYNOPSIS

- Based on analytical data from laboratory studies provided by Spartan Biosciences, Health Canada authorized the sale of the Spartan diagnostic test device on April 11, 2020. The Public Health Agency of Canada had placed orders from Spartan Biosciences for 700 test devices and test kits to perform 1.92 million tests in order to ensure access to point of care testing in regions where it is needed to support rapid turn-around of test results. Before distributing testing devices for clinical use, the National Microbiology Laboratory conducts clinical validation to ensure satisfactory test performance in the real-world clinical setting. On May 1, the National Microbiology Laboratory shared the findings of their clinical validation of the Spartan device with Health Canada. In light of the poor results of clinical performance of the device, Health Canada is amending the Interim Order authorization of this device to “for research use only”. On May 5, 2020, Spartan Bioscience issued a recall on the Spartan Cube, Spartan Test Kits, and Spartan Swabs.

POTENTIAL QUESTION

- Will the health and safety of Canadians be impacted by the results of the Spartan test kit?

KEY MESSAGES

- The Government of Canada is taking all action necessary to protect the health and safety of Canadians during the COVID-19 pandemic.
- Testing is an essential component of Canada’s COVID-19 response.
- The Spartan test is a point of care test that offers rapid test results and is expected to be particularly useful in northern and remote communities.
- As soon as problems were identified with the performance of the Spartan test, Health Canada amended its authorization to limit use of the test to research purposes only. All testing devices that had been sold to date were for research use.

- The National Microbiology Laboratory worked with other public health laboratories to validate the Spartan test and has provided data to Spartan to assist the company with test improvements.

- Canada is implementing an aggressive procurement strategy to meet both current and future demand as testing continues to ramp up across the country.

BACKGROUND

Spartan Biosciences, an Ottawa-based company, created a made-in-Canada rapid COVID-19 analyzer, the Spartan Cube, and test reagents. Spartan's research is supported by the National Research Council of Canada's Industrial Research Assistance Program. The company was awarded a Government of Canada contract to accelerate the development of the rapid COVID-19 diagnostic test.

Based on analytical data from laboratory studies provided by Spartan Biosciences, Health Canada completed a scientific review of the Spartan diagnostic test device on April 11, 2020. The Public Health Agency of Canada had placed orders from Spartan Biosciences for 700 test devices and test kits to perform 1.92 million tests in order to ensure access to point of care testing is in regions where it is needed to support rapid turn-around of test results.

Intersection of COVID-19 and Substance Use

SYNOPSIS

- The COVID-19 pandemic is exacerbating a number of long-standing challenges regarding substance use and the overdose crisis. People who use drugs are currently facing additional barriers to accessing health and social services, increasing the risk of unsafe use and overdose, as well as disease spread and mortality.

POTENTIAL QUESTION

- What is the Government of Canada doing to support people who use drugs during the COVID-19 pandemic?

KEY MESSAGES

- During the pandemic, we must not forget that many regions of the country continue to struggle with historic rates of drug overdose and harms. Tragically, in many communities, the pandemic is compounding a deadly and ongoing public health crisis of opioid overdose and death.

- The Government is very concerned that people who use drugs are at increased risk of COVID-19. This is due to risks that come with multiple close contacts and unique difficulties of social distancing; increased likelihood of underlying health conditions; and increased risks of overdose when using drugs alone.

- In response, the Government has taken important measures to enable the health system to better meet the needs of people with substance use disorder as a part of its response to the pandemic. We have made it easier for them to access the medications they need, such as those necessary for opioid agonist treatment, like Suboxone and methadone. We have also made it easier for overdose prevention sites to be rapidly established in temporary community shelters.

- Health Canada is also supporting community-based projects funded under the Substance Use and Addictions Program in order to allow for funds to be re-directed to support immediate COVID-19 needs in their communities.

- In addition, my department is working to identify additional areas where federal exemptions, national guidelines or funding opportunities could help mitigate the impacts of the dual public health crises of COVID-19 and opioid-related overdose and death. By providing for these new measures, vulnerable people will be better able to get the supports they need, while respecting public health directives for physical distancing and self-isolation.

IF PRESSED ON NATIONAL GUIDELINES FOR OPIOIDS OR RESEARCH FUNDING

- Through the Canadian Institutes of Health Research (CIHR) and the Canadian Research Initiative in Substance Misuse (CRISM) six national guidance documents are being developed to address the specific needs of people who use drugs, service providers, and decision makers in relation to the COVID-19 pandemic.

