COVID-19, PANDEMIC, CORONAVIRUS, PARLIAMENTARY COMMITTEE APPEARANCE ACCOMPLISHMENTS RELATED TO COVID-19

SYNOPSIS
The Government of Canada has addressed this unprecedented situation with an equally unprecedented response. Since Canada received its earliest warning of an illness originating in Wuhan, China at the end of December 2019, the Government has been working collaboratively with provinces and territories as well as leveraging international partnerships to protect the health and safety of Canadians.

POTENTIAL QUESTION
What are the key accomplishments related to the COVID-19 response in Canada?

KEY MESSAGES

- The Government of Canada has addressed this unprecedented situation with an equally unprecedented response – with our Public Health Agency of Canada driving critical parts of our response.

- Canada is recognized internationally as a model example of working across jurisdictions to support a collaborative, whole-of-government response to the COVID-19 pandemic.

- Canada has effectively leveraged domestic and international partnerships to share technical expertise, exchange information, and learn from the experiences of other countries.

- This has helped us build a robust and agile response to the exceptional challenges that we are facing.

- None of these accomplishments would be possible without the strong partnerships that exist at all levels of governments, across jurisdictions and with key stakeholders, who are equally invested in protecting the health and safety of Canadians.

IF PRESSED ON SPECIFIC ACCOMPLISHMENTS

- To reduce the risk of imported cases, the Public Health Agency of Canada enhanced screening measures at Canadian airports, and implemented travel restrictions and mandatory quarantine.

- Also, for the first time in our history, we undertook large-scale and controlled repatriation of Canadians from overseas and established temporary housing at designated quarantine sites.

- We offered public health guidance on how to protect the health and safety of Canadians and reduce the spread of COVID-19.

- We have worked with provinces and territories and other stakeholders to accelerate diagnostic testing capacity in order to detect cases of COVID-19 more quickly.

- We have also established a coordinated approach to the bulk purchase and distribution of personal protective equipment, to ensure that the right supplies get to the right places in Canada.

- We have developed a national approach to data collection and surveillance, to support the continued monitoring of COVID-19 across the country.

- The Public Health Agency of Canada, along with partners, is also working to support the development of a vaccine and treatment.

IF PRESSED ON COMMUNICATIONS

- The Public Health Agency of Canada has been proactive and transparent in its communications with Canadians.

- We have directly addressed the questions and concerns of tens of thousands of Canadians on various aspects of COVID-19 since the beginning of January.

- We have also initiated new ways to connect with Canadians, including the Canada COVID-19 App, an information phone line, and a centralized website.

BACKGROUND

The Government of Canada's top priority is the health and safety of Canadians. The overall response to the COVID-19 pandemic is based on the Federal/Provincial/Territorial Public Health Response Plan for Biological Events, with the goal to support collaboration and engagement amongst federal/provincial/territorial public health, health care delivery and emergency management authorities.

ADJUSTING PUBLIC HEALTH MEASURES

SYNOPSIS

Following a period where many businesses and services across the country were closed to help minimize the spread of COVID-19, restrictions are being gradually lifted, allowing the economy and society to re-open. The Public Health Agency of Canada (PHAC), along with provincial and territorial partners, is continually evaluating and adjusting the response based on the most recent evidence and the current epidemiological situation. Given the recent increase in cases in Canada, we are seeing some health authorities respond accordingly by reinstating stricter public health measures.

POTENTIAL QUESTION

How is the Government adjusting public health measures to address the current situation in Canada?

KEY MESSAGES

- The recent increase in the number of COVID-19 cases in Canada is concerning.

- Even a single person with mild symptoms can start a chain reaction of exposures and infections, both at private gatherings and in public settings.

- We can all do our part to reduce the impact and severity of a fall surge by:

    - Following public health guidelines;
    - Practising physical distancing;
    - Avoiding large gatherings; and
    - Limiting in-person close contacts to a small and consistent circle.

- We are continually evaluating the impact of relaxing and reintroducing public health measures, in collaboration with our provincial and territorial partners.

- We continue to use all evidence and models available on an ongoing basis to help us identify which combinations of public health measures are most likely to help us control the pandemic.

IF PRESSED ON QUEBEC UPDATE ON SELF-ISOLATION REQUIREMENT (10 DAYS) OR OTHER PROVINCIAL/TERRITORIAL-SPECIFIC MEASURES

- Provinces and territories also develop guidance and approaches for their own jurisdictions which may differ, reflecting differences in the pandemic across the country.

BACKGROUND

Public health measures (PHM) are the non-pharmaceutical interventions implemented by federal/provincial/territorial and local public health authorities to control COVID-19 transmission. Measures focus on helping individuals to protect themselves and others, such as personal hygiene, physical distancing, and self-monitoring. Public health organizations also aim to prevent transmission by undertaking testing programs to detect and isolate cases, tracing people exposed to cases and quarantining them so they cannot transmit COVID-19 to others. Community measures such as public education campaigns, restrictions on gatherings and school and workplace measures, help to protect groups and the community at large.

With limited options for treatments and no vaccine available at this time, core PHM (case detection, contact tracing and efforts of individuals such as personal hygiene and self-isolating when sick) will need to be sustained in order to maximize our ability as a society to control the spread of the virus over the long term. Public health authorities will need to continue to rapidly identify and respond to new cases and outbreaks to reduce community-spread, prevent large increases in case numbers and associated hospitalizations. It is important to consider how to reduce the impact of seasonal respiratory infections this fall, so that public health resources and health care system capacity are not overwhelmed when dealing with COVID-19 cases occurring at the same time.

A series of models are being used to identify the potential impact of different combinations of control measures on infection rates in the Canadian population. On an ongoing basis, these models help to identify which combinations of public health measures, applied with what intensity, are most likely to reinforce pandemic control.

PHAC is continually evaluating the impact of PHM on the number of cases reported through surveillance systems, and is adjusting guidance as needed in collaboration with provincial and territorial partners. Community-based PHM are most effective when implemented as early as possible in response to epidemiological triggers of concern

(e.g. increases in unlinked cases). Therefore, preparations for the fall include being ready to re-implement restrictive community PHM by the provinces and territories or at the municipal public health level. It is important to remember that it takes about two weeks before the impact of PHM can be seen in our surveillance data. This is because of the time lapse between when a person is infected, when they are tested and subsequently reported to PHAC as a confirmed case.

On August 28, 2020, Quebec updated the required isolation period for individuals who have COVID-19, or who came into contact with a confirmed case. Quebec's instructions now dictate that individuals can end their isolation period when they meet all of the following conditions:

- 10 days have passed since symptoms started;
- The individual has not had a fever for at least 48 hours, without using fever medication; and
- Symptoms have improved for at least 24 hours, except for cough and loss of smell, which can last longer.

On July 3, 2020, the Atlantic "travel bubble" came into effect. For Atlantic Canada residents, travel within Nova Scotia, New Brunswick, Prince Edward Island and Newfoundland and Labrador is permitted without the requirement to self-isolate. Everyone who travels from outside Atlantic Canada into the bubble (including post-secondary students and those travelling through Atlantic Canada to another destination) must self-isolate for 14 days when they arrive, or for the duration of their stay if it's less than 14 days. If a person from the region travels outside Atlantic Canada they also must self-isolate for 14 days from the day they return, even if they don't have symptoms.

AEROSOL TRANSMISSION OF COVID-19

SYNOPSIS

Scientific information on COVID-19 continues to be produced rapidly and the Public Health Agency of Canada (PHAC) continues to evaluate new evidence regarding aerosol transmission, as it becomes available, to inform our intervention and mitigation strategies. CDC changed its website to acknowledge this route of transmission on Oct 5, 2020. PHAC has engaged in a wide consultative process and is actively engaged on the issue of aerosol transmission.

POTENTIAL QUESTION

What does the best available evidence say about the role of aerosol transmission?

KEY MESSAGES

- COVID-19 spreads mainly by close person-to-person contact with an infected person who is coughing, sneezing, talking or singing.
- The risk of aerosol transmission from small droplets that linger in the air continues to be studied.
- Mitigation measures, such as optimal ventilation, physical distancing and face masks, both for community settings and in healthcare, decreases the risk of aerosol transmission.

IF PRESSED…

- Aerosol transmission means that very small droplets containing the virus – released when an infected person breathes, talks, sings, coughs or speaks – remain infectious even while suspended in the air for a period of time.
- The amount of exposure and circumstances under which infection can occur with aerosols is not well defined. Common characteristics of clusters attributed to aerosol

transmission include that they took place in closed indoor settings, the infected person was pre-symptomatic or had just developed symptoms and there was an extended duration of exposure.

BACKGROUND

Airborne transmission in infection transmission literature refers to small infectious particles (<5um) that are referred to as “aerosols” or “droplet nuclei” that can remain suspended in the air for some time and may travel a distance from the source. Large and small respiratory droplets can be inhaled, however larger droplets fall to the ground faster and may not travel as far as small aerosols. In healthcare, “IPC airborne” refers to airborne precautions, an additional layer of protection used when working with obligate or preferential airborne pathogens. (At this time SARS-CoV-2 has not been recommended for airborne precautions.) Emerging epidemiological and experimental evidence indicates there is some risk of airborne transmission of SARS-CoV-2.

Scientific information on COVID-19 continues to be produced rapidly and PHAC continues to evaluate new evidence as it becomes available to inform our intervention and mitigation strategies.

At present, the best available evidence supports that infectious SARS-CoV-2 virus is present in aerosolized particles. There are simulation experiments, biological monitoring studies from around COVID-19 patients in hospitals and animal transmission experiments that support airborne transmission of SARS-CoV-2.

However, the current evidence has not quantified COVID-19 infection risk from aerosol transmission and the infectious dose of SARS-CoV-2 is currently unknown.

Investigators have demonstrated that infectious virus laden aerosols can be expelled from COVID-19 cases when breathing, talking, singing and coughing.

The virus has been identified in air samples at distances greater than 2 meters from the source.

Experimental evidence had demonstrated that it is feasible for SARS-CoV-2 within aerosols to remain suspended in the air and viable for hours.

Epidemiological investigations of six COVID-19 clusters in different real-world settings (e.g. meat processing plants, indoor choir practice, restaurant, fitness and dance facilities) have concluded that the only explanation for transmission is that airborne transmission occurred. Common characteristics of these clusters is that the event took place in a closed indoor environment, the
infectious index case was pre-symptomatic or had just started exhibiting symptoms, and there was an extended duration of exposure. Suboptimal ventilation, a lack of air

circulation and indoor air currents risk factors in some clusters that explained the pattern of secondary cases.

Fluid dynamic evidence from simulations and theoretical models indirectly supports airborne transmission of SARS-CoV-2. Respiratory droplets have been shown to remain suspended for more than 8 minutes and can travel >7 meters.

ARRIVECAN

SYNOPSIS

ArriveCAN is a mobile application supporting the digital collection of information from travelers entering Canada. The application is designed to increase digital uptake, facilitate data collection and enable early traveler engagement, supporting the Government of Canada's ability to manage increased traveler volumes, improve public health measures and facilitate information sharing with provinces and territories.

The ArriveCAN application launched in April 2020 and is the preferred method for travelers to submit mandatory information to the Government of Canada. An accessible website exists that mimics the functionalities of the mobile app, and information is currently also accepted via paper form.

KEY MESSAGES

- ArriveCAN is a digital alternative to the Traveler Contact Information paper form.
- The ArriveCAN mobile application allows travelers coming into Canada to submit information quickly, easily, and securely to meet Government of Canada requirements upon entry.
- It speeds up processing at the border, which reduces crowding.
- It also allows for faster sharing of information with provincial and territorial governments.
- After entering into Canada, travelers can use the ArriveCAN app to confirm their quarantine location.
- They can also provide updates on any COVID-19 symptoms they may develop.
- The Government of Canada is promoting the ArriveCAN app to ensure travelers are aware of the benefits of using it.

IF PRESSED…

- In addition to ArriveCAN, The Government of Canada has also set up an accessible website travelers can use to submit their information.

- In situations where needed, travelers have the option of completing the paper form or of providing their information verbally to a Border Services Officer at the point of entry.

- Post-border, there is a toll-free number available to complete the voluntary check-in and report on symptoms.

- Exempt travelers must still provide their travel and contact information, and their symptom self-assessment.

BACKGROUND

BORDER MEASURES

SYNOPSIS
The Public Health Agency of Canada (PHAC) has put in place successive border measures in response to COVID-19 under the *Quarantine Act*.

POTENTIAL QUESTION
What is the Government doing to encourage the restart of the Canadian economy while continuing to prevent imported cases of COVID-19?
How is the Government protecting Canadians at the border?

KEY MESSAGES

- In response to COVID‑19, Canada has established robust border measures including quarantine and travel restrictions. These border measures have been effective in helping to protect the health and safety of Canadians, while continuing to permit essential workers to enter the country.

- On October 30, the Government extended the Mandatory Isolation Order and temporary travel restrictions for foreign nationals travelling from non-U.S. countries, unless their travel is for non-discretionary reasons, to November 30, 2020.

- The Government also made some practical adjustments to the Mandatory Isolation Order to exempt groups from quarantine to enable limited Canada-U.S. cross-border travel, specifically:

  - persons in identified border communities when crossing the border to access the necessities of life from the nearest Canadian or American community;

  - children who are subject to shared custody arrangements, along with one adult driver;

- students from the U.S. who regularly cross the border to attend school, along with one driver, conditional on support from provincial and local public health authorities and if they are attending an institution on the designated list of institutions (DLI) with Immigration, Refugee and Citizenship Canada (IRCC); and

- Students from Canada who regularly cross the border to attend school in the U.S., along with one adult driver.

- The Government also introduced new mandatory requirements, beginning November 20, for the digital submission of information through the ArriveCAN app or website. This will allow traveler information to be shared quickly and securely with provinces and territories to contact travelers for public health follow-up, and with law enforcement to verify compliance with the Mandatory Isolation Order.

- To inform potential alternative border measures in the future, the Government is providing an exemption to mandatory quarantine to enable specific border COVID-testing pilots developed in concert with provincial and territorial governments. The Government will continue to monitor international alternatives to quarantine closely and will continue to review the evolving science, including the role, timing, and type of COVID-19 testing, in determining any changes to our current border measures.

IF PRESSED ON FEDERAL QUARANTINE SITES

- Travelers are responsible for arranging a suitable place to quarantine or isolate prior to their arrival in Canada.

- If this is not possible, travelers should make other arrangements for quarantine accommodations within their own financial means prior to their arrival in Canada.

- If no other suitable arrangements to quarantine are possible, individual travelers may be referred to a federally designated quarantine facility, if necessary.

IF PRESSED ON HOW WE SCREEN TRAVELLERS

- Prior to boarding a flight to Canada, travelers undergo a health screening by the airline.

- Anyone showing signs and symptoms of COVID-19 is not allowed to board the plane. All travelers must also wear masks during flights, and at airports.

- Upon arrival in Canada, Border Services Officers conduct preliminary screening of all travelers, based on criteria and questions developed by the Public Health Agency of Canada.

- Travelers must acknowledge they understand and will follow the 14-day quarantine requirement, and provide contact details for follow-up.

- Those who show signs and symptoms of COVID-19, or who indicate that they do not have a suitable plan for quarantine, are directed to a Public Health Agency of Canada official for further assessment and possible referral to a federally designated quarantine site.

IF PRESSED ON WORK WITH PROVINCES TO DATE

- The Public Health Agency of Canada is collaborating with partners to digitize the collection of health-related information from passengers pre-arrival through the ArriveCan app. This will allow traveler information to be shared quickly and securely with provinces and territories to

contact travelers for public health follow-up, and with law enforcement to verify compliance with the Mandatory Isolation Order.

- To inform potential alternative border measures in the future, the Government is providing an exemption to mandatory quarantine to enable specific border COVID-testing pilots with provincial and territorial governments. The Government will continue to monitor international alternatives to quarantine closely and will review the evolving science, including the role and timing of COVID-19 testing, in determining any changes to our current border measures.

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.

- Officials provide handouts at the border, and contact travelers by e-mail and phone throughout their isolation or quarantine period, to remind them of the requirements.

- If travelers cannot be reached, or appear non-compliant with isolation or quarantine requirements, they are referred to local law enforcement for follow-up.

- Under the *Quarantine Act*, penalties for failure to comply with an order can include a fine of up to $1 million or imprisonment for 3 years, or both.

- To provide additional tools to Quarantine Officers and law enforcement, fines can be issued for non-compliance, typically ranging from $275 to $1000. Local law enforcement may choose to issue warnings prior to issuing a ticket.

Alberta, Saskatchewan, and the territories issue fines under their own legislation.

IF PRESSED ON BORDER PRESENCE

- Public Health Agency of Canada's Designated Officers are present at 31 Canadian points of entry that receive international travellers.

- As international travel resumes, the Public Health Agency of Canada will increase its public health presence to 36 points of entry across the country.
- All of Canada's points of entry will continue to have 24/7 access to support from the Public Health Agency of Canada's Quarantine Officers through the remote Central Notification System.

IF PRESSED ON ADDITIONAL EXEMPTIONS FOR IMMEDIATE FAMILY MEMBERS

- In response to concerns expressed by Canadians, the government has taken additional steps to reunite Canadians with their family members.

- On October 8, the government introduced new processes to extend the definition of family in order to support family reunification.

IF PRESSED ON U.S. TRAVELLERS

- U.S. citizens are permitted to travel directly from the United States to Alaska and vice-versa for non-discretionary purposes, such as going for work, and returning home.

- They must respect Canada's public health measures, including provincial and territorial requirements, such as staying in a hotel room and wearing a non-medical mask.

- Some U.S. citizens are also permitted to enter Canada for legitimate work purposes, including providing an essential service as specified under the Orders in Council.

- U.S. citizens should not be taking the opportunity to travel within Canada for personal or discretionary reasons. This is an enforceable offence, with monetary penalties.

- New amendments to the Mandatory Isolation Order now enable specific travelers to be exempt from quarantine to facilitate travel for cross-border students, children in shared custody arrangements, and those in specific remote communities who need access to the necessities of life.

IF PRESSED ON CANADA'S APPROACH TO TRAVEL ADVISORIES AND EASING OF BORDER MEASURES

- We continue to evaluate the evolving COVID-19 pandemic to inform our travel advice to Canadians.

- The experiences of countries around the world with easing border measures has been mixed.

- As we explore a gradual approach to reopening international travel, we must consider our domestic situation, including:

    - The capacity of our public health system;
    - Provincial and territorial perspectives;
    - Our capacity at the borders; and
    - The epidemiological situation within Canada and other countries.