- To ensure that COVID-19 responses are based on the latest evidence, the Canadian Institutes of Health Research also launched a $2 million funding opportunity to support rapid knowledge synthesis of current evidence on mental health and substance use. Results from this research will provide timely, high quality, and relevant evidence to decision makers at municipal, provincial, territorial, and federal levels.

IF PRESSED ON HEALTH CANADA'S ACTIONS TO ADDRESS COVID-19 IN COMMUNITIES WHERE THERE IS CHRONIC OVERCROWDING, INCLUDING A SHORTAGE OF HOUSING

- We understand the unique challenges associated with containing the spread and protecting homeless Canadians from COVID-19.

- On April 6, 2020, we proactively took steps to make it easier for overdose prevention sites to be rapidly established in temporary community shelters for vulnerable individuals (e.g., homeless/housing unstable) exposed to COVID-19, and to allow existing supervised consumption site operators to adjust their services to support physical distancing and respect public health directives.

- We have also developed a set of resources to help frontline service providers understand and comply with existing regulations associated with medications for substance use disorder or as a safer, pharmaceutical grade alternative to the street supply.

- These measures will not only make it easier for people who are staying at shelters to respect public health directives to distance and isolate, they will also protect them from the risks and harms of overdose.

- These efforts will help ensure vulnerable Canadians have access to the health services they need during the serious health threat posed by COVID-19.

IF PRESSED ON FEDERAL INVESTMENT TO ADDRESS ISSUES AT INTERSECTION OF SUBSTANCE USE AND COVID-19

- Budget 2019 committed to address persistent gaps in harm reduction and support communities in their response to problematic substance use.

- Recent investments made through Health Canada's Substance Use and Addictions Program are helping to relieve some of the extraordinary stresses placed on people, communities and health organizations struggling to deal with the dual demands of overdose crisis harm reduction and pandemic response.

- In February of this year, our Government announced funding of over $32 million over five years to support 26 projects across the country that will address a range of harm reduction and treatment needs, including:

    - $10 million to support 13 projects relating to Harm Reduction, Community-led and Front Line Initiatives;
    - $16 million in support of 5 projects aimed at Increasing Access to Pharmaceutical-Grade Medications (also referred to as "safe supply"); and,
    - $6 million to support 8 projects aimed at finding Approaches to Problematic Methamphetamine Use.

BACKGROUND

In March 2020, jointly with the provinces and territories, the Government of Canada released updated data indicating that 14,700 Canadians lost their lives between January 2016 and September 2019 to apparent opioid-related overdoses.

In many regions of the country, the COVID – 19 pandemic is compounding ongoing public health crisis related to high rates of opioid overdose and deaths as well as acute substance use harms. These crises are exacerbated in communities where there is chronic overcrowding, including a shortage of housing or other shelters. At the intersection of these public health crises, people who use drugs (PWUD) are experiencing a number of increased risks:

- **Mortality** due to COVID-19 given higher prevalence of underlying health conditions (respiratory illnesses, immune comprised, etc)
- **Spread** of COVID-19 due to multiple close contacts, including in the community to support drug-seeking behaviours and/or within primary care system for harm reduction/treatment
- **Other severe health risks** such as drug withdrawal for those who must self-isolate or quarantine
- **Overdose** and other harms related to an increasingly toxic illicit supply

Substance use, mental health, and pain and are inter-connected and it is often challenging to manage one without attending to the others. Many people who live with pain are coping with underlying health conditions or receiving pain treatments (ongoing use of opioids and other medications, steroid injections used in pain interventions), which are immune suppressing, placing people living with pain at higher risk of contracting and experiencing severe illness due to COVID-19. Public health measures required to respond to the pandemic have also increased the risk of social isolation, mental illness, and suicidality, which are already prevalent among people with chronic pain. Health and social services that help maintain function and keep disability at bay, such as psychological supports, physical therapies, and self-management options are more difficult to access. Canadians living with pain are therefore reporting decreased functional capacity and quality of life, fear and anxiety, cancellations of needed in-person care, surgeries and diagnostics, and drug shortages of certain pain medications (i.e., opioids, hydroxychloroquine).