IF PRESSED ON INTERNATIONAL STUDENTS

- The Government of Canada is working with provinces and territories to ensure that learning institutions are able to

safely welcome international students.

- The learning institutions designated by provinces and territories are expected to provide information to international students on health and travel requirements before they arrive in Canada, help students with their quarantine plans, and provide guidance or assistance in acquiring the necessities of life, such as food and medication, during their quarantine.

- Like any other traveller arriving in Canada, international students need to have suitable quarantine plans in place before they arrive, and will be required to quarantine for 14 days.

BACKGROUND

Between February 3, 2020 and October 30, 2020, the Governor in Council has made 33 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.

The Public Health Agency of 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:

- Foreign nationals entering from the United States (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 U.S., with some exceptions, such as those delivering essential services; and
- Foreign nationals entering from any country with signs or symptoms of respiratory illness.

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

On October 30, the Government extended the Mandatory Isolation Order and temporary travel restrictions for all travelers from non-US countries, unless their travel is for non-discretionary reasons, to November 30, 2020.

The Government also made some practical adjustments to allow limited Canada-U.S. cross-border travel. Effective October 31st, 2020, residents of Campobello Island, New Brunswick, Stewart, British Columbia, Northwest Angle, Minnesota, and Hyder, Alaska are exempt from mandatory 14-day quarantine to access the necessities of life (e.g., food, medical services) from the nearest Canadian or American community. In addition, students from Canada and the U.S. who regularly cross the border to attend school, along with one driver, and children who are subject to shared custody arrangements, along with one parent, are exempt from mandatory 14-day quarantine. The new provisions to ease pressures related to cross-border students is conditional upon support from provincial and local public health authorities.

In addition, the Government is providing an exemption to mandatory quarantine to enable specific border COVID-testing pilots with provincial and territorial governments. The Government of Canada will continue to monitor international alternatives to quarantine closely and will review the evolving science, including the role, timing and type of COVID-19 testing, in determining any changes to our current border measures.

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. 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.

Canada has 117 land border points of entry, 12 large international airports, 4 commercial marine ports, and 3 rail stations. PHAC has increased the physical presence of its designated officers, including quarantine officers, at 31 points of entry across Canada, including major land borders.

On October 8, 2020, new processes were also introduced to extend the definition of family in order to support family reunification.

On October 8, 2020, the Government of Canada implemented a new process to allow foreign nationals to come to Canada for compassionate reasons, in limited circumstances, and with limited exceptions from quarantine.

Effective October 20, 2020 international students are able to enter Canada to attend school if
their learning institution has a COVID-19 readiness plan that has been approved by their respective provincial or territorial government and the local health authority, and posted on a website managed by Immigration, Refugees and Citizenship Canada.

Enforcement:
PHAC undertakes compliance and enforcement to ensure that travelers are abiding by the requirement to isolate/quarantine for 14 days. In those instances, where compliance cannot be confirmed, PHAC refers these travelers to the RCMP for compliance follow-up. 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* gives 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 (this does not apply in AB, SK and the territories, as these jurisdictions have not signed on to the contraventions regime).

Travel Advisories

The Government of Canada's current travel advice to all Canadians is to avoid all non-essential travel outside of Canada (Level 3) and to avoid all cruise ship travel (Level 3). Although this travel advice is not binding on Canadians choosing to travel abroad, some travel insurance providers no longer cover travel booked on or after March 13, 2020, when these advisories came into effect.

Using a gradual and phased approach to updating travel health advisory levels for countries that are at a decreased relative risk may reduce the risk of transmission and importation to Canada but will not fully eliminate it. For example, travelers can be exposed while in transit and/or in areas reporting low or no COVID-19 transmission.

U.S. PROPOSAL TO ALLOW BULK IMPORTS OF PRESCRIPTION DRUGS FROM CANADA

SYNOPSIS

- On October 1, 2020, the United States published the final rule on the *Importation of Prescription Drugs*. The rule comes into effect on November 30, 2020, and creates a pathway for licensed U.S. pharmacists or wholesalers to import in bulk certain prescription drugs intended for the Canadian market. The rule could worsen the existing problem of drug shortages in Canada and put the health of Canadians at risk.

POTENTIAL QUESTION

- What is the Government doing to protect Canada's drug supply from U.S. bulk importation schemes?

KEY MESSAGES

- Ensuring that Canadians have access to the medicines they need is a top priority for our Government.

- Canada's drug market is too small to meet the demand for prescription drugs of both Canadian and American consumers.

- Our government will employ all necessary measures to safeguard the drug supply, preserving access to needed drugs for Canadians.

IF PRESSED ON POSSIBLE INCREASED DRUG PRICES FOR CANADIANS DUE TO THE U.S. RULE

- We do not expect that the U.S. rule will lead to increased drug prices for Canadians. The Government of Canada is committed to improving Canadians' access to, and the affordability of, necessary prescription medicines.

- Canadians are protected from excessive prices for patented medicines through the Patented Medicine Prices Review Board. This protection will remain in place and we will

continue to work with key partners to ensure all Canadians have access to the medicines they need.

BACKGROUND

U.S. Rule on the Importation of Prescription Drugs

On September 24, 2020, the final rule for the U.S. regulatory proposal on the *Importation of Prescription Drug*s was published. When the rule comes into effect on November 30, 2020, it will create a pathway for licensed U.S. pharmacists or wholesalers, working within a state-sponsored program approved by the U.S. Food and Drug Administration (US FDA), to import in bulk certain prescription drugs intended for the Canadian market. Under this plan, eligible drugs must be FDA- and HPFB-approved drugs labeled for sale in Canada, with exclusions for higher risk drugs. The Canadian seller must be licensed by Health Canada for wholesaling, be registered with a provincial authority, and must also be registered with the FDA. The importer must submit a pre-import request to the FDA at least 30 days in advance of product entry and arrival into the U.S. The program allows only a direct supply chain of one manufacturer, one Canadian seller and one importer for each imported drug.

If prescription drugs intended for the Canadian market were to be imported into the U.S. in bulk, it could further exacerbate the existing problem of drug shortages in Canada, putting the health of Canadians at risk.

On March 9, 2020, the Government of Canada submitted comments during the U.S. consultation process to publicly document Canada's opposition to the proposed rule, given that it is not deemed to be an effective solution to high drug prices in the U.S. and that it could exacerbate drug shortages in Canada. The comments also made it clear that the Government of Canada will take the necessary measures to safeguard Canada's drug supply.

There is state support for bulk importation programs of prescription drugs from Canada. Florida, Colorado, Maine, Vermont, New Hampshire and New Mexico have already enacted legislation to authorize such a program, and 18 other states have similar legislation in progress. The Department of Health and Human Services confirmed that, as of September 24, 2020, no state had submitted a formal importation plan for U.S. FDA review, but that there had been expressions of interest.

There are two key limitations to prescription drug importation in the U.S. rule. First, the U.S. legislation excludes certain categories of drugs from importation under these programs (e.g., controlled substances, biologics, infused drugs, intravenously injected drugs, and drugs inhaled during surgery). Second, the legislation only allows drugs to be imported if there will be a cost savings to U.S. consumers. The variance in price differences between both countries, as well as between states in the U.S., makes it difficult to predict which drugs would be imported until individual states propose their pilot programs.

Industry and patient advocacy groups are calling on the Government to “act swiftly, firmly and publicly” in response to U.S. plans. Large industry players, representing 90-95% of pharmaceutical distribution in Canada, have indicated that they do not intend to participate when the U.S. proposal is in place. However, there is the potential for smaller players in the market to participate, and any industry uptake could have an impact on the Canadian drug supply.

COVID Alert app and Privacy

SYNOPSIS

- In response to the global pandemic, the Government of Canada turned to digital solutions to help reduce the spread of the virus. Specifically, an exposure notification app (COVID Alert) was developed to help address the pandemic in Canada.

POTENTIAL QUESTION

- What is the Government doing to ensure COVID Alert will protect Canadians' privacy?

KEY MESSAGES

- The government is committed to protecting the privacy of Canadians, while taking appropriate steps to reduce the spread of COVID-19.

- COVID Alert has been thoroughly reviewed to ensure it is privacy protective.

- The Privacy Commissioner of Canada indicated that he support the use of COVID Alert.

- As provinces onboard and functionalities are added, the privacy analysis is adjusted and updated. We also ensure that the Office of the Privacy Commissioner is continually updated and briefed on any changes being considered.

IF PRESSED…

- The COVID Alert app does not disclose the identity of users, nor is location data or personally identifiable information collected.
- Strong governance and oversight is being put in place for this collaborative initiative, which will help to promptly address any issues as they arise to ensure broad adoption of the app by Canadians.

IF PRESSED ON ANDROID LOCATION TRACKING…

- Android 11 no longer requires the location setting to be on for Bluetooth technology to work.

- To use Bluetooth scanning, Android phones 6 to 10 need the Location setting on for all apps. However, COVID Alert has no way of knowing where you are, and does not use location tracking.

BACKGROUND (NOT FOR PUBLIC USE)

COVID Alert Exposure Notification App

- In an effort to reduce the spread of the COVID-19 virus, while also gradually easing restrictions on individuals and allowing the economy to being to re-open, the Government of Canada committed to launching a single national COVID-19 exposure notification app (COVID Alert).

- Health Canada, with support from the Canadian Digital Services and Innovation, Science and Economic Development Canada, developed the COVID Alert exposure notification app as a minimally intrusive approach intended to be used in combination with and in support of current public health measures.

- COVID Alert serves to notify app users if they have been near someone who has tested positive for COVID-19 and is also using the app, and to encourage them to take appropriate steps and adjust their behaviour to avoid putting others at risk.

- The COVID Alert app has undergone a privacy assessment in line with the Office of the Privacy Commissioner's (OPC) *Framework for the Government of Canada to Assess Privacy-Impactful Initiatives in Response to COVID-19.* The OPC was consulted on the app and published their review of the app on their website.
- Ontario began providing the one-time keys on July 31, 2020 followed by Newfoundland and Labrador on September 3, 2020, New-Brunswick and Saskatchewan on September 18, 2020, Manitoba on October 1, 2020, Quebec on October 5, 2020, Prince Edward Island on October 8, 2020 and Nova Scotia on October 15, 2020. Health Canada is working with the other provinces and territories to have COVID Alert implemented in all jurisdictions.

SUPPLEMENTARY ESTIMATES (B) 2020-21
CANADIAN INSTITUTES OF HEALTH RESEARCH

SYNOPSIS

- As a result of Supplementary Estimates (B) 2020-21, CIHR's overall available authorities for 2020-21 will increase by approximately $250 million to a total of approximately $1.6 billion.

QUESTION

- Why is CIHR seeking an increase in its authorities for 2020-21?

KEY MESSAGES

- The Supplementary Estimates (B) 2020-21 include a proposed increase of $250 million for the Canadian Institutes of Health Research—or CIHR.

- The government is making a total investment of $144.2 million in medical countermeasures, funding meritorious research proposals which were submitted through CIHR's Phase II COVID-19 Rapid Response competition, as well as to launch a Phase III funding competition to address current and emerging knowledge research gaps.

- The government's commitment to students and youth impacted by COVID-19 includes an investment of $87.5 million for eligible recipients of CIHR funding to ensure the continuity of the research enterprise and the health research pipeline during the disruptions caused by the COVID-19 pandemic.

- On behalf of the COVID-19 Immunity Task Force, PHAC provided $12.4 million to support meritorious research projects aligned with its mandate.

- PHAC is transferring $3.2 million for the Canadian Immunization Research Network (or CIRN) to support urgent

activities related to COVID-19 vaccine clinical trials and to provide vaccine-related research outcomes that will inform effective, equitable and timely COVID-19 public health decision-making.

- As part of the *Safe Restart Agreement*, PHAC is providing $1.2 million to collect data through a COVID-19 module by the Canadian Longitudinal Study on Aging, adding to federal investments in testing, contact tracing and data management.

BACKGROUND

(In $ millions)	Vote 1 Operating Expenditures [1]	Vote 5 Grants	**Subtotal**	Statutory Items[2]	**Total**
Authorities to Date	61.0	1,188.6	**1,249.6**	119.6	**1,369.2**
Supplementary Estimates (B)	0.2	27.4	**27.6**	222.5	**250.1**
Proposed Authorities to Date	***61.2***	***1,216.0***	***1,277.2***	***342.1***	***1,619.3***

[1] *Includes salary and other operating.*
[2] *Includes statutory authorities pursuant to the Public Health Events of National Concern Payments Act* and *Contributions to employee benefit plans.*

Supporting research for medical countermeasures (votes 1b and 5b)

The Government of Canada, through the CIHR, is invested approximately $144.2 million in order to continue delivering an immediate and scientifically rigorous research response to the remaining key research gaps. From this investment, a total of $133.7 million must be expensed by December 31, 2020 under the *Public Health Events of National Concern Payments Act*.

The remaining $10.5M is distribute between $10M through vote 5b and $500K through Vote 1b.

Supporting students and youth impacted by COVID-19

To lessen the impact due to COVID-19 on students funded through research grants, CIHR will has provided $87.5 million in additional funding to eligible grant recipients.

This additional funding to support trainees (students, postdoctoral fellows) and research support personnel paid through grants recognizes the need to continue supporting their salaries and stipends. This funding will contribute to the continuity of the research enterprise and the health research pipeline during the disruptions caused by the COVID-19 pandemic.

This was accessed through the statutory authorities under the *Public Health Events of National Concern Payments Act*.

Supporting projects aligned with the COVID-19 Immunity Task Force (vote 5b)

$12.4 million is being provided to the Canadian Institutes of Health Research (CIHR) to support 22 meritorious projects submitted to its May 2020 rapid response funding opportunity which are aligned with the mandate of Canada's COVID-19 Immunity Task Force. By providing a more precise picture of immunity in the country and by collaborating within networks, Canadian researchers will contribute to make important contributions to understanding and responding to the SARS-CoV-2 virus.

Supporting the Canadian Immunization Research Network (CIRN) (vote 5b)

$3.2 million was allocated to CIRN through PHAC. With this funding, CIRN will address four research areas including COVID-19 vaccine clinical trials, population prioritization and modeling, vaccine hesitancy and uptake, and coordination and information sharing.

Supporting the Safe Restart Agreement

$1.2 million is being provided in statutory funding to support the implementation of a COVID-19 module to collect data using the Canadian Longitudinal Study on Aging (CLSA) platform. This module and the CLSA platform will provide a unique opportunity for researchers to access data relevant to COVID-19 that can help assess urgent issues and the long-term impact of the pandemic on older Canadians.

This will be accessed through the statutory authorities under the *Public Health Events of National Concern Payments Act*.

Other Transfers Included in the Supplementary Estimates (B)

To CIHR (Vote 5b):

- $1.0 million from NSERC and SSHRC to increase innovation through partnerships between Canadian colleges, universities and local companies.
- $1.0 million from the Department of Health for research to support the assessment of the impact of supervised consumption sites on public health.
- $94,000 from the Department of Indigenous Services to support Indigenous Gender and Wellness Development Grants.

Internal Transfer:

- $250,000 in internal reallocation of resources from Grants for Research Projects and Personnel Support program to the Institute Support Grant program.

From CIHR:

- $377,553 from CIHR to the Department of Veterans Affairs to support research on the potential therapeutic benefits and harms associated with cannabis.

- $169,000 from CIHR and various organizations to the Treasury Board Secretariat to support the Government of Canada Financial and Materiel Management Solution Project (vote 1b).

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 and research that will tell us how widely the virus has spread in Canada and provide reliable estimates of potential immunity and vulnerabilities in Canadian populations.

POTENTIAL QUESTIONS

- Who will be doing the testing?
- When will the results become available?
- 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?
- How will research projects be chosen for funding under the COVID-19 Immunity Task Force?

KEY MESSAGES

- The Government of Canada established the COVID-19 Immunity Task Force to determine how widespread COVID-19 infection is in the Canadian population.

- We are allocating up to $300 million for this work over the next two years.

- Our understanding of the potential levels of immunity in our population and in groups at higher risk of infection, such as health care workers and older Canadians, supports our public health response.

- On September 8, initial results from a study of blood donors showed very low rates of exposure to the virus.

- This indicates that, overall, Canadians remain susceptible to COVID-19 infection.

- As cases occur across the country, we will use this data and evidence to inform our work to prevent the spread of COVID-

19 in Canada.

- The COVID-19 Immunity Task Force is also actively contributing to, and benefiting from, international research and evidence.

IF PRESSED …

- The membership of the COVID-19 Immunity Task Force includes partners from provincial and territorial Ministries of Health, as well as experts from across the country.

- The Task Force website hosts a web portal called “Sero-Tracker”, that summarises serological studies from around the world.

- Other organisations across the country are all actively contributing their testing results to the larger national data.

- The Public Health Agency of Canada is providing scientific expertise, and is collaborating with Public Services and Procurement Canada to purchase thousands of serological test kits for researchers and provincial laboratories.

BACKGROUND

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 helps determine the extent of COVID-19 infection among those who did not seek health care either because they were asymptomic or had mild symptoms that did not require health services.

Targeted sero-surveys on the levels and trends in immune status amongst specific groups can help to direct proactive preventive efforts with vaccines and disease-modifying or even disease-preventing therapies should they become available, and inform targeted surveillance efforts to contain and stop further outbreaks.

The COVID-19 Immunity Task Force, a pan-Canadian consortium for COVID-19 serology surveillance and targeted research studies, has been 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 and unique populations across Canada.

This work will also contribute to what is happening globally, for example, as part of the World Health Organization's Solidarity II Studies, a global initiative that provides standardized protocols and pools findings from large-scale antibody studies around the world.

The COVID-19 Immunity Task Force website provides details of activities and findings, connects and engages scientists within Canada and globally, and links with 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 pandemic.

The COVID-19 Immunity Task Force is actively interacting with various groups to ensure representation and input, including an Indigenous Advisory Circle, Federal, Provincial and Territorial Chief Medical Officers of Health, and the Canadian Institutes of Health Research.

EARLY HISTORY (WARNINGS AND STEPS TAKEN) IN COVID-19

SYNOPSIS

Canada first became aware of a respiratory illness originating in Wuhan, China via a GPHIN report received on December 31, 2019. Precautionary steps were taken as Canada sought additional information, and progressive escalation followed Canada's first presumptive case.

POTENTIAL QUESTION

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

KEY MESSAGES

- The Government of Canada was alerted to an illness in Wuhan, China on December 31, 2019.

- Within two days the Chief Public Health Officer alerted Medical Officers of Health across the country.