Federal actions to date on this issues have been:

Increasing the reach of health system, including enabling Opioid Agonist Treatment (OAT)
Issued on March 19, 2020 exemptions that, if permitted within the applicable provincial/territorial scopes of practice: permit pharmacists to extend and/or transfer prescriptions; permit prescribers to issue verbal orders to extend or refill a prescription; and permit pharmacy employees to deliver prescriptions of controlled substances to patient's location. These measures facilitate self-isolation or quarantine to prevent the spread of COVID-19.

- Fully implemented in BC, AB, SK, ON, QC, NB, NS; Partially implemented (no verbal prescriptions) in PEI, NL; Being considered in MB, YU, NU; No information NWT

Flexible access to harm reduction services
Issued on April 6, 2020 class exemptions for all provinces and territories, for a duration of 6 months, allowing them to modify the operations of existing supervised consumption sites and

establish new temporary spaces for the safe consumption of drugs, without having to apply to Health Canada. This saves valuable time for local officials who want to establish temporary overdose prevention services within shelters or other temporary sites to house homeless or housing unstable people.

- No formal notice of implementation in any provinces to date, however Health Canada has requested to be informed if provinces implement. We have not received formal notification.

Disseminating information and guidance
Developed and disseminated new "tool kit", on May 5, 2020, to support service provides and PWUD to socially distance and self-isolate:

- Providing an easy-to-understand summary of the various exemptions now in place for health care practitioners (HCP) and allied HCP which facilitate flexible models of care during the pandemic;
- Consolidating prescribing and practice guidelines for HCP to foster an increase in prescribing of medications to address symptoms of withdrawal experienced by PWUD, including Suboxone, methadone and medications considered "safer supply" (hydrophone, prescription grade heroin); and
- Assisting PWUD, harm reduction advocacy groups and families who support PWUD to understand how to effectively navigate the changing healthcare environment to secure medications and treatment supports as well as educate on harm reduction measures.

Increasing access to mental health supports, including those for problematic substance use, and provide advice for overall well-being during the pandemic to reduce risk of overdose death and prevent spread of COVID-19

Leveraging the existing mental health as well as crisis lines and services, including the Federal COVID-19 – Mental Health and Substance Use Portal, to provide support for substance use and people experiencing chronic pain, including referrals to community services.

COVID-19 Test Kits

SYNOPSIS

- On March 18, 2020, the Minister of Health approved an Interim Order (IO) to expedite the review of medical devices, including test kits.

POTENTIAL QUESTION

- What is Health Canada doing to ensure Canada has access to the testing devices needed during the COVID-19 pandemic?

KEY MESSAGES

- Early diagnosis is critical to slowing and reducing the spread of COVID-19 in Canada.

- The Government of Canada is ensuring quicker and more flexible approval to import and sell medical devices that are necessary for Canada's response to COVID-19. This includes test kits.

- A medical device is authorized only after a scientific assessment by Health Canada reviewers to ensure that it is supported by evidence showing it meets standards for safety and effectiveness.

- Health Canada has authorized 19 test kits through an expedited regulatory review process under the Interim Order for medical devices issued on March 18, 2020.

- Only tests authorized by Health Canada can be imported or sold in Canada. Unauthorized tests may not produce accurate results, leading to potential misdiagnosis.

IF PRESSED… on authorization for serological tests:

- Health Canada has authorized 17 nucleic acid-based tests and two serological tests as of May 14.

- Nucleic acid based testing diagnoses COVID-19 infection and detects the virus itself. Public health laboratories across Canada and worldwide use it to detect active infections of COVID-19.

- Following priority scientific review, Health Canada has now authorized the sale of two serological tests - the DiaSorin LIAISON® test (authorized May 12) and the Abbott ARCHITECT SARS-CoV-2 IgG Assay (authorized May 14).

- Serologic tests are not used to diagnose COVID-19. They detect antibodies developed against the virus and could be useful in assessing the extent of COVID-19 spread in the population.

- The US FDA has faced criticism on allowing the marketing of ineffective serological tests. They announced on April 30th a new "umbrella" pathway for serology tests under which these tests can be submitted for validation by an interagency testing group.

- My department is working with leading regulators and world-renowned national laboratories to identify serological tests that will produce accurate and reliable results.

IF PRESSED… on the authorization of serological tests

- Following priority scientific review, Health Canada has now authorized the sale of two serological tests - the DiaSorin LIAISON® test (authorized May 12) and the Abbott ARCHITECT SARS-CoV-2 IgG Assay (authorized May 14).