- Between that point and Canada's first presumptive case of COVID-19 in late January, the Government took several steps to respond:

    - Canadian Ministers of Health and Chief Medical Officers of Health were convened;
    - Screening processes were implemented at airports; and
    - A travel alert was issued.

- Timely intelligence gathering, in collaboration with domestic and international partners, allowed early and coordinated action by the Government of Canada to protect the health and safety of Canadians.

IF PRESSED…

- The Public Health Agency of Canada has taken many steps to give Canadians the information they need quickly
- The Public Health Agency of Canada has directly addressed the questions and concerns of tens of thousands of

Canadians on various aspects of COVID-19 since the beginning of January.

- In January, the Agency launched a website and opened a 1-833 number for the public to ask questions about COVID-19.

- As the situation evolves, we will continue to provide Canadians with accurate and up-to-date information.

BACKGROUND

Canada first became aware of a respiratory illness originating in Wuhan, China via a Global Public Health Intelligence Network (GPHIN) report received on December 31, 2019. This information was shared by the Chief Public Health Officer on January 2, 2020 with all provincial and territorial Chief Medical Officers of Health.

The World Health Organization (WHO) posted its first event notification on January 5, 2020 regarding a cluster of pneumonia of unknown etiology reported in Wuhan, 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 online platform 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 to discuss domestic preparedness. PHAC activated its Health Portfolio Operations Centre (HPOC) 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, screening processes were implemented in international airports in Toronto, Montreal, and Vancouver for travelers arriving from China.

Progressive escalation followed Canada's first presumptive case (January 25, 2020). On January 28, 2020, PHAC escalated the HPOC from Level 2 to Level 3 to further support effective coordination of federal, provincial and territorial (FPT) preparedness and response. Critical public health emergency management infrastructure was mobilized for the COVID-19 response, including:

- First meeting of FPT Ministers of Health on January 24;
- First meeting of FPT Special Advisory Committee on COVID-19 on January 28, 2020; and
- First meeting of G7 Ministers of Health on 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 travelers from the Province of Hubei, China (February 9, 2020).

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

EVOLUTION OF COVID-19 SCIENCE

SYNOPSIS

The Public Health Agency of Canada recognizes the continually evolving evidence and understanding related to COVID-19, and develops guidance based on the best current scientific knowledge, expert opinion and public health practices.

POTENTIAL QUESTION

How does the federal government evaluate emerging scientific evidence related to the COVID-19 pandemic, and how does it decide when to change guidance provided to Canadians?

KEY MESSAGES

- Our understanding of the virus evolves as new scientific evidence becomes available.
- Canadian public health guidance related to COVID-19 will also evolve, based on new evidence.
- The Government of Canada continually reviews and evaluates the latest scientific evidence as it becomes available, working with scientific experts and other partners across the country and around the world.
- When we determine that the body of evidence has gained sufficient credibility, and is accepted by the scientific community, we update our advice and guidance as quickly as possible, often in collaboration with provinces and territories.
- Provinces and territories also develop guidance for their own jurisdictions which may differ, reflecting regional circumstances in response to the pandemic across the country.

BACKGROUND

In Canada, and around the world, researchers are actively investigating all aspects of the novel coronavirus causing COVID-19. Although our knowledge of COVID-19 is

continually growing, it is incomplete, and we will keep learning more as the science continues to evolve. Canada's public health advice will continue to be based on science, which will help ensure the health and safety of the Canadian population in the face of this unprecedented pandemic.

To support the global pandemic response, Canada's research and scientific communities have been mobilized to advance research and technology development. Through the Canadian Institutes of Health Research (CIHR) Rapid Research Response program, the Government of Canada has invested a total of $54.2 million to support 99 research teams from across the country.

Furthermore, CIHR, in partnership with Public Health Agency of Canada (PHAC), is leveraging the existing Canadian Immunization Research Network (CIRN) to address the COVID-19 pandemic. CIRN has received $1 million through a direct grant to gather data related to COVID-19 symptoms, as well as possible treatments and risk factors, which will inform Canada's public health response to COVID-19.

PHAC is an active participant in a number of expert groups that are examining how the disease is transmitted, developing models to predict how it may spread, and developing guidance for infection prevention and control based on the most recent information.

PHAC continues to liaise with international partners, including the World Health Organization (WHO), to better understand the epidemiology of this disease.The WHO continues to update and modify its recommendations to public health decision-makers based on emerging evidence and data. PHAC, along with provincial and territorial counterparts and dedicated experts, are reviewing the WHO's recommendations to consider how they can further support Canada in providing the best and latest evidence-informed advice to Canadians so that they can protect themselves and each other. The WHO guidelines are only one of many resources that inform Canada's guidance.

We are also closely following the emerging scientific literature and the experiences of other jurisdictions. Their work enables Canada to continue doing risk-based analysis and making evidence-informed decisions.

Exposure Notification Mobile App

SYNOPSIS

On July 31, 2020, the Prime Minister announced that COVID Alert, a voluntary national exposure notification app, is available for download. The app uses Bluetooth and mobile technology to notify users that they have been in close contact with someone who later tested positive for COVID-19.

COVID Alert is a collaboration between Health Canada, the Canadian Digital Service, Innovation, Science and Economic Development Canada, and the Ontario Digital Service. It builds upon an exposure notification solution developed by Shopify volunteers in coordination with the non-profit Linux Foundation Public Health. It is also the work of a team of developers from across the country.

While the app is national in scope, provincial and territorial health authorities are responsible for providing the one-time keys to users who test positive for COVID-19. The one-time keys can then be entered into the app to notify users of a possible exposure. Eight provinces have onboarded and are able to issue one-time keys:

- Ontario on July 31, 2020
- Newfoundland and Labrador on September 3, 2020
- Saskatchewan and New Brunswick on September 28, 2020
- Manitoba on October 1, 2020
- Quebec on October 5, 2020
- Prince Edward Island on October 8, 2020
- Nova Scotia on October 15, 2020

Health Canada is working with the other provinces and territories to have COVID Alert implemented in all jurisdictions.

POTENTIAL QUESTION

- Why did the Government of Canada develop and implement an exposure notification app?

KEY MESSAGES

- The COVID Alert app is part of a suite of tools and guidance developed by the Government of Canada to help slow the spread of COVID-19.

- Since its launch, more than 4.9 million Canadians have downloaded the app and more that 2,876 users who tested

positive for COVID-19 have notified others of a possible exposure.

- The app uses strong measures to protect the privacy and confidentiality of any data it collects.

- We encourage Canadians to use this app, as it will keep our friends, neighbours, and communities safe.

IF PRESSED ON APPROACH CHOSEN

- A national approach supports cross-border towns and interprovincial travel.

- The approach chosen was an exposure notification app as opposed to contact tracing as it allows for user to be notified of a possible exposure without using personally identifiable data or location tracking.

- The decision to develop the app using Apple and Google's Exposure Notification Framework was based on international experiences and advice from IT and security and privacy experts.

- Several other countries that used different frameworks have run into technical (e.g., battery drain), security and privacy issues.

IF PRESSED ON UPTAKE

- Evidence has shown that exposure notification apps can have a positive impact at all levels of uptake.

- The more people who use the app, the more effective it will be.

- As Canadians begin to move more freely across Canada, we

are confident they will see the value in this app in helping them to modify their behaviour and limit the spread of COVID-19.

- We are continuing to implement a robust public awareness campaign with the goal of increasing the number of downloads.

IF PRESSED ON PRIVACY

- The protection of Canadians' privacy is a priority for the Government of Canada.

- The Office of the Privacy Commissioner of Canada continues to be engaged on COVID Alert, and supports its use by Canadians.

- The app uses Bluetooth technology, does not record users' locations and does not collect identifiable information.

- The app has undergone a thorough privacy assessment, and all data provided to the app will be securely stored and protected.

IF PRESSED ON WHEN THE APP WILL BE AVAILABLE IN ALL JURISDICTIONS

- COVID Alert is available for download to all Canadians.

- We are pleased to report that we have eight provinces onboard COVID Alert including Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, and Newfoundland and Labrador.

- The government is working with the remaining provinces and territories to have COVID Alert implemented in all jurisdictions so that all Canadians can benefit from the exposure notification app.

IF PRESSED ON B.C. DECISION NOT TO ONBOARD AT THIS TIME

- B.C. is requesting functionality changes to COVID Alert that could have privacy implications.

- While we are continuing our discussions with British Columbia to implement COVID Alert, at this time, we are unable to commit to changes that would affect the privacy of the app.

- The Government of Canada's approach is to proceed with an exposure notification app rather than a contact tracing app. Contact tracing involves using phone numbers, addresses and known locations to track down individuals who were in contact with someone who tested positive for COVID-19.

- The app is designed to complement manual contact tracing by provincial and territorial public health authorities, which will continue to be an important part of Canada's COVID-19 response.

IF PRESSED ON NOTIFICATION EXPOSURE WINDOW

- As of Oct 30, COVID Alert was updated to more closely align with current public health guidance on manual contact tracing.

- The app will now ask users who have tested positive for COVID-19 to provide the date of their symptom onset or their testing date to provide a better estimation of the period when they may have been most infectious to others.

- This means that the app will notify other app users who were in close contact with the case while they were most likely to be most infectious.

- The new features - to report testing date or symptom onset date -are optional and not required to use the app.

- COVID Alert will be continually re-assessed and updated as it rolls out across the country based on public health guidance, provincial needs and participation, user research, analysis and updates to the underlying framework by Apple and Google.

IF PRESSED ON COST

- The Government of Canada has benefited from the volunteer efforts of Shopify, which has developed the code at its own cost, and from Blackberry, which is reviewing the security of the source code on a pro bono basis.

- The bulk of the cost of this app will be to work with provinces and territories to support the integration of the app within their existing systems, and to set up the necessary systems, such as technical support, so that Canadians can use the app with confidence.

- This will be a very important tool to support Canadians as we continue restart the economy and manage increased case counts.

IF PRESSED ON EQUITY/AVAILABILITY FOR CANADIANS WITHOUT SMARTPHONES OR OLDER SMARTPHONES

- COVID Alert uses the Exposure Notification Framework (ENF) developed by Apple and Google, which requires the phone to be running Android 6.0 or later, or iOS 13.5 or later.

- With existing specifications, the app can help protect those who don't have a smartphone or who own older technology. For example, if a user receives a notification, they may decide not to visit a friend or relative.
- This means that friend or relative will be protected from potential exposure, even if they do not have the app.

BACKGROUND

On June 18, 2020, the Prime Minister announced a national exposure notification app. On July 31, 2020, the Prime Minister of Canada announced that the app, called COVID Alert, is available for download by all Canadians.

The app, originally developed by the Government of Ontario, will help Canadians and public health officials identify and isolate the spread of the virus more quickly. Use of the app will be
voluntary. If someone tests positive for COVID-19, a health care provider will give them a one-time key they can enter into the app. Other users who have downloaded the app and come in close contact with that person will then be notified, through the app, that they may have been exposed to the virus. The app will provide users with information on steps they can take to keep themselves and others safe. Health Canada is working with the provinces and territories so they can customize public health information based on their jurisdictions context.

It builds upon an exposure notification solution developed by Shopify volunteers in coordination with the non-profit Linux Foundation Public Health. It is also the work of a team of developers from across the country. The app underwent a security review by BlackBerry and the Canadian Centre for Cyber Security. It incorporates Bluetooth technology provided by Apple and Google to log instances where users have come into close contact without collecting personally identifiable information or tracking a user location. The Office of the Privacy Commissioner has been engaged on the app and the Commissioner has indicated they support the use of the app by Canadians.

Ontario began providing the one-time keys on July 31, 2020 followed by Newfoundland and Labrador on September 3, 2020, New Brunswick and Saskatchewan on September 18, 2020, Manitoba on October 1, 2020, Quebec on October 5, 2020, Prince Edward Island on October 8, 2020 and Nova Scotia on October 15, 2020. Health Canada is working with the other provinces and territories to have COVID Alert implemented in all jurisdictions.

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 continues to take 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 our Government'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.

- 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 health products making false or misleading claims related to COVID-19 and has issued compliance letters to multiple companies directing them to immediately stop selling such products and remove references to these products from their websites.

- 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.

IF PRESSED…

- Health Canada has followed up on numerous 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

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. For example, in April 2020, Health Canada inspectors, in collaboration with the RCMP, seized over 1500 unapproved COVID-19 test 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.

FEDERAL/PROVINCIAL/TERRITORIAL PUBLIC HEALTH RESPONSE PLAN FOR ONGOING MANAGEMENT OF COVID-19

SYNOPSIS

On August 25, 2020 the Federal/Provincial/Territorial Public Health Response Plan for Ongoing Management of COVID-19 was published on the Canada.ca website to promote a long-term approach to the COVID-19 response.

POTENTIAL QUESTION

What is new or different about this Plan?

KEY MESSAGES

- Canada's COVID-19 response has been unprecedented, with rapid implementation and public adoption of public health measures.

- The Federal/Provincial/Territorial Public Health Response Plan for Ongoing Management of COVID-19 was developed to help federal, provincial and territorial public health officials, Indigenous partners, and other stakeholders plan for the long-term management of COVID-19 in Canada.

- The plan reflects the need to manage this pandemic in a balanced way to support a long-term, sustainable response.

- It is intended to stimulate active planning, and the review of current response efforts and our system capacity.

- This plan may be adjusted as our scientific knowledge increases, the epidemiological picture evolves, and new technologies and treatments become available.

IF PRESSED ON REASONABLE WORST CASE SCENARIO

- The plan includes a "reasonable worst case scenario" for planning purposes in order to prepare for different possible scenarios, including those that are less likely.

- It is provided as a possible scenario, and is not a prediction.

BACKGROUND

The Federal/Provincial/Territorial (FPT) Public Health Response Plan for Ongoing Management of COVID-19, drafted by the Public Health Agency of Canada and approved by the FPT Special Advisory Committee, acknowledges jurisdictional roles and responsibilities, identifies when national approaches are anticipated and when provincial/territorial (P/T) flexibility and customization are expected.

Key elements of this F/P/T plan include: goals and objectives that are aimed at mitigating both the health and societal impacts of the pandemic, planning assumptions, a reasonable worst case scenario and summaries of current and planned response activities for each main component of the public health response (which include: surveillance, laboratory response activities, public health measures, infection prevention and control and clinical care guidance, vaccination, international border and travel health measures, health care system infrastructure, risk communications and research). There is also content specifically addressing planning with Indigenous Communities, planning for high-risk settings and populations, and the role of modelling in the response.

Much like other technical guidance, this document may require updating as our scientific knowledge of the SARS-CoV-2 pathogen increases, the epidemiological picture evolves in Canada and globally, pandemic control measures change, and new medical countermeasures become available (e.g., a vaccine, effective treatment).

GLOBAL PUBLIC HEALTH INTELLIGENCE NETWORK (GPHIN)

SYNOPSIS

The Globe and Mail has published a series of articles critical of the Public Health Agency of Canada's early response to COVID-19, and focussed on what it describes as the decline of the Global Public Health Intelligence Network (GPHIN). In response, the Minister of Health has ordered an independent review of GPHIN.

POTENTIAL QUESTIONS

- What is the Government of Canada doing to respond to concerns about Canada's pandemic warning system?

KEY MESSAGES

- The Government of Canada is committed to scientific excellence and I am committed to ensuring this country has an effective early warning system for potential emergencies – including pandemics.

- That is why, in the coming weeks, I will launch an independent review of Canada's global public health monitoring system.

- To be clear, the Global Public Health Intelligence Network was never shut down, and GPHIN continues to play an important role in the response to COVID-19.

- The results of the review will help inform future decisions around Canada's global public health monitoring system.

IF PRESSED FOR DETAILS ON THE INDEPENDENT REVEW

- We are establishing a diverse panel of professionals with the appropriate experience and expertise to conduct this review.

IF PRESSED ON THE ISSUANCE OF ALERTS

- The issuance of alerts will be examined as part of the independent review of Canada's global public health

monitoring system.

- While the number of alerts decreased in recent years, at no time has GPHIN been directed to cease or slow its information gathering and sharing activities.

- Canadian users continue to receive timely information about public health issues through a daily GPHIN report and have ongoing access to the GPHIN database. This includes federal, provincial, and territorial government officials.

IF PRESSED ON SOURCES OF INFORMATION

- GPHIN source information includes a global news database and research platform that contains nearly 33,000 sources. This includes newswires, media, publications, government sources, and medical expert forums.

BACKGROUND

GPHIN: KEY FACTS

The Public Health Agency of Canada's (PHAC) Global Public Health Intelligence Network (GPHIN) is an early-warning and situational awareness system for potential chemical, biological, radiological and nuclear public health threats worldwide, including outbreaks of infectious disease. GPHIN users include non-governmental public health agencies and organizations, as well as government authorities who conduct public health surveillance. GPHIN requires a free subscription from eligible users. GPHIN is a significant contributor to the World Health Organization's (WHO) Epidemic Intelligence from Open Sources.

GPHIN consists of two critical components:

- a professional multidisciplinary team of life science analysts conducting rapid risk assessments to detect public health threats; and
- an Information Management Tool that uses machine learning and natural language processing to facilitate the work of the analysts.

Every day, GPHIN analysts conduct their daily review of, on average, 7,000 articles in nine languages (Arabic, Farsi, English, French, Portuguese, Russian, Spanish, and simplified and traditional Chinese) to validate and assess the data for inclusion in reports, including the GPHIN Daily Report published each morning. This report goes directly from GPHIN to Canadian public health practitioners at the federal, provincial and territorial levels, including senior management at the Public Health Agency of Canada (PHAC) and other government departments.

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. There are also concerns about the health care system's capacity to cope with future waves of the virus.

POTENTIAL QUESTION

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

KEY MESSAGES

- The Government of Canada is investing more than $19 billion to support provinces and territories as they safely restart their economies, including funding to help ensure health care systems are ready for possible future waves of the virus.

- This funding includes support for vulnerable Canadians – including those in long-term care, home care, and palliative care – who are at risk of more severe cases of COVID-19, and support and protection for people experiencing challenges related to mental health, substance use, or homelessness.

- The Government is also supporting virtual care services and online screening assessments to take pressure off of emergency departments and to support physical distancing.

- The Government has invested $240 million to expand virtual care and mental health tools to support provinces and territories in their work.

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

- 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 is informing decisions on how to allocate resources.

- 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

- We know 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 balance public health restrictions with available capacity and careful tracking of resource use in hospitals (like intensive care bed use), and why the Government of Canada committed additional funding to support the safe restart of economies and health care systems.

BACKGROUND

- Provinces and territories took a range of actions to increase system capacity and meet projected needs in the early days of the pandemic. This included cancelling elective surgeries, physically reconfiguring spaces to fit more beds and create more isolation areas, and transferring patients to other settings. These measures may be revisited if capacity issues become a concern again.

- Provinces and territories 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.

- Governments have been sharing 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. While provinces and territories continue to protect capacity for COVID-19 patients, they have been reintroducing previously postponed services (e.g.

elective surgeries and procedures) to make progress against the backlogs built up during the early weeks of the pandemic. Some estimates suggest that it could take up to 24 months to address the backlogs.

Safe Restart Agreement

On July 16, the Prime Minister announced a federal investment of more than $19 billion to help provinces and territories safely restart their economies and make the country more resilient to possible future waves of the virus. New federal funding will address seven priority areas:

- enhanced capacity for testing, contact tracing, and data management and information sharing to mitigate future outbreaks;
- investments in health care to respond to the pandemic, including support for Canadians experiencing challenges with substance use, mental health, or homelessness;
- support for vulnerable Canadians – including those in long-term care, home care, and palliative care – who are at risk of more severe cases of COVID-19;
- funding to secure a reliable source of personal protective equipment, and to recover some of the costs from previous investments made by provincial and territorial governments;
- support to ensure that safe and sufficient child care spaces are available to support parents' gradual return to work;
- joint funding with the provinces and territories to support municipalities on the front lines of restarting the economy, including by putting in place precautions for public spaces and essential services to reduce the spread of the virus, as well as a dedicated stream of funding for public transit; and
- a temporary income support program that will provide workers who do not have paid sick leave with access to 10 days of paid sick leave related to COVID-19.

INTERNATIONAL ISSUES

SYNOPSIS

Since the beginning of the COVID-19 pandemic, Canada has engaged with international partners bilaterally and multilaterally, through the G7, the G20, the World Health Organization (WHO) and the Pan American Health Organization (PAHO), 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

- We remain committed to advancing a whole-of-government and multi-sectoral response to COVID-19.

- I have been engaging with my G7 counterparts on a regular 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 Germany, 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.

- We remain committed to advancing a whole-of-government and multi-sectoral response to COVID-19.

IF PRESSED on the U.S. Terminating its Relationship with the WHO

- Canada remains strongly committed to constructive engagement in multilateral institutions, including the WHO and PAHO, which are now, more than ever, essential to help us accomplish together more than any one country can do alone.

- We will continue to work with other Member States to ensure that the WHO and PAHO are strong, accountable and well-governed institutions.

- Canada has no plans to cut funding to the WHO.

IF PRESSED on U.S. Allegations of Undue Chinese Influence in WHO

- We have valued the WHO's global leadership and coordination during this pandemic, and have confidence that the organization is working with all Member States, for all Member States.

- Our continued commitment to the WHO includes our interest in making it a strong, accountable, inclusive and well-governed institution, whose actions and recommendations are guided by Member States, and the best available science and evidence.

- We will continue to participate in oversight and accountability processes to help reinforce transparency, confidence, and trust in the organization.

- As the COVID-19 situation continues to evolve around the world, Canada will continue to work closely with its international partners, including the WHO and China, to reduce risks to Canadians and the global community.

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

- As highlighted in the Resolution adopted at the World Health Assembly in May, a comprehensive post-crisis review of the global response should be undertaken when the time is right – as soon as feasible.

- We welcome the establishment by the WHO of the

Independent Panel on Pandemic Preparedness and Response, who will lead an impartial and independent evaluation of the response to the COVID-19 pandemic. We are pleased that a prominent Canadian, Dr. Joanne Liu, will be contributing her significant global health expertise and experience.

- We look forward to engaging in the process to identify important lessons learned.

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, research and recovery planning.

- Technical staff of Public Health Agency of Canada have also been engaged with their technical counterparts at the CDC since early in January to exchange information and best practices.

If pressed about the Government of Canada working with international partners on access to vaccines for all….

- Equitable, timely, and affordable access to vaccines, therapies, and diagnostics is critical for controlling and ending the pandemic. For this reason, Canada supports the work of the Access to COVID-19
- Tools Accelerator – a global collaboration to accelerate their development and deployment.

- In June 2020, Canada co-hosted the launch of the pledging event, with a commitment of $120 million. Canada is also a

member of the Accelerator's Facilitation Council in order to continue advocating for and supporting its work.

- The Government of Canada is working closely with its international partners to protect the health and safety of Canadians and the global community.

If pressed on the failure to reach G7 consensus on the WHO Roadmap

- Canada is disappointed that a consensus could not be reached on discussions toward a G7 roadmap to strengthen the WHO's role in global health emergency preparedness and response.

- Canada values the WHO's leadership and coordination role in the COVID-19 response. Our continued commitment to the WHO includes our interest in making it a strong, accountable, and well-governed institution.

- We will continue to work collaboratively with G7 partners and others around the world, as we prepare for a possible second wave of infections and to coordinate recovery efforts.

BACKGROUND

Since February, Canada has participated in regular 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.

In addition, technical staff of PHAC have engaged with their counterparts in a variety of fora, both bilaterally and multilaterally (e.g. WHO, CDC, GHSI, GOARN), to exchange information and best practices, that have informed and enhanced Canada's response to COVID-19.

<u>Research and Development</u>

Canada, through the Canadian Institutes of Health Research (CIHR), played a key role in establishing the World Health Organization (WHO) global research and innovation

roadmap on COVID-19. CIHR is also supporting the Canadian Treatments for COVID-19 Trial (CATCO), which is contributing to the WHO SOLIDARITY trial seeking to find effective treatments for COVID-19. Further, CIHR's Scientific Director of the Institute of Infection and Immunity currently co-chairs the Global Research Collaboration for Infectious Diseases (GloPID-R), which continues to be a key hub in facilitating the fast-moving collaboration that is needed across a multiplicity of players domestically and internationally.

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 launch of the Coronavirus Global Response. At the initial event, Canada pledged over $850 million towards the fundraising target of $8 billion USD to support the development of rapid coronavirus diagnostics, treatments and vaccines. At the closing event of the campaign on June 27, Canada pledged an additional $120M for the Access to COVID-19 Tools Accelerator – a global collaboration between governments, scientists, businesses, philanthropists and global health organizations to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines. As of July 12, 2020 $17.9 billion USD, more than twice the original target amount, has been pledged. Canada is also a member (represented by Minister Gould) of the recently launched Facilitation Council for the Accelerator, which will provide support for its work through political leadership, advocacy, and mobilization of additional resources.

World Health Organization (WHO)

As a founding member, Canada has long been a strong supporter of the 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. With the Region of the Americas at the epicenter of the pandemic, Canada continues to support the WHO regional office of the Americas (PAHO)'s critical coordinating and technical role in responding to the health challenges that the region is facing.

On April 14, 2020, U.S. President Donald Trump announced that the U.S. would 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. This did not apply to the U.S.' assessed contributions due to PAHO.

Subsequently on May 29, 2020 President Trump announced that the U.S. was terminating its relationship with the WHO and would look to divert the funding allocated to the organization elsewhere. On July 7, 2020, the White House provided the Secretary-General of the United Nations with formal notice of its intention to withdraw from the WHO. The withdrawal will become effective as of July 6, 2021, barring any

further developments.

Canada has consistently expressed support for an independent, comprehensive review of the global response post-crisis, which would consider the actions of all actors and partners, including the WHO, to be undertaken at an appropriate time.

At the 73rd session of the World Health Assembly (WHA), which convened virtually on May 18-19, 2020, Canada co-sponsored a resolution on COVID-19, which provides a consensus-based foundation for next steps in the global COVID-19 response and includes a call to initiate, at the earliest appropriate moment, an independent, comprehensive review of the WHO-coordinated international health response to COVID-19.

As follow up to the resolution on July 9, 2020, the Director General of the WHO announced the creation of the Independent Panel on Pandemic Preparedness and Response (IPPR), co-chaired by former New Zealand Prime Minister and UNDP Administrator Helen Clark, and former President of Liberia Ellen Johnston Sirleaf. The IPPR will be responsible for taking forward the independent evaluation called for in the WHA resolution. Terms of reference will be developed in the coming months. Canadian physician and former president of MSF International, Dr. Joanne Liu, was selected as one of the eleven panelists by the IPPR co-chairs in September 2020.

On August 3, 2020, the Director-General announced that the WHO advance team that traveled to China to work with Chinese counterparts to prepare plans for identifying the zoonotic source of the SARS-CoV-2 virus had concluded their preliminary mission. As a result, WHO and Chinese experts have drafted the Terms of Reference for the studies and programme of work that will be undertaken by a WHO-led international team.

In May 2020, 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, 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.

INTERSECTION OF COVID-19 AND SUBTANCES USE

SYNOPSIS

- Tragically, the COVID-19 pandemic is exacerbating long-standing challenges regarding substance use and the overdose crisis, with many communities now reporting increases in overdose deaths and harms, to record breaking levels in some cases. In addition to the dangers of COVID-19, people who use drugs are also facing additional barriers and risks related to the toxicity of the illegal drug supply and reduced access to health and social services, including life-saving harm reduction and treatment.

POTENTIAL QUESTION

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

KEY MESSAGES:

- Tragically, over the past few months, the COVID-19 pandemic has exacerbated long-standing challenges regarding substance use and the opioid overdose crisis, with devastating impacts for people, families, and communities across the country. Many jurisdictions are reporting increases in overdose deaths and harms, including record breaking levels in British Columbia and other jurisdictions.

- At the outset of the COVID-19 pandemic, the Government took action to enable the health system to better meet the needs of people struggling with problematic substance use and avert the harms associated with the increasingly toxic supply of street drugs that has been made even worse by the impacts of the COVID-19 pandemic.

- To date, we have made it easier for people with substance use disorder to access the medications they need and have also made it easier for overdose prevention sites to be established rapidly in temporary community shelters and other locations.

- 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. We remain committed to working closely with our provincial, territorial, and municipal partners, along with other key stakeholders, to advance innovative solutions to address this devastating dual crisis.

IF PRESSED ON FURTHER ACTIONS

- Building on these early efforts, the Government is also supporting community-based projects funded under the Substance Use and Addictions Program that address the dual crises of COVID-19 and substance use, including those that provide safer, pharmaceutical grade alternatives to the toxic illegal drug supply.

- Given the deeply worrying data about the surge in overdose deaths and growing concerns about the impact of the pandemic, the Government is identifying additional areas where federal actions, including exemptions, guidelines or funding, could help mitigate and reverse the current trend, including ways to address urgent needs and strengthen the continuum of care.

IF PRESSED ON IMPACT OF COVID-19 ON OVERDOSE DEATHS

- The Government of Canada remains deeply concerned about the devastating impact that the opioid overdose crisis continues to have on people, families and
- communities across the country. There is further concern that the response to the COVID-19 pandemic may have unintended negative consequences, including as it relates to opioid-related overdose deaths and problematic substance use in Canada more broadly.

- The British Columbia Coroners Service has reported alarming data showing record numbers of illicit drug toxicity deaths in the province. There were over 170 illicit drug toxicity deaths per month from May to July, with a record 183 in June. Deaths have remained high into the fall, with 127 deaths recorded in September 2020, compared to 60 deaths in September 2019. In total, from March to September 2020, there were 1,048 suspected illicit drug toxicity deaths in B.C. To put this in perspective, this is approximately four times the total number of persons who have tragically died in B.C. from COVID-19. B.C. paramedics responded to over 1,603 overdose calls in August. Tragically, overdose deaths among First Nations people in B.C. have also surged, almost doubling between January and May 2020 compared to 2019.

- Other jurisdictions across the country are reporting similar trends. For example, Alberta reported a record high 301 opioid poisoning deaths from April-June 2020, more than double the number that occurred from January-March. Saskatchewan is reporting 296 suspected/confirmed

drug toxicity deaths so far in 2020, breaking the record total in 2018, and, in Quebec, July saw the highest number of overdoses in Montreal in over five years.

- The Government of Canada remains committed to addressing the crisis of opioid-related overdoses and continues to work to identify ways to maintain lifesaving supports, including treatment and harm reduction services for people who use drugs.

IF PRESSED ON RESEARCH FUNDING

- On April 23, our Government announced new funding for COVID-19 research, including $10 million for the COVID-19 and Mental Health Initiative, led by the CIHR. Under this research initiative, CIHR is supporting rapid research on mental health and substance use to ensure that COVID-19 responses are based on the latest evidence. Last month, CIHR granted funding to 45 research teams across the country to conduct rapid knowledge synthesis of current evidence on mental health and substance use, with a focus on priority and vulnerable populations. Preliminary results from this research are now available and provide timely, high quality, and relevant evidence to decision makers at municipal, provincial, territorial, and federal levels.

- Under the COVID-19 and Mental Health Initiative, CIHR also launched – in partnership with four provincial research agencies – a funding opportunity to better understand mental health and/or substance use needs of individuals and communities due to the pandemic, and support the development of innovative adaptations of mental health and substance use services.

- Through the Canadian Institutes of Health Research (CIHR) and the Canadian Research Initiative in Substance Misuse (CRISM), national guidance documents have been produced and disseminated that address the needs of people who use drugs, services providers, and decision makers in relation to COVID-19.

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 September 2, 2020, we proactively took steps and extended the exemptions 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. These exemptions have been extended to September 2021.
- 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 THE INTERSECTION OF SUBSTANCE USE AND COVID-19

- On July 16, 2020, the Government of Canada committed to providing $500 million to address immediate needs and gaps in the support and protection of people experiencing challenges related to mental health, substance use, or homelessness. This investment is part of the more than $19 billion invested through the Safe Restart Agreement to help provinces and territories safely restart their economies and ensure Canadians have the support they need in these challenging times.
- Budget 2019 committed $30.5 million over 5 years, starting in 2019–20, with $1 million in ongoing funding, to address persistent gaps in harm reduction and treatment in their response to problematic substance use. In July 2019, we announced an additional investment of $76.2 million to scale up key life-saving measures, help circumvent the toxic illegal drug supply, and identify and address emerging drug threats.

- Recent investments made through Health Canada's Substance Use and Addictions Program (SUAP) 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.

- For example, 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.

- Furthermore, we are supporting community-based projects funded under SUAP by allowing funds to be re-directed to support immediate COVID-19 related needs, and are funding six additional projects that will provide access to safer, pharmaceutical grade medications as an alternative to the toxic illegal drug supply for people with severe opioid use disorders.

IF PRESSED ON SAFER SUPPLY

- We know that the pandemic has led to a more uncertain and dangerous illegal drug supply, even while services to people who use drugs are being limited, and we have seen the tragic increases in overdose deaths in British Columbia and elsewhere.

- The Government of Canada has taken actions to reduce barriers to providing people who use drugs with a safer, pharmaceutical-grade alternative to the toxic illegal drug supply.

- For example, we have issued class exemptions to pharmacists, and eased restrictions on the transportation of controlled substances, to make it easier for people to access the medications they need during the pandemic while following public health advice, such as physical distancing.

- In addition to the five safer supply pilot projects that we were funding through Health Canada's Substance Use and Addictions Program, we have now committed to providing short-term funding to an additional six sites to address immediate needs.

- These innovative projects will be independently evaluated and this assessment will contribute to building the evidence base to support the scaling up of effective models.

IF PRESSED ON THE OPEN LETTER CALLING FOR THE DECRIMINALIZATION OF THE PERSONAL POSSESSION OF DRUGS

- The Government of Canada is committed to a comprehensive public health approach to the overdose crisis that is focused on reducing harms, saving lives, and getting people the supports they need.

- We encourage cross-disciplinary collaboration, including the formation of partnerships between law enforcement and health and social services to help divert people who use drugs away from criminal sanctions and towards health and social services.

- The Government is not considering the decriminalization or legalization of illegal drugs at this time. We will continue to work with civil society organizations to assess options that could better support the needs of people who use drugs, during this difficult time.

- Our government's response has also included significant actions to improve access to treatment, harm reduction and social services and strengthen the public health response, such as:

    - Investing $150 million in the Emergency Treatment Fund, through Budget 2018, for provinces and territories to improve access to evidence-based treatment services; and

    - Making legislative changes to streamline the application process for supervised consumption sites, and reducing regulatory barriers for accessing a safe supply of pharmaceutical-grade medications to improve treatment.

    - Issuing guidance to public prosecutors to pursue suitable

alternative measures and diversion from the criminal justice system for simple possession cases.

THE RELEASE OF THE CANADIAN ASSOCIATION OF CHIEFS OF POLICE REPORT ON DECRIMINALIZATION

- As we fight the COVID-19 pandemic, we cannot forget the opioid overdose crisis has exacted a heavy toll on thousands of families in communities throughout the country. This crisis, now intensified by the pandemic, continues to be one of the most serious public health threats in Canada's recent history, and our Government remains committed to a comprehensive and compassionate approach to address it.

- Problematic substance use is first and foremost a health issue. That is why the actions we have taken have focused on advancing a public health approach to addressing substance use and expanding the accessibility of vital health and social services for people who use drugs.

- These actions include passing the *Good Samaritan Drug Overdose Act*, funding programs like drug treatment courts for those whose substance use contributes to their offending, supporting enhanced access to harm reduction services such as supervised consumption sites, access to pharmaceutical-grade medications, also known as safer supply, and an expanded range of treatment options.

- In July, the Canadian Association of Chiefs of Police released a report that recognizes substance use as a public health issue and examines a range of alternatives to criminal sanctions in response to the offence of simple possession. We welcome their endorsement of a holistic approach including harm reduction and diversion, and thank them for their recommendations.

BACKGROUND

In September 2020, jointly with the provinces and territories, the Government of Canada released updated data indicating that at least 16,364 Canadians lost their lives between January 2016 and March 2020 to apparent opioid-related overdoses. This most recent national data indicated that, from January to March 2020, 77% of accidental apparent opioid-related deaths involved fentanyl or fentanyl analogues, compared to 54% in 2016. The presence of fentanyl and its analogues in the illegal drug supply is therefore the main driver of recent overdose deaths.

In many regions of the country, the COVID-19 pandemic is compounding the ongoing public health crisis related to high rates of overdoses and deaths as well as acute substance use harms. In British Columbia

in September 2020, there were 127 suspected illicit drug toxicity deaths. This is more than double the number of deaths seen in September 2019 (60). The June 2020 total represented the highest number of illicit drug toxicity deaths ever recorded in a month in B.C (183). Postmortem toxicology results suggest that there has been a greater number of cases with extreme fentanyl concentrations in April-September 2020, compared with previous months. During that time period, approximately 15% of cases had extreme fentanyl concentrations as compared to 8% from Jan 2019 to March 2020. Ontario, Alberta, Saskatchewan, Manitoba, Quebec, P.E.I., Yukon, and Northwest Territories are also reporting increases in toxicity of the illicit drug supply, overdose deaths and/or emergency medical service (EMS) calls.