- Both tests are authorized to detect antibodies specific to the virus. Serological tests provide evidence of a previous

exposure to the virus that causes COVID-19 by testing for the presence of antibodies.

- A condition is applied to the authorization issued to serology-based tests to monitor the ability of the test to perform as intended once in use by the Canadian health care system.

- Serology-based tests will play a key role in determining the degree/extent of exposure to the virus though sero-surveillance studies.

IF PRESSED… on the accuracy of the test kits:

- Health Canada has maintained a science-informed approach to managing the pandemic.

- A medical device is authorized only after a scientific assessment by Health Canada to ensure that it is supported by evidence showing it meets standards for safety and effectiveness.

- As with all medical devices, Health Canada will assess and monitor the safety and effectiveness of the tests once they are on the market.

IF PRESSED… on the accuracy of Spartan test kits:

- Health Canada completed its scientific review to ensure that the device was supported by evidence that it meets requirements for safety and effectiveness. The scientific review relied on analytical data from laboratory studies provided by the company, and took into consideration that further clinical validation would be carried out by public health laboratories in order to determine performance in clinical settings.

- Clinical trials are key in identifying any performance issues that could not have been identified in a laboratory setting. The report identified that while the device performed in a laboratory setting, as per manufacturer specifications, there were performance issues identified in the clinical trial.

- It's important to note that the company informed the Department that none of the tests were used for diagnosis purposes.

IF PRESSED… on fraudulent test kits:

- Health Canada has identified companies engaging in non-compliant advertising activities associated with COVID-19 and unauthorized products including test kits.

- In these cases, Health Canada works to verify compliance and will take action should any non-compliance be identified.

BACKGROUND

Early diagnosis and isolation of patients infected with COVID-19 are essential to slowing the spread of the novel coronavirus across Canada. Diagnostic testing is important for clinical care and public health management.

Under the IO, manufacturers must submit an abbreviated application to support the safety, effectiveness and quality of their medical device. Fees associated with an application through the IO pathway are waived.

The majority of submissions received by Health Canada are for two types of testing devices:

1. nucleic acid-based tests (detection of the virus)

Public health laboratories across Canada and around the world use nucleic acid-based testing to reliably diagnose COVID-19 infection by detecting the virus itself. The review of diagnostic tests using nucleic acid technology has been prioritized to increase the number of tests available in Canada to detect active infections of COVID-19.

2. serological-based tests (detection of antibodies)

Serologic tests detect the antibodies developed against the virus. Health Canada is not aware of a serological-based test that can diagnose COVID-19. Serological tests are not appropriate for early diagnosis of COVID-19, given the time required after infection to develop antibodies.

On May 12, Health Canada issued the first authorization for the sale of a serological test in Canada under the Interim Order process. On May 14, an additional serological test was authorized for sale in Canada under the Interim Order process. The DiaSorin LIAISON® test and the Abbott ARCHITECT SARS-CoV-2 IgG Assay are authorized to detect antibodies specific to the SARS-CoV-2 virus. They are not authorized for diagnosis but rather they~~i~~ provide~~s~~ evidence of a previous exposure to the SARS-CoV-2 virus. Health Canada's position regarding serological assays is in line with the World Health Organization's (WHO) view that serological assays will play an important role in research and surveillance but are not currently recommended for case detection. Serological tests will play an important role in an overall testing strategy for Canada as they will provide evidence in assessing the true extent of COVID-19 in the general population.

Health Canada collaborates with the National Microbiology Laboratory and provincial public health laboratory partners and will leverage the studies of immune responses and serological technologies underway in Canada and internationally. The uses for which serological technologies are authorized will depend on the type of evidence that Health Canada receives from the manufacturer and from these studies.

Testing Capacity

SYNOPSIS

- The Public Health Agency of Canada works closely with provincial and territorial laboratories to conduct laboratory testing for the virus that causes COVID-19. As of May 17, 2020, over 1,296,000 people in Canada were tested for COVID-19. Over the last week, an average of 28,541 individuals were tested a day in Canada. Shortages of testing supplies will present a barrier to the significant ramp up of testing anticipated in provinces and territories as we enter the recovery phase of the epidemic and begin to open up the economy.

POTENTIAL QUESTION

- Will the health and safety of Canadians be impacted by a lack of testing capacity in Canada?