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 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).

On May 13, 2020, the Ministers of Health, Public Safety and Emergency Preparedness, and Justice, received an open letter from Richard Elliott, Executive Director of the Canadian HIV/AIDS Legal Network, on behalf of more than 50 civil society organizations from across Canada. The letter highlights a series of factors that increase people's vulnerabilities during the pandemic and calls on the Government to decriminalize personal use drug possession as a public health measure to mitigate harms from the parallel public health emergencies caused by COVID-19 and the ongoing crisis of overdoses and deaths. On July 9, 2020, the Canadian Association of Chiefs of Police (CACP) released their Findings and Recommendation Report entitled "Decriminalization for Simple Possession of Illicit Drugs: Exploring Impacts on Public Safety and Policing." The report positions substance use as a public health issue, and examines and endorses current best practices in harm reduction, including supervised consumption sites and safer supply projects. In the report, the CACP endorses alternatives to criminal sanctions for simple possession of illegal drugs, and recommends a national task force to recommend alternatives to criminal sanctions for the simple possession of controlled substances.

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.

- Health Canada has received formal notice from British Columbia and Quebec that they have adopted the class exemption and Saskatchewan has indicated its intention to do so. No other formal notices of implementation by provinces or territories have been received to date. Health Canada has requested to be informed if there is a decision to implement.

Disseminating information and guidance
Developed and disseminated new "tool kit", on May 5, 2020, to support service providers and PWUD to socially distance and self-isolate, and the web link was made available as of June 11, 2020:

- 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" (hydromorphone, 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 the risk of overdose death and prevent the 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.

Since April, CIHR has launched three funding opportunities under the COVID-19 and Mental Health Initiative to support rapid research on mental health and substance use in the COVID-19 context:

- *CRISM Operating grant*: CIHR is currently providing support to CRISM to undertake urgent activities related to challenges faced by people who use drugs (PWUD), service providers and decision makers in relation to COVID-19. This includes the development of six national guidance documents and a rapid assessment of the issues PWUD are experiencing during the COVID-19 crisis, and the health service interventions to support them. All six CRISM national guidance documents are now available (telemedicine for addiction services; supervised consumption and safer supply in emergency shelters; acute care services for PWUD; harm-reduction worker safety; supporting recovery services; supporting patients to self-isolate).
- *Knowledge synthesis grants:* CIHR is supporting 45 research projects to support rapid knowledge synthesis and mobilization of current evidence on mental health and substance use services, delivery, and related guidelines, in the COVID-19 context. These include projects with a focus on priority populations, including people who use drugs. Preliminary results from the knowledge syntheses are now available online.
- *Operating grants:* On June 4, 2020, CIHR launched a new funding opportunity to support implementation science and population-level intervention research to address the

impacts of the
COVID-19 pandemic and its containment measures on mental health and substance use. Four provincial health research funding agencies are partnering with CIHR on this funding opportunity: the Michael Smith Foundation for Health Research (BC), the New Brunswick Health Research Foundation, the Ontario Ministry of Health and Long Term Care, and the Saskatchewan Health Research Foundation.

LABELLING ON CERTAIN IMPORTED PRODUCTS

SYNOPSIS

- The COVID-19 pandemic has created unprecedented challenges to Canada's health care system, and there is an urgent need for products to help limit the spread of COVID-19, such as hand sanitizers and disinfectants, household and workplace cleaners, and hand and body soaps in support of the response.

POTENTIAL QUESTION

- Why did Health Canada temporarily allow English-only labelling and safety information on some imported and domestically manufactured products during the COVID-19 pandemic?

KEY MESSAGES

- Health Canada's top priority is the health and safety of Canadians, and the Department has been 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, in March 2020, Health Canada began facilitating access, on a temporary and emergency basis, to allow certain products labelled in only one official language to increase access to products in high demand.

- Health Canada proactively ended the use of unilingual labelling and require bilingual labelling:

    - As of June 8, 2020, all importers of household cleaners, cleaning products used in the workplace, hand and body soaps, hard-surface disinfectants and hand sanitizers are required to have bilingual labelling text available to consumers, employers and workers.
    - As of June 8, 2020, all Canadian manufacturers of hand sanitizers who previously used unilingual labelling are required to use bilingual labelling.

- Health Canada is aware of the concerns expressed in the recent report by the Commissioner of Official Languages and is reviewing the report's findings.

- The Department is committed to upholding the Official Languages Act and fostering linguistic duality.

IF PRESSED…

Bilingual Language Requirements for Domestic and Imported Products

- The Department is committed to upholding the Official Languages Act and fostering linguistic duality.

IF PRESSED….
Use of Unilingual Labelling During COVID-19

- In light of the unprecedented demand and urgent need for products to help limit the spread of COVID-19, in March 2020, Health Canada began facilitating access, on a temporary and emergency basis, to allow certain products labelled in only one official language to increase access to products in high demand.

- This emergency measure was in effect until June 8, 2020. The objective was to alleviate supply issues so that Canadians had access to products that help limit the spread of Covid-19.

- This has included facilitating the importation of products from countries with similar regulatory frameworks as well as the expedited approval of domestic products.

- While Health Canada facilitated access to products labelled in only one official language on an interim basis, the Department still strongly encouraged the use of bilingual labels.

- As supply of these products began to improve, and in response to Canadians' concerns about the risks associated with unilingual labelling and safety information, Health Canada proactively required all importers of these products to have bilingual labelling text available to consumers and employers and all domestically manufactured hand sanitizers to have bilingual labelling by June 2020.

IF PRESSED
Proactive removal of the Interim Policy on Unilingual Labelling

- Following the temporary and urgent need for these products, Health Canada proactively required all importers of these products to have bilingual labelling text and safety information, where required, available to consumers, employers, and workers. As of June 8, 2020, all importers were required to have bilingual label and safety information text available on their websites and a means for sellers to inform consumers, workers and employers of this website at the time of sale.

- Health Canada proactively communicated the end of this interim measure both on its website and directly to regulated parties.

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

IF PRESSED….
Commissioner of Official Languages' Report on Unilingual Labelling

- Health Canada is aware of the concerns expressed in the recent report by the Commissioner of Official Languages and is reviewing the report's findings.

- The Department is committed to upholding the Official Languages Act. Due to the unprecedented demand for products to limit the spread of COVID-19, Health Canada enacted temporary and emergency measures to ensure a sufficient and consistent supply of these products.

- Health Canada acknowledges the seriousness of the official language complaints received.

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, Hazardous Products Acts, and Canada Consumer Product Safety Act. These measures have enabled access to the Canadian marketplace, health care settings, and commercial and industrial settings.

The interim policies included:

- facilitating the importation of products that are not fully compliant with Health Canada requirements (e.g., English-only labelling, different packaging from what was authorized).
- allowing domestic manufacturers of alcohol-based hand sanitizers in unilingual regions to use unilingual labelling to expedite Canadians' access to these products

Importers of these products must have bilingual labelling text and safety information, where required, available to consumers, employers, and workers. 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.

Given the increase in availability of hand sanitizers, as of June 8, 2020, all Canadian manufacturers of hand sanitizers who previously used unilingual labels under the interim measure are required to use bilingual labelling.

Domestic manufacturers of cleaning products and hand and body soaps were not included in this interim measure. As such, Canadian companies of these products were always required to manufacture products with labels and, if required, safety data sheets in both official languages.

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

Health Canada will lift the interim measures for imported products when the regular supply chain stabilizes.

Stakeholder Engagement

Health Canada is actively engaging with stakeholders to proactively identify, engage and provide support to manufacturers, 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.

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, and United States Environmental Protection Agency to share information on best practices and evidence-based approaches for hand sanitizers and disinfectants.

LONG-TERM CARE HOMES

SYNOPSIS

Long-standing issues in supportive care, particularly long-term care, have been starkly revealed by the COVID pandemic. Tragically, in the first 7 months of the pandemic, long-term care and retirement home residents and staff represented 25% of all COVID-19 cases. Approximately 80% of all COVID-19 deaths in the country were connected to long-term care and seniors' residences.

In Fall 2020, outbreaks in long-term care facilities are on the rise. The proportion of long-term care homes with outbreaks in Ontario has tripled since early September. In Quebec, according to Montreal's regional director of public health, seniors 65 and older accounted for 6% of COVID-19 cases in mid-September, but that proportion had increased to 15% of all positive tests in October.

As of October 27, Québec and Ontario remain the most affected provinces and territories, with at least 120 known active outbreaks in LTC/assisted living facilities in Québec and 87 in Ontario, followed by Alberta (30), British Columbia (19), Manitoba (19), and New Brunswick (1). Additional outbreaks may be active across provinces and territories.

POTENTIAL QUESTION

- What is the federal government doing to support provinces and territories in addressing major issues in long-term care facilities and avoiding the results seen in the spring in long-term care facilities?

KEY MESSAGES

- The federal government is taking a number of steps to respond to the significant challenges faced by long-term care facilities across the country in order to help avoid a repeat of the experience of Spring 2020.

- The Government of Canada and provincial/territorial governments have reached a Safe Restart Agreement, supported by over $19 billion in federal investments, to help provinces and territories restart the economy, while making Canada more resilient to waves of the virus.

- This includes $740 million in funding to support our most vulnerable populations, including incremental infection prevention and control measures to protect those in long-term care, and those receiving home care and palliative care.

- The government also continues to work with the Canadian Red Cross to support provinces and territories facing outbreaks in long-term care. The Red Cross is already working closely with local authorities in order to provide assistance in outbreak situations in long-term care homes.

- We will continue taking any action we can to address challenges in long-term care institutions and support seniors while working alongside the provinces and territories. ***IF PRESSED ON ADDITIONAL SUPPORT PROVIDED BY THE FEDERAL GOVERNMENT…***

IF PRESSED ON ADDITIONAL SUPPORT PROVIDED BY THE FEDERAL GOVERNMENT…

- The Public Health Agency of Canada has provided guidance on the care of residents in long-term care, as well as infection prevention and control guidance to help prevent COVID-19 infections among residents and workers in long-term care and assisted-living facilities, as well as in home care. This guidance was developed with the National Advisory Committee on Infection Prevention and Control and endorsed by the Pan-Canadian Special Advisory Committee.

- Up to $3 billion in federal funding has been provided to support provinces and territories to increase the wages of low-income essential workers, which could include front line workers in hospitals and long-term care facilities.

- The Government of Canada adapted the *Investing in Canada Infrastructure* program to respond to the impacts of

COVID-19. A new temporary COVID-19 Resilience stream has been created to provide provinces and territories with added flexibility to use existing resources to fund quick-start, short-term projects, including health infrastructure such as long-term care homes.

- In collaboration with partners, the Health Canada-funded Canadian Foundation for Healthcare Improvement and Canadian Patient Safety Institute have launched an initiative to spread promising practices in preventing and mitigating the impact of COVID-19 on long-term care and retirement homes. The goal of the initiative is to better position participating facilities to prevent and manage any future outbreaks.

IF PRESSED ON THE SAFE RESTART AGREEMENTS…

- The Government of Canada is working to ensure that Canada has the resources it needs to restart the economy safely, while protecting the health of Canadians.

- In partnership with the provinces and territories, federal efforts will focus on priorities to address Canadians' immediate needs within the next six to eight months, including vulnerable populations.

- Canadians receiving long-term care, home care and palliative care are at an increased risk of more severe cases of COVID-19. As the economy restarts, it is important to have continued protections and supports in place for these vulnerable populations.

- Under the Safe Restart Agreement, the Government of Canada has invested $740 million to help provinces and territories to support one-time costs for measures to control

and prevent infections. This can include addressing staffing issues and providing personal protective equipment in long-term care, home care, and palliative care facilities and services. Funding can also be used to support other vulnerable populations.

- To support the restart of the economy, the Government of Canada also continues to work with provinces and territories to support procurement of personal protective equipment.

IF PRESSED ON THE SPEECH FROM THE THRONE…

- The Government announced its intention to work with the provinces and territories to set new national standards for long-term care so that seniors get the best support possible.

- The Government will also look at further targeted measures for personal support workers, who do an essential service helping the most vulnerable in our communities. Canada must better value their work and their contributions to our society.

- The Government of Canada will work with Parliament on Criminal Code amendments to explicitly penalize those who neglect seniors under their care, putting them in danger.

BACKGROUND

Reports and recommendations

Since the onset of COVID-19, a number of organizations such as the Royal Society of Canada, Ontario Long-Term Care Association and the Registered Nurses Association of Ontario, have released reports calling for action from the Government of Canada to improve the quality of care for seniors living in LTC facilities. Recommendations for the improvement for LTC include:

- increasing procurement of personal protective equipment
- addressing workforce issues (e.g. increased staffing, national human resources strategy, improved pay/benefits)
- providing capital investment to build and redevelop existing LTC homes

- developing national standards,
- enhancing data collection
- planning for management of resurgence of COVID-19
- Improving access to rapid testing

As well, the Health Canada-funded Canadian Foundation for Healthcare Improvement (CFHI) and Canadian Patient Safety Institute (CPSI) released a report in summer 2020 outlining promising practices in six key areas that have the potential to help long-term care and retirement homes prepare for possible future COVID-19 outbreaks, or mitigate their effects:

- Preparation;
- Prevention;
- People in the workforce;
- Pandemic response and surge capacity;
- Planning for COVID-19 and non-COVID-19 care; and
- Presence of family.

During Fall 2020, CHFI and CPSI are leading an initiative called LTC+ to spread these promising practices among participating long-term care and retirement homes.

Current situation and investigations in long-term care facilities

Several provinces and territories have launched inquiry processes related to long-term care facilities, including Alberta, Ontario, Quebec, Nova Scotia and Prince Edward Island. The majority of the ongoing investigations do not have set timelines for reporting results.

On September 21, 2020, Nova Scotia released its review into Halifax's Northwood nursing home, following a deadly COVID-10 outbreak in the spring. The findings and recommendations include a focus on improving infection prevention and control, reviewing and updating pandemic plans, addressing staffing challenges, and improving governance and accountability. NS will invest $26M this fiscal year and $11M over the next two years to implement the recommendations, including a robust infection prevention and control program.

On October 23, 2020, Ontario's Long-Term Care COVID-19 Commission released five initial recommendations, including: 1) increasing the supply of personal support workers and LTC staff; 2) providing more full-time positions for those workers, 3) making permanent investments for a comprehensive human resources strategy; 4) creating a minimum daily average of four hours of direct care per resident through better staff to resident ratios; and 5) ensuring that families and caregivers have ongoing, safe and managed access to LTC residents.

Families of residents in long-term care facilities have publicly reported their frustration and concern regarding how their loved ones are cared for, as well as the poor conditions in the residences. Families are calling for increased accountability and

systematic changes in how long-term care facilities are operated. A number are bringing legal action against facilities over their COVID-19 response.

Government of Canada Actions

While long-term care is primarily a provincial and territorial responsibility, including the oversight of publicly and privately operated long-term care homes, the federal government is taking a number of steps to respond to the significant challenges faced by long-term care facilities across the country in the context of the COVID-19 pandemic. These actions are laid out in the Key Messages and If pressed sections.

LTC+: Acting on Pandemic Learning Together" initiative: To help the long-term care sector share learnings and strengthen pandemic preparedness, The Canadian Foundation for Healthcare Improvement CFHI partnered with the Canadian Patient Safety Institute to launch the LTC+: Acting on Pandemic Learning Together initiative. It is based on the findings captured in their report "Reimagining Care for Older Adults: Next Steps in COVID-19 Response in Long-Term Care and Retirement Homes", and focuses on promising practices in six key areas that have shown potential to help organizations prepare for possible future outbreaks or mitigate their effects. The six areas are preparation; prevention; people in the workforce; pandemic response and surge capacity; planning for COVID-19 and non-COVID-19 care; and, presence of family. Participating teams receive seed funding from CFHI to support needed improvements, access to training sessions and materials, and coaching on the implementation of the program's key components.

To date, there have been over 90 teams that have registered/are in the process of registering to participate.

In the Speech from the Throne delivered on September 23, 2020, the Government announced its intention to work with the provinces and territories to set new national standards for long-term care so that seniors get the best support possible. The Government will also look at further targeted measures to support personal support workers.

Long-Term Care Facility Ownership Breakdown

On September 24, CIHI released a breakdown of the type of ownership of publicly funded LTC homes offering 24-hour nursing care across the country. Ownership of these facilities can be public or private. Privately owned LTC homes can be subdivided into for-profit and not-for-profit organizations.

The proportion of private and publicly owned LTC homes varies by province/territory. Overall, 54% of LTC homes in Canada are privately owned (28% for-profit, 23% not-for-profit and 3% no breakdown) and 46% are publicly owned.

Federal government ownership of long-term care facilities

Neither Veterans Affairs Canada (VAC) and Indigenous Services Canada (ISC) own any long-term care facilities,.

The last facility/hospital run by VAC was Ste Anne's Hospital in Quebec. It was transferred to the province in April 2016.

VAC now supports about 4000 Veterans in over 1150 provincially and privately owned and operated long-term care facilities across the country. This can include subsidized accommodation or meal costs or funding for facilities on an annual basis to support an enhanced level of services and specialized programs for veterans. VAC has agreements with private and public long term care facilities for the placement of veterans.

MASK-WEARING

SYNOPSIS

Current evidence supports that wearing a non-medical mask is effective in limiting the transmission of COVID-19. Scientific information on COVID-19 continues to be produced rapidly and the Public Health Agency of Canada continues to evaluate new evidence as it becomes available to inform our intervention and mitigation strategies.

POTENTIAL QUESTION

What is the Government of Canada's position on mask-wearing?

KEY MESSAGES

- Evidence indicates there are benefits to wearing non-medical masks, particularly in enclosed or crowded public spaces, or when physical distancing cannot be maintained.

- Masks are not a substitute for physical distancing – every effort should be made to maintain 2 meter physical distancing

- The Federal, Provincial, and Territorial Special Advisory Committee on COVID-19 has recommended that people wear non-medical masks or cloth face coverings as an additional layer of protection in settings where physical distancing might not be possible.

- Since the beginning of the COVID-19 pandemic, masks have been recommended for symptomatic people suspected of or confirmed to have COVID-19, to prevent transmission to others.