KEY MESSAGES

- The Government of Canada is taking all action necessary to protect the health and safety of Canadians during the COVID-19 pandemic.

- Testing is an essential component of Canada's COVID-19 response. We are supporting provinces and territories as they deploy testing to detect and control the spread of COVID-19.

- Shortages of COVID-19 testing supplies are a global problem. Canada is implementing an aggressive procurement strategy to meet both current and future demand as testing continues to ramp up across the country.

- On March 18, 2020, the Government of Canada approved an interim order to expedite the review of medical devices, including test kits. An interim order is one of the fastest mechanisms available to address large-scale public health emergencies.

IF PRESSED ON HOW CANADA IS INCREASING TESTING CAPACITY…

- My health portfolio continues to work with colleagues in Public Services Procurement Canada and Innovation, Science and Economic Development Canada to identify new products and platforms.

- As new test products or platforms become available and approved for use in Canada, the Public Health Agency of Canada will work with provincial public health laboratories to acquire them to augment existing testing capacity.

- These efforts will help ensure Canadians have access to the testing they need during the serious health threat posed by COVID-19.

IF PRESSED ON SEROLOGY TESTING …

- The National Microbiology Laboratory is working on developing a number of in-house serological tests in addition to evaluating a variety of commercial tests for COVID-19.

- Developing and applying a serological test for COVID-19 poses challenges as this is an emerging virus and the performance of new tests require additional time and research.

- The National Microbiology Laboratory, working with Health Canada and other partners, is currently assessing a number of serological tests and is collecting blood samples to evaluate and identify serological tests that will produce accurate and reliable results.

BACKGROUND

The Public Health Agency of Canada works closely with provincial and territorial laboratories to conduct laboratory testing for the virus that causes COVID-19. As of May

17, 2020, over 1,296,000 patients in Canada were tested for COVID-19. Over the last week, an average of 28,541 individuals were tested a day in Canada.

Testing in Canada is focused on people who present with symptoms consistent with COVID-19. Canada's testing strategies continue to evolve as the outbreak spreads. PHAC continues to work with provincial and territorial partners on a national testing strategy that will help maximize the impact of testing resources and delay the spread of COVID-19 in high-risk settings, such as hospitals and long-term care facilities.

Health Canada has been working with manufacturers to enable market access for commercial diagnostic devices in order to increase Canada's COVID-19 diagnostic capacity.

TRIKAFTA

SYNOPSIS

In October 2019, the US Food and Drug Administration approved Trikafta, the first triple combination therapy available to treat patients with the most common cystic fibrosis mutation. The annual cost of treatment with Trikafta is over $300,000 USD. Although Health Canada has not received a new drug submission for Trikafta, as of May 6, 2020, there have been 95 Special Access Program (SAP) requests for this drug for 98 patients. Media interest is high around the funding and availability of the drug, particularly because of its use in the pediatric population. The Department has also received many letters from patients and their supporters expressing their desire to have this drug available in Canada.

POTENTIAL QUESTION

- What is Health Canada doing to make Trikafta available to Canadians with cystic fibrosis?

KEY MESSAGES

- The health and safety of Canadians is our top priority.

- Health Canada recognizes the importance of patient access to new therapies for serious or life-threatening conditions. To date, the manufacturer of Trikafta has not submitted an application to market this product in Canada.

- While Health Canada encourages manufacturers to submit an application for authorization of this drug for sale in Canada, it is the manufacturer's decision whether or not to apply to market their product in Canada.

- For serious or life-threatening conditions, such as cystic fibrosis, physicians may request access to the drug through Health Canada's Special Access Programme (SAP). As of May 6, 2020, there have been 95 SAP requests for Trikafta for 98 patients.

- To help Canadians get better access to effective treatments, we are working with provinces, territories and other partners to develop a national strategy for high cost drugs for rare diseases. This is an important step in working with provinces and territories on national pharmacare.

IF PRESSED ON THE DRUG APPROVAL

- Health Canada carefully reviews new drugs to determine that they are safe, effective and of good quality. This decision is distinct from price-setting and reimbursement decisions, which are managed by agencies separate from Health Canada.

- One of the first steps in a new drug approval process is to conduct clinical trials which can also be a potential way to access unauthorized drugs. Although there are currently no clinical trials for Trikafta open in Canada, Health Canada is available to provide guidance to a sponsor wishing to conduct a clinical trial.