- Additionally, medical masks are recommended for those who are required to have direct contact with someone suspected or confirmed to have COVID-19, to protect against exposure.

BACKGROUND

In Canada, and around the world, researchers are actively investigating all aspects of the novel coronavirus causing COVID-19. Though our knowledge of COVID-19 is continually growing, it is incomplete, and we will keep learning more as the science continues to evolve. Canada's public health advice will continue to be informed based on science that will ensure the health and safety of the Canadian population in the face of this unprecedented pandemic.

Guidance related to the use of masks has evolved with emerging evidence that the virus can be transmitted by infected people before they develop symptoms of COVID-19 (pre-symptomatic transmission), and by people who never develop symptoms of COVID-19 (asymptomatic transmission).

Current evidence supports the wearing of non-medical masks or cloth face coverings in specific community situations and settings as part of a comprehensive approach to suppress SARS-CoV-2 transmission.

Studies suggest that community-wide mask wearing may contribute to the control of COVID-19 by reducing the amount of saliva and respiratory droplets emitted from infected individuals, including those who may be pre- or asymptomatic, thus reducing the risk of a healthy individual coming into contact with virus laden droplets.

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 understands the need to have a variety of medical devices, including test kits to meet Canadians' public health needs.

- 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 443 COVID-19 medical devices including:
  - 43 testing devices; and
  - 400 devices including personal protective equipment, decontamination devices for NIOSH 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.

- Early diagnosis is critical to fighting the spread of COVID-19. Health Canada is making it a priority to review all types of COVID-19 tests including new innovative testing options.

- 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 NIOSH 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 NIOSH N95 respirators.
- Health Canada has authorized nine devices to decontaminate NIOSH 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 October 28, 2020, Health Canada has authorized:
  - 12 investigational testing authorizations, and four applications are under review; and
  - 42 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 October 28, Health Canada has added 240 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* (IO) 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. In 2020, Health Canada has received over 3,034 IO applications, this amount is fivefold the volume of non-COVID related applications. Average processing time of IO applications is significantly shorter under the IO process than under the regular process for higher risk devices (e.g. Class III (ventilators) 32 days vs 154 and Class IV (testing devices) 88 days vs 138).

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.

We have:

- addressed shortages by permitting the importation and sale of medical devices that are not approved in Canada, subject to certain requirements;
- 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.

Guidance for new manufacturers of COVID-19 medical devices

Health Canada has published guidance on several topics, including serology tests, ventilators, , swabs, PPE including face coverings and respirators. Webinars were held with provincial and territorial healthcare partners, industry and healthcare professionals to provide information and guidance on the safety, effectiveness and quality requirements for these medical devices. Several new Canadian manufacturers have received IO authorization for these medical devices.

Decontamination of NIOSH N95 respirators

Health Canada has authorized nine decontamination systems. The Department continues to evaluate new decontamination method applications submitted under the Interim Order for medical devices. Webinars were held with provincial and territorial healthcare partners, industry and healthcare professionals to provide information and guidance on the decontamination and re-use of NIOSH N95 respirators.

MENTAL HEALTH AND SUBSTANCE USE TOOLS DURING COVID-19

SYNOPSIS

- The Government remains committed to increasing access to mental health and substance use resources and supports for Canadians whose regular services are not accessible.

POTENTIAL QUESTION

- What is the Government doing to address the increased stress, worry, and anxiety that Canadians are experiencing due to COVID-19?

KEY MESSAGES

- The Government of Canada recognizes that COVID-19 continues to create 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 that provides access to a virtual network of psycho-social supports.
- **Wellness Together Canada** is the first national program of its kind, providing 24/7 access to free evidence-based tools and resources.
- Through **Wellness Together Canada,** Canadians across the country can access supports ranging from self-assessment and peer support, to confidential sessions with social workers, psychologists and other professionals.

- **Wellness Together Canada** is meant to support existing provincial and territorial services, not replace them.

- All services are available in both official languages, and phone counseling sessions are supported by instantaneous interpretation in 200 languages and dialects.

- To date, the Government of Canada has invested $46M in Wellness Together Canada.

- **Wellness Together Canada** adds to the suite of virtual tools, such as the Canada COVID-19 mobile app, ensuring that Canadians have access to information, resources, and other supports during this difficult time.

- The COVID-19 pandemic is particularly challenging for families who may be especially vulnerable to stress given the uncertainty and disruption to their daily routines.

- Our Government is quickly mobilizing efforts to develop and disseminate reliable and timely public health resources to help families, including parents caring for children with Autism Spectrum Disorder, navigate through these difficult times.

  Our government recognizes that the mental health of young people are particularly vulnerable during these difficult times, and their access to needed supports are often limited. As a part of the Consortium managing the Wellness Together Canada portal, Kids Help Phone is providing support to young people via phone, text and live chat.

- In addition to this actions, the Government of Canada is investing $5 billion over ten years to provinces and territories via negotiated bilateral agreements to help them

expand access, which includes community-based mental health and addiction services for children and youth.

IF PRESSED ON THE COMPETITIVE BIDDING PROCESS THAT HEALTH CANADA UNDERTOOK TO AWARD THE CONTRACT FOR WELLNESS TOGETHER CANADA…

- Health Canada with Public Services and Procurement Canada launched a competitive process to provide funding through a targeted request for proposals (RFP).

- A targeted approach was necessary due to the scope and complexity of services required and the urgency to provide mental health and substance use supports to Canadians during COVID-19.

IF PRESSED FOR INFORMATION ON THE CONSORTIUM OF ORGANIZATIONS MANAGING WELLNESS TOGETHER CANADA

- Wellness Together Canada is the result of the work of a broad consortium of organizations:

- **Stepped Care Solutions** is an interdisciplinary and cross-sector team of clinician-researchers, leaders and pioneers in the areas of Stepped Care 2.0 and e-mental health.

- **Kids Help Phone** is Canada's only 24/7 national service offering support to young people via phone, text and live chat, and is a global leader in developing and delivering virtual mental health solutions. Maintaining good mental health during this time is a priority for our government. That

is why we are investing an additional $7.5M in Kids Help Phone – a leader in responding to the needs of young Canadians.

- **Homewood Health** is a Canadian leader in the development and delivery of national, evidence-based mental health, trauma, and addiction treatment and services.

- **Greenspace Health** is a leader in mental healthcare technology.

- **Wellness Together Canada** receives support from additional partners and stakeholders, such as Bell Let's Talk, Canada Health Infoway, Mental Health Commission of Canada, Canadian Psychological Association, and Medavie.

IF PRESSED ON THE COLLECTION OF PERSONAL INFORMATION...

- The portal strictly adheres to all privacy and health information legislation and standards to maintain the security and confidentiality of personal information.

IF PRESSED ON THE NEED TO PROVIDE SERVICES TO DIVERSE POPULATIONS…

- Wellness Together Canada provides culturally appropriate services to Canadians that are designed to meet the needs of varying age groups and specific populations, including those in isolation or remote areas, sexual minorities, youth and Indigenous people.

BACKGROUND

Pressure on Existing Provincial/Territorial Mental Health Services

With Canadians physical distancing and isolated, there is an unprecedented need for virtual services, such as telehealth and other information lines (e.g., 811), and provinces/territories are not able to absorb the increased demand.

It is critical that Canadians have access to effective tools to self-monitor, promote their mental well-being, obtain credible and reliable information, and access services when deemed necessary. Canadians need to be re-assured that there are supports available to help alleviate their stress, fear and anxiety.

Government Actions and Investments to Address Impact Of Covid-19 On Canadians' Mental Health

Increasing Mental Health System Capacity

Health Canada has invested $25 million in Wellness Together Canada, a free 24/7 portal for mental health and substance use supports. An amendment had been finalized that will augment supports, expand the portal's reach and capabilities in needed areas, and extend free access to the portal until December 2020.

The funding for the portal is part of the $240.5M investment (described below) to increase access to virtual services and digital tools to support Canadians' health and well-being during COVID-19*:*

- $25M for Wellness Together Canada
- $15M to support the growing family of digital products that includes the Canada COVID-19 app
- $200M to expand virtual care services across Canada in partnership with provinces, territories and other federal partners, such as Canada Health Infoway.

Funding to Provincial and Territorial Governments

The Government of Canada is investing $5 billion over ten years to improve Canadians' access to mental health services. The investment is being provided directly to provinces and territories via negotiated bilateral agreements to help them expand access to community-based mental health and addiction services for children and youth, integrated services for people with complex needs, and spread proven models of community mental health care and culturally appropriate interventions linked to primary health services.

Promoting Mental Health and Preventing Mental Illness

Through the Public Health Agency of Canada's (PHAC) Mental Health Promotion Innovation Fund, the Government of Canada is investing $39 million from 2019-2028 to address multiple risk and protective factors to promote mental health for children, youth, young adults and populations susceptible to mental health inequities (e.g., low-income families, immigrants and refugees, First Nations, Inuit, Métis, LGBTQ2+, people living with disabilities and people with other socio-economic risk factors).

PHAC is providing $7.5 million to Kids Help Phone to respond to the increased demand for mental health services for children and youth.

$9 million is being provided to the United Way (through New Horizons) for practical services for seniors.

Mobilizing Data and Evidence

The Canadian Institutes of Health Research (CIHR) is currently leading a COVID-19 and Mental Health Research Initiative in collaboration with PHAC and Health Canada. This initiative currently supports 101 research projects, representing a total investment of $13.5M from CIHR and partners. This work is guided by an Expert Advisory Panel composed of leading Canadian experts in mental health and substance use. New knowledge generated through these projects will be mobilized to ensure it will inform policy making in a timely manner.

Statistics Canada developed and administers a web panel survey, the "Canadian Perspectives Survey Series". Each month, approximately 4,600 people in the 10 provinces have been responding to the new iteration of the survey. The Canadian Community Health Survey also resumed in September 2020.

Suicide Prevention

The Government of Canada is providing $21 million over five years to the Centre for Addiction and Mental Health (CAMH) to implement and sustain a fully operational pan-Canadian suicide prevention service in partnership with the Canadian Mental Health Association and Crisis Services Canada. This service will provide people across Canada with access to 24/7/365 bilingual crisis support from trained responders, using the technology of their choice (voice, text or chat). The Federal Framework for Suicide Prevention was released November 2016. It focused on raising public awareness, reducing stigma, disseminating information and data, and promoting the use of research and evidence-based practices. Progress Reports on the Framework are available on Canada.ca, with the next report planned for release in December 2020.

Post-Traumatic Stress Disorder

Pursuant to the *Federal Framework on Post-Traumatic Stress Disorder Act*, Canada's first Federal Framework on Posttraumatic Stress Disorder (PTSD) was tabled in Parliament on January 22, 2020 and made public on February 13, 2020. To inform the development of the framework, in accordance with the Act, the Minister of Health convened a National Conference on PTSD in April 2019 with the Ministers of National Defence, Veterans Affairs, and Public Safety and Emergency Preparedness, partners and stakeholders, including people with lived-experience.

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 supports planning our response to the COVID-19 epidemic.

- Models tell us the number of COVID-19 cases that could occur nationally depending on how effective we are in controlling the epidemic.

- Current modelling results, as well as the experience with this epidemic to date, underscore the need to follow all recommended public health measures to bring the epidemic under control.

- Data shared with federal officials by the provinces and territories supports national COVID-19 models. Provinces do their own modelling to reflect their unique situations.

- The methods used by the Public Health Agency of Canada to develop national models are being published in peer-reviewed journals, and the models are being made publicly available via the National Collaborating Centre for Infectious Diseases.

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 the introduction of a range of public health measures. Restrictive closures mostly controlled the epidemic of COVID-19, but as Canada re-opens, increasing cases are occurring in many jurisdictions, and in these places enhancement of public health measures will be required to control transmission.

- Restrictive closures mostly controlled the epidemic of COVID-19, but as Canada re-opens, increasing cases are occurring in many jurisdictions, and in these places enhancement of public health measures will be required to control transmission.

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 (PHAC) 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 use knowledge of how COVID-19 is transmitted from the emerging literature, and case data. Dynamic models 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.

Multi-system inflammatory syndrome in children (MIS-C) temporally linked with COVID-19

SYNOPSIS

Reports of multi-system inflammatory syndrome in children (MIS-C) associated with COVID-19 infection have been issued in the U.K., Italy, the U.S. and elsewhere around the world.

In Canada, there have been media reports of children with MIS-C at Ste. Justine Hospital in Montreal, at Sick Kids Hospital in Toronto, and in the provinces of Quebec and Alberta. Several provinces had made MIS-C a reportable condition to be able to quantify the numbers of cases.

KEY MESSAGES

- Our top priority is the health and safety of Canadians.
- Multi-system inflammatory syndrome in children is being reported in Canada and abroad, and we are working with our provincial and territorial public health partners and our network of pediatricians to support detection of cases and care of children.
- We are advising Canadians to contact their healthcare provider if their child shows symptoms of COVID-19 infection or of multi-system inflammatory syndrome, such as fever, gastrointestinal illness or if their child seems very unwell.
- We will continue to provide Canadians with reliable information about COVID-19 to prevent further spread and to protect Canadians from serious illnesses.

BACKGROUND

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

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, all children affected in Canada have done well and recovered.

Linkage to COVID-19

Many children with multi-system inflammatory syndrome (MIS-C) 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 syndrome and must maintain a high index of suspicion to identify cases. The cause of MIS-C is unknown. It is suspected an immune response to COVID-19 activates an inflammatory process in genetically susceptible children. However, other mechanisms are also possible.

The global pediatric medical community is rapidly studying this issue. Canada and PHAC have representation on the WHO expert group that is now looking at this issue.

So far, children have had far less COVID-19 disease than adults. However, 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 response to the COVID-19 pandemic, the PHAC monitors for MIS-C activity in three different ways:

- most provincial and territorial public health authorities report all cases of MIS-C 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 has been modified to capture cases of MIS-C, even in the absence of a positive test for COVID-19 to increase available data concerning this emerging condition.

As of October 24th, 2020, 25 MIS-C cases were reported to PHAC by provincial and territorial public health authorities. Two of these cases tested positive for COVID-19, and one case was epidemiologically linked to a laboratory confirmed COVID-19 case. Note that some provinces and territories are in various stages of implementing their MIS-C reporting systems; therefore, data are preliminary and are subject to change as

PHAC receives updates on cases.

Although the CPSP began implementing their MIS-C surveillance study protocol in May 2020, PHAC has since identified several data quality issues, including issues affecting case classification. PHAC is working to address these issues with the CPSP so that reporting can continue.

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.

NATIONAL EMERGENCY STRATEGIC STOCKPILE MANAGEMENT AND PERSONAL PROTECTIVE EQUIPMENT AND MEDICAL DEVICE PROCUREMENT

SYNOPSIS

The global COVID-19 pandemic has resulted in an unprecedented shortage of personal protective equipment (PPE),medical equipment, and 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 and additional pandemic stockpile, 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?
- What is the Government of Canada doing to prepare for resurgence and/or mass vaccination campaign scenarios?

KEY MESSAGES

- The Government of Canada is continuously working to secure critical personal protective equipment, or PPE, as well as medical equipment and supplies.

- We are also working to expedite the delivery of this equipment to our frontline healthcare workers.

- Canada is receiving a steady supply of PPE with shipments arriving daily, and we rapidly allocate the inventory to the provinces and territories.

- We allocate PPE and medical equipment and supplies based on an 80/20 formula, with 80% being allocated to provinces and territories to distribute within their jurisdiction. This formula has developed in consultation with provinces and territories.
- In response to urgent requests for assistance from provinces

and territories, we are also deploying PPE, medical equipment and supplies from the National Emergency Strategic Stockpile, or NESS.

- The NESS was designed to provide health emergency assets when provincial, territorial and local resources are exhausted.

- With the unprecedented nature of the current pandemic, the role of the NESS has evolved to include more proactive procurement of PPE, medical equipment and supplies.

- Lessons learned will inform the future of our approach to the NESS

IF PRESSED ON STOCKPILING OF PPE AND THE CANADIAN PANDEMIC INFLUENZA PLAN

- The Canadian Pandemic Influenza Plan is a federal, provincial, and territorial guidance document for the healthcare sector.

- Its purpose is to assist jurisdictions with their emergency planning, including their requirements to stockpile PPE, medical equipment and supplies.

- Provincial and territorial governments are responsible for providing medications, supplies and equipment required for healthcare services.

IF PRESSED ON HOW THE GOVERNMENT OF CANADA IS WORKING TO SECURE A SUFFICIENT QUANTITY OF PPE IN CANADA

- The Government of Canada has supported Canadian industry to increase domestic manufacturing capacity, including re-tooling facilities to produce PPE, medical equipment and supplies.

- As of August 28, Public Services and Procurement Canada has confirmed contracts for a variety of PPE, medical equipment and supplies including:
    - over 153 million N95 respirators and equivalents (e.g., KN95 respirators; FFP2);
    - 396 million surgical masks;
    - 60.3 million face shields;
    - 1.1 billion pairs of gloves;
    - 132 million protective gowns; and,
    - 40 thousand ventilators.

- The Public Health Agency of Canada has established additional pandemic supply of PPE to increase resurgence capacity.

- The Public Health Agency of Canada is receiving staggered delivery of shipments, and allocating them to provinces and territories.
- The Public Health Agency of Canada is working with Health Canada, provinces and territories to review the supply and demand of PPE, medical equipment and supplies, based on worst-case epidemiological scenarios, to determine maximum needs.

- The Public Health Agency of Canada also continuing to work with provincial and territorial partners in identifying supply gaps and ongoing bulk procurement needs.

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

- Due to intense global competition for PPE, medical equipment and supplies, countries have needed to engage with new suppliers and manufacturers.
- As a result, PPE, medical equipment and supplies received by the Public Health Agency of Canada – whether procured internationally or domestically – are verified to meet the technical specifications for healthcare settings before they are distributed to provinces and territories. To date, a large majority of the products received by the Government of Canada have met the technical specifications for healthcare settings for the COVID-19 response.
- As a result of the Public Health Agency of Canada's stringent review process, approximately 10 million KN95 respirators were assessed as not meeting the specifications for health care workers.
- Supplies that do not meet specifications are then assessed for potential use in non-healthcare settings.

IF PRESSED ON THE MADE-IN-CANADA VENTILATORS

- Earlier this year, as part of the Plan to Mobilize Industry to fight COVID-19, contracts were awarded to four Canadian suppliers for the procurement of ventilators.

- These ventilators receive authorization by Health Canada in order to be considered for use in a healthcare setting

- The Public Health Agency of Canada continues to receive ventilators from both international and domestic suppliers.