IF PRESSED ON THE IMPACT OF THE MODERNIZING THE PMPRB

- Our Government is committed to improving Canadians' access to, and the affordability of, necessary prescription medicines.

- Canada will continue to be an important market for new medicines. In fact, many countries with much lower medicine prices gain access to new medicines in the same time frame, or even faster than Canada.

- Our Government has also streamlined regulatory processes supporting faster access to the Canadian market for products.

BACKGROUND

Trikafta, by the drug manufacturer Vertex Pharma, is the first triple combination therapy available to treat patients with the most common cystic fibrosis mutation. It is reported to increase lung function by an average of 14%, which is a significant improvement for many patients struggling with the effects of cystic fibrosis.

Under the *Food and Drug Act* and Regulations, all products sold or marketed in Canada and making a therapeutic claim need to be approved by Health Canada. The drug authorization process is initiated when a manufacturer submits an application to Health Canada for review. Every submission is then reviewed by scientists to assess the product's safety, efficacy and quality. At this time, Health Canada has not received a new drug submission for Trikafta although Health Canada and Vertex Pharma have been in contact in regards to this product. While Health Canada encourages manufacturers to submit an application for authorization of this drug for sale in Canada, it is the company's decision whether or not to submit a new drug application.

Products containing compounds found in Trikafta are approved by Health Canada for use in treating Cystic Fibrosis. The products are:

- KALYDECO (Ivacaftor)
- SYMDECO (Ivacaftor and Tezacaftor)
- ORKAMBI (Ivacaftor and Lumacaftor)

All drug products approved for sale in Canada are listed on the Drug Product Database, available at: https://health-products.canada.ca/dpd-bdpp/index-eng.jsp.

The Special Access Program (SAP) considers requests from practitioners treating patients with serious or life-threatening conditions for drugs that are unavailable for sale in Canada when conventional treatments have failed, or are deemed unsuitable for the patient. Decisions by SAP are taken on a case-by-case basis. They are based on the clinical details of the patient's unique situation as well as the clinical reasons why other marketed therapies may not be suited for a patient. As of May 6, 2020, SAP has received 95 requests for access to Trikafta for 98 patients.

SAP does not provide drug funding to Canadians for access to medication and does not have a role in the drug reimbursement process. Decisions on insurance coverage or funding are under the jurisdiction of the provinces and territories.

The Government of Canada is committed to improving the affordability and accessibility of prescription drugs for all Canadians. That is why we are working with provinces and territories as an active member of the pan-Canadian Pharmaceutical Alliance (pCPA) to combine the governments' collective buying power to negotiate lower prices on brand name drugs for all public plans, including high cost drugs for rare diseases.

Additionally, in August 2019, the Government announced final amendments to the *Patented Medicines Regulations.* These amendments will give the Patented Medicine Prices Review Board (PMPRB) the tools it needs to protect Canadians from excessive prices and make patented medicines more affordable for all payers - public and private drug plans, as well as Canadians who pay out of pocket for their prescription drugs, including high cost drugs for rare diseases.

Vaccine Research and Timelines

SYNOPSIS

- The Government of Canada is committed to supporting the timely development of a COVID-19 vaccine. On April 23, 2020, the Prime Minister announced more than $1 billion in support of a national medical research strategy to fight COVID-19 that includes vaccine development, the production of treatments, and tracking of the virus.

KEY MESSAGES

- The Government of Canada is committed to protecting the health and safety of Canadians and has invested more than $1 billion in support of a national medical research strategy to fight COVID-19.

- Through this investment, the Government of Canada is supporting multiple organizations who are working at unprecedented speed to develop candidate vaccines.

- In Canada, there are currently 14 candidate vaccines in early development and it is anticipated that several of these will advance to human clinical trials in the coming months.

- On May 15, 2020, Health Canada authorized CanSino Biologics Inc. to conduct Phase 1/2 clinical trials in healthy adults in Canada. The trial will be conducted in collaboration with the Canadian Immunization Research Network at the Canadian Center for Vaccinology at Dalhousie University.

IF PRESSED…

- New funding announced on April 23 builds on the previous Government of Canada investment of $275 million to support COVID-19 vaccine and therapeutics research and development.

- For example, vaccine development investments to date have been announced for Quebec-based Medicago and Saskatchewan-based VIDO-Intervac.