- The Public Health Agency of Canada is working with provincial and territorial governments to develop an allocation strategy for these ventilators.

- The Public Health Agency of Canada will also be retaining an inventory of ventilators in the National Emergency Strategic Stockpile to meet the future needs of the healthcare sector.

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

- The Canadian Centre for Occupational Health and Safety is developing guidelines for various sectors based on public health guidance.

- The federal government is working with experts to better assess the PPE, medical equipment and supply needs of Canada's society and economy, based on the most up-to-date public health advice.

BACKGROUND

Canada's National Emergency Strategic Stockpile (NESS) contains supplies that provinces and territories (PTs) can request in emergencies, such as infectious disease outbreaks, natural disasters and other public health events, when their own resources are exhausted. These supplies include a variety of items such as: medical equipment and supplies; pharmaceuticals; and social service supplies, such as beds and blankets.

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).

<u>NESS Mandate</u>

The fundamental basis underpinning federal emergency management and the NESS is that provincial, territorial and local governments are prepared to be able to respond in a reasonable manner to the most common emergencies in their jurisdictions. This includes being responsible for the procurement and management of personal protective equipment and other medical supplies.

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

- It provides surge capacity support 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.

In an August 5, 2020 article by the Canadian Medical Association, it was suggested that a $300-million emergency stockpile of pandemic supplies be privatized or run on a commercial basis by a Crown corporation. The article noted that certain doctors blame PHAC for what they argue was mismanagement of the stockpile, which resulted in waste and shortages of emergency medical equipment and supplies.

PHAC acknowledges that the pandemic created unprecedented demand for certain types of supplies. Canada, like most countries, is applying the lessons learned from the COVID-19 outbreak to our stockpiling strategies and considering all options going forward to ensure that the most effective stockpile practices are implemented and maintained.

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 capacity support.

As of 2019, all NESS holdings were consolidated in eight warehouses in six cities. In Spring 2020, two additional NESS warehouses were leased in addition to 10 warehouses secured through third-party contracts, given the volume of supplies being donated to and purchased by the NESS as part of the federal government's COVID-19 response. The warehouse footprint grew from approximately two hundred thousand square feet in January 2020 to over one million, three hundred thousand square feet.

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.

NESS Funding

In 2010-11, the ongoing annual base funding for the NESS, including salary and operating costs was $5.6 million. By 2012-13, the annual base funding for the NESS was reduced to $3 million. Additional funding has historically been provided to the NESS through internal reallocation

decisions and incremental funding decisions through which PHAC has received funding linked to specific purchases, such as a four-year investment in medical countermeasures against smallpox and anthrax that began in 2015-16.

More than $5 billion has been invested in the NESS since the onset of the COVID-19 outbreak in Canada.

Canadian Pandemic Influenza Plan PPE Guidance

The **2006 CPIP** recommended *"a 16-week supply (i.e. two pandemic waves) of both influenza and non-influenza related materials to address sporadic interruptions of supply*

chains (e.g. resulting from mail and courier disruptions, border closures, supply limitations)".

The **2011 CPIP** indicates that methods to estimate PPE requirements are beyond the scope of the CPIP, and notes that PTs are responsible for ensuring the provision of medications, supplies, and equipment required for provision of pandemic health care services.

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.

Access is further facilitated by Health Canada, by expediting regulatory approvals of products 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 required to notify the Minister of Health of medical device shortages 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.

Health Canada is also modeling PPE, medical equipment and supplies supply and demand at provincial and territorial, as well as pan-Canadian levels, to understand and plan for possible pressure points across different sectors of the economy and to inform future procurement plans of PPE, medical equipment and supplies.

In addition, the government is also exploring opportunities for more environmentally conscious federal PPE, medical equipment and supply procurement.

PPE Testing and Quality Assessments

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

Government of China Customs Regulations

In response to international criticism concerning the quality of PPE, the Government of China has imposed more stringent certification and customs regulations for masks and other PPE.

As a result, PHAC, as an importer, is now required to sign a joint declaration with the exporter attesting that the products meet the standards and certification requirements of the destination country.

For products that are not certified as medical devices in China, the joint declaration will also stipulate that the item is “not for medical use” even if it meets Canada’s technical specifications

for healthcare settings. These products are subsequently labelled in Simplified Chinese as “not for medical use” both on the outer shipping boxes and inside each of the individual product package.

As noted above, all supplies procured internationally continue to undergo quality verification by PHAC prior to distribution to PTs. To maintain the integrity of the PPE packaging, PHAC will be labelling the outer shipping boxes, confirming quality and stating that it is suitable for use in healthcare settings. PHAC will not be removing labels inserted inside each of the individual product boxes, as the process of removing these inserts in Simplified Chinese would cause significant delays in the distribution.

KN95 Respirators

On May 8, the 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. The number not meeting specifications has since increased to approximately 10 million. PSPC has suspended shipments from this supplier and is pursuing the appropriate recourse on behalf of PHAC. Where possible, supplies that do not meet specifications are subsequently assessed for potential use in non-healthcare settings.

Federal/Provincial/Territorial (FPT) Allocation and Distribution

As agreed to by FPT Ministers of Health, PHAC is allocating procured PPE using an 80/20 formula: 80% is distributed to PTs 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 to support the requirements of First Nations on reserve. The purpose of the NESS is to provide surge capacity to PTs when their own resources are not sufficient.

Made-in-Canada Ventilators

As a result of ISED's Call to Action, the Government of Canada identified four Canadian companies capable of manufacturing made-in-Canada ventilators in support of the fight against COVID-19. Each has been contracted to provide made-in-Canada ventilators (for a total of up to 37,500): FTI Professional Grade (FTI), CAE, Canadian Emergency Ventilators/Starfish and Vexos.

Prior to delivery of ventilator units to PHAC, each of these companies must obtain authorization under Health Canada's Interim Order. Additionally, once authorized, all ventilator units undergo quality verification by PHAC as part of the NESS in-take process before they are designated ready for deployment to provinces and territories.

OUTBREAK MONITORING

SYNOPSIS

The Government of Canada is working with provincial, territorial and international partners to detect signals and investigate transmission patterns to closely monitor the emergence and spread of COVID-19 in communities across Canada.

POTENTIAL QUESTION

How is the federal government monitoring new outbreaks of COVID-19?

KEY MESSAGES

- The Government of Canada understands the importance of continued outbreak monitoring.

- Multiple data sources are used to monitor the current situation in Canada, including daily case information by province and territory, and any developing outbreaks.

- Provinces and territories share data with the Public Health Agency of Canada, which are analyzed on a daily basis to monitor the patterns of transmission.

- We continue to use early warning systems to collect and exchange timely information on illness clusters in Canada and internationally.

- The Canadian Network for Public Health Intelligence platform is also facilitating the secure, timely exchange of information between local/regional, provincial/territorial and federal public health officials related to events of public health concern.

IF PRESSED ON WASTEWATER SURVEILLANCE…

- Testing samples of wastewater can provide an early warning of the presence of COVID-19 in communities.

- Scientists from the Public Health Agency of Canada and other government departments are working together to lay the foundation for community-wide surveillance programs in various locations across the country.

- A COVID-19 wastewater surveillance initiative is being developed to collect and test sewage samples in First Nations, Northern and remote communities, as well as wastewater leaving hospitals and large cities.

- Evidence collected through this initiative will inform public health interventions for the ongoing management of COVID-19.

BACKGROUND

Outbreak monitoring and response is part of the core work of the Public Health Agency of Canada (PHAC). Existing early warning initiatives are based on many years of epidemiological expertise and include both technological solutions as well as communication channels. Initiatives include:

- Public Health Alerts (PHA), administered and distributed by the Canadian Network for Public Health Intelligence (CNPHI), facilitate secure, timely exchange of information between local/regional, provincial/territorial (PT) and federal public health officials regarding events of public health concern.
- FluWatch is an online health surveillance system that helps track the spread of influenza and influenza-like illness across Canada and is an important part of Canada's national influenza surveillance program.
- The Global Public Health Intelligence Network (GPHIN) scans publicly available information in order to give early-warning of illness clusters in Canada and internationally.
- Outbreak intelligence is gathered via web scraping of PT websites/press releases and media coverage, and information is assessed daily by epidemiologists.

These initiatives have been leveraged to effectively monitor and respond to this unprecedented pandemic. This includes collecting granular and near real-time data, and the use of new and complementary data streams.

Detecting the COVID-19 virus by testing samples of wastewater can provide an early warning of the presence of this virus in communities. People with COVID-19 shed the virus through stool, and testing wastewater can alert a community to the presence of the virus or provide early warning of a resurgence. Some studies suggest that early detection of the virus causing COVID-19 in wastewater may provide a 5-10-day warning before there are a large number of cases in the community, allowing for important intervention opportunities to try to stop further spread.

Scientists from PHAC are working in collaboration with Environment and Climate Change Canada, Indigenous Services Canada, and Statistics Canada to lay the foundation for community-wide surveillance programs in various locations across the country. A COVID-19 wastewater surveillance initiative is being developed to collect and test sewage samples in First Nations, Northern and remote communities as well as wastewater leaving hospitals and large cities. Participation in the initiative begins with the consent of municipalities who submit wastewater for testing and have ownership over the results. The National Microbiology Lab will conduct the analysis of the samples, including detection of the virus. Results will be shared with the local health authorities in the respective jurisdictions so appropriate public health measures can be taken if necessary. Other groups and organizations are also conducting research on wastewater surveillance. For example, the University of Guelph is developing a COVID-19 early warning system that will sample and test wastewater from its student residences.

Engagement with PTs

PHAC works closely with provinces and territories (PTs) to monitor and respond to outbreaks. PTs report case level data to PHAC, which are analyzed on a daily basis in order to monitor epidemiological trends for early detection of new patterns of transmission.

PHAC also supports PTs with the management of outbreaks of national concern. PHAC is called upon by PTs to investigate and to provide additional technical expertise or specialized skills as required. This includes deployment of specialized teams (including field epidemiologists and public health officers) to support the investigation of outbreaks.

PHAC provides ongoing national coordination and federal leadership for multijurisdictional COVID-19 outbreaks, or complex single jurisdiction COVID-19 outbreaks. Since early May 2020, PHAC has been involved in the investigation of a number multijurisdictional or complex outbreaks, including:

- industrial worksite outbreaks in northern Alberta;
- a gathering-associated outbreak in northern Saskatchewan and Alberta;
- Ontario agricultural sector outbreaks (including by providing support to mobilized field epidemiologists);
- a condominium tower outbreak in Alberta; and
- outbreaks amongst Hutterite colonies in Saskatchewan, Alberta and Manitoba.

PHAC is promoting rigorous epidemiologic investigations of COVID-19 outbreaks in Canada in order to respond more effectively to these outbreaks and to increase our understanding of COVID-19 transmission dynamics and risks, and is developing guidance for epidemiologic investigation of COVID-19 outbreaks.

From a national perspective, there is considerable interest in monitoring case clusters and outbreaks related to COVID-19, especially heading into fall/winter respiratory illness season. Presently, PHAC is working closely with PTs to produce guidance on outbreak

investigations in schools to support a systematic approach to outbreak response in this setting.

Defining an "Outbreak"

The purpose of the "outbreak" definition is to trigger management activities (e.g., an investigation of the source, and implementation of measures to control spread). The definition of an outbreak of an infectious disease is contextual – it is typically defined as the occurrence of disease cases in excess of what is usually expected. As COVID-19 is a novel disease, the threshold required to initiate public health management activities is low; in other words, every case detected remains of public health interest and triggers active prevention and control activities.

Outbreak definitions for COVID-19 may differ across PTs depending on settings. PTs have varying definitions of outbreaks for different settings, typically with a minimum of 1-2 cases occurring in a setting within a certain period of time. In closed populations or settings with vulnerable individuals (e.g., correctional facilities, long-term care facilities, shelters), there tends to be a lower threshold, where only one confirmed case is needed in these settings in order declare an outbreak.

Use of Personal Protective Equipment

SYNOPSIS

Public health advice on the use of personal protective equipment (PPE) has evolved with the scientific evidence on transmission. The Public Health Agency of Canada (PHAC) develops and updates guidance on infection prevention and control for acute health care settings and long-term care facilities. PHAC 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 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 essential to prevent the spread of COVID-19.

- Expert guidance is supporting the appropriate use of PPE in health care settings.

- This guidance will evolve as science provides more information on COVID-19 transmission.
- The Government of Canada emphasizes that, for all Canadians, physical distancing, hand hygiene and wearing a non-medical mask are effective ways to prevent transmission of the COVID-19 virus.

- We encourage Canadians and businesses to:

    - Follow their local public health authority's advice on the use of PPE and non-medical masks; and
    - Follow the advice of provincial and territorial environmental authorities and municipalities on their proper disposal.

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

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

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 N95 respirators. It is extremely important that we have enough supply of medical masks for healthcare workers where they are 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.

In new technical guidance, PHAC recommends that all healthcare workers in acute health care settings wear medical masks and eye protection/face shields for the full duration of a shift. 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.

PPE may be a 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.

<u>Environmental impacts from increased PPE usage</u>

Increased PPE use is creating more PPE waste, which is not currently recyclable or biodegradable. While single-use PPE is the current standard for medical settings, options are becoming increasingly available for reusable masks for non-medical purposes and the general public. These options are more cost-effective and

environmentally friendly than single-use, disposable masks, particularly as more jurisdictions make mask-wearing mandatory in certain contexts.
Since the beginning of the pandemic, a number of federal initiatives are investing in PPE technology advancements. These advancements, such as innovative solutions to disposable masks and gowns, will help reduce the amount of PPE waste from both medical and non-medical settings. The government also continues to work with provinces and territories through the Canadian Council of the Ministers of the Environment (CCME) to explore how PPE waste can be diverted away from landfills.

Provinces, territories and local governments are also providing vital leadership in developing programs to reduce litter, prevent plastic pollution and recover materials through recycling services and material depots.

CANADA HEALTH ACT – COVID TESTING IN PRIVATE CLINICS

SYNOPSIS

- On October 5, 2020, media reported that private medical clinics are offering COVID-19 tests to Canadians willing to pay a fee to circumvent lengthy lineups at government sites and long waits for results from laboratories.

POTENTIAL QUESTIONS

- What is the Minister doing to ensure these clinics do not open the door to two-tier health care that prioritizes treatment based on a person's ability to pay over need?

KEY MESSAGES

- Testing is a key pillar of Canada's response to the COVID-19 pandemic, enabling the detection, prevention and public health management of the virus.

- Testing should be available for free to all Canadians who meet the guidelines and criteria on testing developed by our public health officials.

IF PRESSED on private testing …

- Provided private pay testing does not adversely impact public health testing capacity, private payment for COVID-19 testing may be appropriate for individuals who do not meet public health guidelines and criteria on testing.

IF PRESSED ON WHETHER COVID TESTING FALLS UNDER THE CHA…

- Canadians who meet the testing requirements determined by public health officials should have free access to COVID-19 testing and not be charged for the service.

IF PRESSED ON WHETHER CANADIANS WILL HAVE TO PAY FOR ACCESS TO COVID-19 VACCINES…

- Canada's universal health care system, based on need rather than ability to pay, is a source of national pride.

- Our Government will always take action to keep our health care system that way.

- All governments are committed to reducing the health impact of COVID-19, and a vaccine is a critical element in this effort.

BACKGROUND

On October 5, 2020, media reported that private medical clinics are offering COVID-19 tests to Canadians willing to pay a fee to circumvent lengthy lineups at government sites and long waits for results from laboratories. According to the article, the for-profit clinics serve individual patients as well as companies that require employees to test negative for the coronavirus before returning to work. Individuals pay anywhere from $50 to $250 for a test.

Critics say the clinics open the door to two-tier health care that prioritizes treatment based on a person's ability to pay over need, "upending the very foundation of Canada's publicly funded system".

Ontario Health, the agency providing COVID-19 swabs has been directed by the Ontario government not to provide swabs to clinics that charge patients for the test and looking to ensure the practice is discontinued. A spokesperson for Ontario Minister of Health, Christine Elliot stated "It has been brought to our attention that some providers are asking patients to pay in order to receive a COVID-19 test. This is not permitted."

As a part of the public health response, COVID-19 screening and testing have proven to be a key public health tool to prevent the spread of the virus. Coordination between federal, provincial and territorial governments has been integral to an effective and efficient response to the pandemic, while recognizing that responsibility for testing regimes is within provincial and territorial jurisdiction. To ensure Canadians continue to have confidence in COVID-19 testing requirements:

- COVID-19 testing should be free and accessible for all Canadians who meet the public health testing and screening criteria as determined by jurisdictions.

- Private payment for other COVID-19 testing may be appropriate provided private pay testing does not adversely impact public health testing capacity.

RACE/ETHNICITY DATA COLLECTION

SYNOPSIS

The Public Health Agency of Canada (PHAC) is working to collect additional data on race/ethnicity and Indigenous identity to improve our understanding of the overall impact of COVID-19 in Canada and, in particular, health inequities associated with COVID-19.

POTENTIAL QUESTION

How does the federal government work with provinces and territories on the collection of race/ethnicity-based data on deaths and active cases?

KEY MESSAGES

- As the pandemic has unfolded in Canada, it has become clear that we need more information on certain groups at higher risk for exposure to, or severe outcomes of, COVID-19.

- Given this, we are working hard with our partners to gather more detailed and complete data – including data on race/ethnicity and Indigenous identity.

- Federal, provincial and territorial public health partners have agreed to a new national data set for COVID-19, which includes new variables to help understand the impact for racialized groups in Canada.

- In addition to improving our national case data set, we are supplementing this information through research and other data collection activities. Together, these efforts will improve Canada's understanding of, and therefore ability to prevent and respond to, COVID-19 among racialized populations in Canada.

- In doing this work, we are ensuring privacy laws are being respected and that a health equity lens is applied to these efforts.

BACKGROUND

The health consequences of the pandemic differ across sub-populations. Those Canadians who before the pandemic were at greater risk of poor health are likely to be

at greater risk of suffering its consequences. There is also emerging evidence that COVID-19 may be widening health inequalities. Given this, the Public Health Agency of Canada (PHAC) and partners are undertaking activities to generate evidence on the impact of COVID-19 among racialized and Indigenous communities.

PHAC has completed a review of published literature on race/ethnicity and COVID-19. While there is limited evidence available overall and in Canada, studies to date show that those of Black, Asian or Hispanic backgrounds appear to have a higher chance of acquiring COVID-19 infection than those who identify as White. Evidence suggests that underlying health inequalities and socio-economic factors place certain racialized populations at greater risk of COVID-19.