- We are working closely with academia and the private sector to advance research and development of candidate vaccines by partnering on pre-clinical research, bio-manufacturing requirements to support large-scale production, enhancing capacity and access for clinical trials, and seeking solutions for domestic capacity.

BACKGROUND

Vaccine development is a highly complex and long process that typically takes over 10 years due to the extensive research required to ensure a safe and effective product for human use. Global efforts are underway to develop a COVID-19 vaccine and work is progressing at an unprecedented pace. At present, there are over 100 COVID-19 candidate vaccines at different stages of development by academia and industry. As of May 18, 2020, nine of these candidate vaccines have demonstrated promise and have advanced to Phase 1 clinical trials in China, the U.S., and Europe, with early results expected as early as July 2020. Additionally, one of these candidate vaccines has also entered Phase 2 clinical trials in China and another candidate has recently received approval to launch a Phase 2/3 trial in the UK later this spring.

Government of Canada investments

On March 11, 2020, the Government of Canada announced a $1 billion package to help Canadians cope with the COVID-19 outbreak, which included $275 million for coronavirus research and medical countermeasures. Major investments to date include supporting vaccine development efforts by Quebec-based Medicago and Saskatchewan-based VIDO-Intervac. On April 23, 2020, the Prime Minister announced more than $1 billion in support of a national medical research strategy to fight COVID-19 that includes vaccine development, the production of treatments, and tracking of the virus. Investments were announced for the National Research Council of Canada to enhance its bio-manufacturing capacity to prepare for production of a COVID-19 vaccine, while investments through the Strategic Innovation Fund continue to support COVID-19 vaccine and therapy research and development led by the private sector. Funding will also support academia and research networks to conduct vaccine-related research and clinical trials, and to enhance Canada’s capacity to monitor vaccine safety and effectiveness. These investments contribute to Canada’s commitment to the Coronavirus Global Response, an online global pledging event that aims to raise more than $8 billion (USD) to help researchers and innovators develop solutions to test, treat, and protect people, and to prevent the further spread of COVID-19.

Vaccine research and development in Canada
As of May 18, 2020, of the 100+ global candidates noted above, there are currently 14 candidate vaccines in early development in Canada. It is expected that several will advance to Phase 1 clinical trials in the coming months.

On May 15, 2020, Health Canada authorized CanSino Biologics Inc. (CanSinoBio) vaccine candidate for Phase 1/2 clinical trials in healthy adults Canada. Referred to as Ad5-nCoV, the vaccine candidate received Chinese regulatory approval earlier this year, allowing CanSinoBio to move ahead with human clinical trials in China. It is one of only a handful of vaccine candidates in the world against COVID-19 so far approved for initial safety testing in humans, and was the first candidate vaccine to begin conducting Phase II human clinical trials.

On May 12, 2020, the National Research Council of Canada (NRC) announced the collaboration with CanSinoBIO to advance bioprocessing and clinical development in Canada of a candidate vaccine against COVID-19, noting that the new COVID-19 vaccine is also produced using HEK293 cell lines that were designed and developed at the NRC. By bringing their respective technologies and expertise together to fight COVID-19, CanSinoBio and the NRC are aiming to pave the way for future clinical trials in Canada, in collaboration with the Canadian Immunization Research Network at the Canadian Center for Vaccinology in Halifax, Nova Scotia. This collaboration will also allow the NRC to advance a scale-up production process for the vaccine candidate, using its proprietary HEK293 cell line. As a preparatory step, the Government of Canada has already announced $44 million in funding to support upgrades to the NRC's facilities in Montreal to enable compliance with Good Manufacturing Practice (GMP) standards, to ensure readiness for Canadian bioprocessing of potential vaccine candidates as they become available.

While every effort in Canada is being made to expedite vaccine development - safety, efficacy and quality must not be compromised. However, the Government of Canada is reviewing its regulatory pathways to help expedite access to safe and effective vaccine for Canadians.

We are also working with international regulators and partners to help fast-track clinical trials and applications for vaccines, treatments and diagnostic tests and share information on any signals of global supply disruptions.

Preparing provinces and territories for COVID-19 vaccine deployment
Provincial and territorial governments deliver vaccination programs and determine public health requirements in their jurisdictions. Early planning is underway to prepare for vaccine availability and administration through public immunization programs.