Federal/provincial/territorial (FPT) governments have approved the inclusion of race/ethnicity and enhanced information on Indigeneity within the national data set for COVID-19, to be collected and reported to PHAC. The new national data set will be operationalized in October 2020, and some PTs have already begun collecting this information. PHAC, in collaboration with Indigenous Services Canada and Regional Indigenous Organizations, is working with the PTs to ensure complete and standardized reporting on all variables, including race and Indigeneity.

To complement the national data set, efforts are underway to deepen our understanding of trends within those populations identified at greater risk of impacts related to COVID-19. Specifically, PHAC is working with PTs and other partners to:

- Undertake specialized surveys and enhanced surveillance activities among key populations of interest, including studies to explore the impact of COVID-19 and the consequences of COVID-19-related public health measures on racialized communities; and
- Expand the knowledge base on racialized communities and COVID-19, including through leveraging Statistics Canada's race-based data from new data collection initiatives, and coordinating efforts with the Canadian Institutes for Health Research (CIHR) to facilitate research activities related to the burden and impact of COVID-19 among racialized communities.

It is important that this work be done in a way that avoids stigmatization of population sub-groups, respects privacy laws, and ensures individual autonomy (in choosing whether or not to provide this information to the health care system and public health).

LIVING WITH COVID-19 – NEW NORMAL

SYNOPSIS

As we prepare to enter the winter months, the Government is focussed on three objectives related to COVID-19 and health: sustained epidemic prevention and control overall and management of ongoing outbreaks where they arise; enhanced readiness to respond to resurgence; and vaccines and treatments to enable a longer-term recovery. 10 areas of activity ranging from testing and tracing to PPE to communications form part of the strategy. The approach is risk-based: public health measures will continue to be critical and actions will be balanced with economic and social impacts.

POTENTIAL QUESTION

What is the Government's longer-term plan to help Canadians live with COVID-19?

KEY MESSAGES

- Canadians have shown strong solidarity as we've worked to address the challenges posed by COVID-19. We must maintain this solidarity in the months ahead as we live with COVID-19.

- The Government is focused on three main objectives: first and foremost, sustained efforts to prevent and control the spread of the virus and ensuring that we are managing outbreaks where they occur; secondly, continuing to prepare our health systems to respond to significant resurgence; and finally, working on longer-term solutions like vaccines and therapeutics.

- We are working in a comprehensive way to advance work on all necessary aspects of a COVID-19 response, from testing and tracing to personal protective equipment and vaccine development.

- Our approach is and will continue to be informed by the most recent evidence and rigorous science.

- We are also working to ensure that decisions to maintain, strengthen, or ease public health measures are balanced

against real economic and social impacts felt by Canadians. This includes the very real consequences of COVID-19 for the mental and physical health of Canadians.

- We will continue to provide guidance to help Canadians in all walks of life, from business owners to students, assess and mitigate their personal risk.

BACKGROUND

The Government's Risk Management Strategy for Living with COVID-19 is based on three key goals:

- Sustained epidemic prevention and control and rapidly addressing outbreaks and resurgences;
- Continuing to enhance readiness to respond to resurgence; and
- Vaccines and treatments to enable a longer-term recovery

To support these goals, work is advancing across 10 comprehensive and interrelated areas:

1) Surveillance and Data, e.g., symptom tracking, environmental surveillance;
2) Borders, e.g., risk-based approach, with initial focus on high value, low risk travellers;
3) Public Health Measures, e.g., online guidance for schools and businesses;
4) Health System Capacity, e.g., Safe Restart Agreement funding to support incremental costs, staffing, infection prevention and control, and surge capacity e.g., mobile hospitals;
5) Vulnerable Populations, e.g., addressing challenges in long-term care homes, for temporary foreign workers, and unintended effects;
6) Testing and Contact Tracing, e.g., national approach, made-in-Canada supply chain, exposure notification app;
7) Personal Protective Equipment (PPE), e.g., targeted procurement, domestic manufacturing, demand and supply modelling;
8) Vaccines and Other Medical Countermeasures, e.g., work to secure access to vaccines;
9) Communications, e.g., targeted risk communications, vaccine readiness
10) Research, e.g., ensuring the Canadian research community is mobilized to respond.

As part of this plan, the Government has developed four areas of surge capacity that can be drawn on when local resources are insufficient:

- The Federal COVID-19 Rapid Response Team to provide technical expertise to support local health authorities in assessing and responding to outbreaks;
- The COVID Testing Assistance Response Team to respond to surges or targeted testing needs;
- Federal laboratory support for testing; and,

- Surge support for outbreak and crisis management

Key aspects of the plan also include:

- Strong focus on best available evidence, science, and data;
- Scenario planning;
- Whole of Government approach;
- Collaborative approach with provinces and territories;
- Leveraging business, academia, and other stakeholders

RECALL OF RESPIRATORS

SYNOPSIS

- The COVID-19 pandemic has resulted in the increased importation, sale and use of varying kinds of medical devices in order to protect healthcare workers and treat patients. While most of these medical devices have functioned properly, a subset of Class I medical devices, including personal protective equipment (PPE) such as respirators, have been found to be of substandard quality, misrepresented or counterfeit. Respirators that do not meet required standards may not provide consistent and adequate protection.

- Health Canada will continue to actively monitor information related to the safety and effectiveness of respirators and will take prompt and appropriate action if needed to protect the health and safety of Canadians.

POTENTIAL QUESTION

- What is Health Canada doing to ensure the quality of respirators used by Canadians?

KEY MESSAGES

- The quality, effectiveness and safety of health products is a top priority for the Government.

- The Government of Canada verifies the effectiveness of all respirators procured by the Government to confirm that they meet performance standards before we distribute to the provinces and territories for frontline healthcare workers.

- We continue to assess and take action when respirators do not meet safety and effectiveness standards by asking companies to recall and re-label respirators as face masks for use in settings where 95% filtration is not required.

- Respirators that are confirmed to be counterfeit are removed from the market and are not permitted to be sold in Canada.

- Health Canada maintains a list of manufacturers and respirators that are subject to recall/re-labelling on its website.

IF PRESSED ON WHAT HEALTH CANADA IS DOING TO PROTECT CANADIANS…

- Health Canada assesses all sources of information related to respirators that may not meet safety and effectiveness standards, including testing conducted by the National Institute for Occupational Safety and Health (NIOSH), the Public Health Agency of Canada and other laboratories.

- Health Canada also conducts inspections of licensed importers/distributors and assessments of referred shipments at the border to prevent the sale of non-compliant respirators in Canada.

- The Department directs all companies who may have imported or distributed respirators that may not meet safety and effectiveness standards to stop sale and re-label any impacted products as face masks for use in settings where 95% filtration is not required.

- Respirators that are confirmed to be counterfeit are removed from the market and are not permitted to be sold in Canada.

- Health Canada continues to provide guidance to industry on the detection of substandard, misrepresented and counterfeit products.

IF PRESSED ON RECALLS…

- Companies have been directed to recall respirators that do not meet performance standards. Recalled products must be re-labelled as face masks to be used in settings where a 95% filtration is not required.

- Health Canada maintains a list of manufacturers and respirators that are subject to recall/re-labelling on its website and will continue to update it as required.

IF PRESSED ON RESPIRATORS PURCHASED BY THE GOVERNMENT OF CANADA

- PPE and medical supplies received by the Government of Canada, whether donated or procured internationally or domestically, are verified by the Public Health Agency of Canada (PHAC) to ensure they meet Government of Canada technical specifications for healthcare settings for COVID-19 response.

- If PHAC cannot account for the quality of devices, they will not be allocated to the provinces and territories for frontline healthcare response.

- Provincial and territorial health authorities and health care institutions have been advised to review their inventories of respirators to confirm that they meet the Government of Canada technical specifications for healthcare settings for COVID-19 response on a regular basis.

BACKGROUND

Regulation of Medical Devices in Canada

All medical device products, including N95 and KN95 respirators and other Personal Protective Equipment (PPE), are subject to the safety and effectiveness requirements of the *Medical Devices Regulations*. Manufacturers of medical devices are responsible for

ensuring that they are safe and effective.
Most PPE (e.g., respirators, gowns, masks) are classified as Class I devices in Canada. Class I devices are considered the lowest risk Class of devices and do not require pre-market authorization by Health Canada, which means they are not assessed by the Department for safety and efficacy prior to import or sale in Canada.

A Medical Device Establishment Licence (MDEL) is required to import and distribute Class I devices. MDELs are issued based on an attestation to requirements related to documented procedures for complaint handling, distribution records, recalls and problem reporting.

Improving Access to Medical Devices During COVID-19

Health Canada implemented three different measures to expedite the availability of medical devices in support of COVID-19 response efforts:

1. Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 - provides an expedited authorization pathway for medical devices for sale in Canada. Health Canada reviews the scientific evidence provided by the manufacturers through this pathway to support the safety and effectiveness of devices before issuing authorizations for these devices.

2. Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19 - builds on an existing practice to facilitate access to alternative supplies of health products to help prevent and alleviate shortages resulting directly or indirectly from COVID-19. Under this Interim Order, companies must report shortages of medical devices related to COVID-19 to Health Canada to help the health care system prepare for supply disruptions.

3. Expedited review and approval of MDEL applications for companies applying to supply medical devices in support of COVID-19 response efforts. Between April 22 and May 25, the Department implemented a temporary measure to expedite access to PPE and avoid delays at the border while maintaining quality and safety requirements. Through this temporary measure, MDEL applicants were assigned a Submission Number while the MDEL applications continued to be processed. As of July 27, all Submission Numbers have been transitioned to MDELs or withdrawn and no further Submission Numbers are being issued. Health Canada continues to expedite the review of MDEL applications related to COVID-19 products, and to date has authorized 3063 MDELs to support the response to the COVID-19 pandemic.

Recalls

Health Canada is assessing all available information on a daily basis to identify companies that may be selling or importing respirators that do not meet the labelled performance claims. Health Canada will continue to take action to ensure that products that do not meet the applicable standards are re-labelled as face masks for use in settings where 95% filtration is not required. Health Canada will also continue to update

the online list of devices that must be re-labeled as face masks in order to be distributed in Canada.

This action does not implicate KN95 respirators purchased by the Government of Canada and tested by the Public Health Agency of Canada (PHAC). Before allocating any personal protective equipment to the provinces or territories for frontline healthcare workers, PHAC conducts a quality verification. For KN95 respirators, this includes a visual inspection to check for defects in design and construction, and testing to confirm that they meet filtering specifications.

SAFE RESTART

SYNOPSIS

Recognizing that provinces and territories (PTs) have had to respond to COVID-19 in unique ways, on July 16, 2020, First Ministers agreed to a Federal/Provincial/Territorial (FPT) Safe Restart Agreement, supported by over $19 billion in federal investments, to help PTs restart their economies over the next six to eight months while making Canada more resilient to possible future waves of the virus.

On September 16, 2020, the Prime Minister announced that the premiers have now submitted the response letters and the federal funding will be transferred to the provinces and territories.

POTENTIAL QUESTION

What is the FPT Safe Restart Agreement?

KEY MESSAGES

- On July 16, First Ministers agreed to a Federal/ Provincial/ Territorial Safe Restart Agreement – supported by over $19 billion in federal investments.

- As of September 16, the premiers have now all submitted their response letters and the federal funding will be transferred to the provinces and territories.

- This agreement helps provinces and territories restart their economies, while protecting the health of Canadians.

- We recognize that provinces and territories have had to respond to COVID-19 in unique ways, and have already made major investments, and will continue to do so.

- Funding under the Safe Restart Agreement will help provinces and territories in critical areas, such as healthcare, childcare, sick leave and municipal services.

- This includes investments to support our collective efforts on testing, contact tracing and data management, health system capacity, mental health and substance use, personal

protective equipment, and protecting seniors and other vulnerable people.

- First Ministers agree that continued collaboration is key to ongoing success, and will build on the Team Canada approach that has taken place throughout this pandemic.

BACKGROUND

On July 16, 2020, First Ministers agreed to an FPT Safe Restart Agreement, supported by over $19 billion in federal investments, to help PTs restart the economy over the next six to eight months while making Canada more resilient to possible future waves of the virus.

Provinces and territories were asked to outline in a letter how these funds would best be allocated within their jurisdictions, based on their priorities. On September 16, the Prime Minister announced that the premiers have now submitted the letters and the federal funding will be transferred to the provinces and territories.

Funding includes support for expanding testing and contact tracing capabilities so that provincial and territorial health authorities are able to mitigate outbreaks of COVID-19. This funding will also support capacity in health care services; procurement of personal protective equipment, including for essential workers; and support for Canadians facing mental health challenges, including problematic substance use. First Ministers also agreed to jointly provide support to municipalities to maintain the delivery of critical services.
In addition, there is a dedicated stream of funding for public transit. Funding will also support measures to protect vulnerable populations, including seniors in long-term care facilities, and child care services, so parents can return to work. Under the agreement, the Government of Canada will establish a temporary income support program to provide workers with up to ten days of paid sick leave related to COVID-19. PTs will establish job protected sick leave legislation or regulation in their respective jurisdictions.

Funds include:

- $700 million to support health care system capacity to respond to a potential future wave of COVID-19;
- $500 million to address immediate needs and gaps in the support and protection of people experiencing challenges related to mental health, substance use and homelessness; and
- $4.28 Billion to support PTs with the costs of increasing their capacity to conduct testing, perform contact tracing and share public health data that will help fight the pandemic.

COVID-19 SAFE VOLUNTARY ISOLATION SITE PROGRAM

SYNOPSIS

The Government of Canada has established a Safe Voluntary Isolation Site Program ($100M over 2 years), as part of Canada's growing list of rapid response tools against the spread of COVID-19. The program aims to decrease community transmission of COVID-19 by addressing gaps identified for individuals who live in housing that may be crowded or have insufficient space for proper distancing from household contacts to self-isolate. The voluntary isolation sites will help reduce the risks of spread of the virus among household contacts, especially in Canada's most densely populated urban centres.

POTENTIAL QUESTION

How will funding voluntary isolation facilities help with our fight against COVID-19?

KEY MESSAGES

- The Government of Canada is taking action to support individuals who lack the space and means to undertake an effective isolation.
- The availability of such facilities is expected to help lower the rate of COVID-19 community spread via reduced transmission among those living in crowded housing.
- The Public Health Agency of Canada is providing funding for voluntary isolation sites in Canada's urban centres. We are working to identify cities and municipal regions that would benefit from this program.

IF PRESSED on voluntary isolation sites vs. Designated Quarantine Sites…

- Voluntary isolation sites are different from Designated Quarantine Sites.
- Designated Quarantine Sites are for individuals who are ordered to stay under the *Quarantine Act* should they not have an appropriate isolation plan upon entry into Canada. These sites are operated under federal jurisdiction.
- Voluntary isolation sites are meant for individuals who cannot safely isolate at their usual place of residence due to

crowded housing or resource constraints. These sites are operated by local public health officials.

IF PRESSED on the location of selected sites…

- The program exists to fill a gap for urban centres and municipalities that are at risk of high rates of transmission resulting from crowded housing.

- The Public Health Agency of Canada is working to identify possible cases where epidemiological trends, demographics and/or other relevant considerations suggest a voluntary isolation site might be warranted.

IF PRESSED on why the City of Toronto was chosen as the pilot for this program…

- The City of Toronto sent a request to the Public Health Agency of Canada for funding of their proposed safe voluntary isolation site. The decision to fund the Toronto site was based on evidence-based rationale for how the proposed project would contribute to reducing community transmission of COVID-19.

- The City of Toronto is one of Canada's most densely populated urban centres. This can make it difficult for some individuals to safely self-isolate at home, which contributes to a higher risk of contracting COVID-19. We are pleased to support Toronto Public Health who recognized that this issue was contributing to levels of community transmission, and is trying to address it, in part by providing a centralized location where eligible individuals can safely self-isolate for the required period.

- We are pleased to support Toronto Public Health who recognized that this issue was contributing to levels of community transmission, and is trying to address it, in part by providing a centralized location where eligible individuals

can safely self-isolate for the required period.

BACKGROUND

When presenting with symptoms of COVID-19, self-isolation is one of the most effective ways of reducing the risk of spreading the virus. However, for some Canadians, crowded housing conditions and restrictive costs can make it unsafe or impossible to effectively self-isolate at home.

Within the context of the broader COVID-19 pandemic response, evidence has emerged that individuals facing socio- and economic challenges are at higher risk of contracting COVID-19. Evidence suggests that densely populated neighbourhoods have been disproportionately affected by COVID-19, including its most severe outcomes. Individuals from these neighbourhoods may have more difficulty properly isolating themselves due to factors such as overcrowding and/or resource constraints. The establishment of voluntary self-isolation sites aims to assist in addressing this issue.

Role of Eligible Recipients

Sites selected under the Program will provide a centralized location where identified individuals can safely self-isolate for the required period. Regular monitoring and reporting will be conducted in coordination with local public health officials. The sharing of best practices will be encouraged among the selected sites to optimize effective site operation and administration of services under the objectives of the Program.

Costs Covered by Federal Funding

Federal funding will include: transportation to and from the site, lodging, meals and incidentals such as bedding and other necessities for residents, as well as on-site security and cleaning personnel for the facility will be provided. It is also understood that related activities may be required, such as those performed by public health professionals in the context of infection prevention and control.

Eligibility to access the self-isolation site

Through its case and contact management process, local public health officials will identify individuals to be offered transfer to the isolation site on a voluntary basis.

For example, if a person is COVID-19 positive and lives in a home where there is no separate room in which they can isolate, they may be considered as a candidate for the voluntary self-isolation site. Individuals who are household contacts will also be considered if, for example, the individual cannot isolate safely from positive case(s). Those awaiting test results may also be considered.

The total number of individuals housed per site will depend on the need that arises throughout the next 12 months.

COVID-19 FEDERAL RAPID SURGE CAPACITY

SYNOPSIS

The Government of Canada has established a COVID-19 Federal Rapid Surge Capacity initiative to assist provinces and territories in managing the impacts of COVID-19 outbreaks. It is available for consideration when needs exceed municipal, provincial, and territorial capabilities.

POTENTIAL QUESTION

How is the Government of Canada assisting jurisdictions with surge capacity needs?

KEY MESSAGES

- As part of our ongoing support to the provinces and territories, we have now established a COVID-19 Federal Rapid Surge Capacity initiative.

- This represents further investment by the Government of Canada, in addition to the Safe Restart Agreements, which provided provinces and territories with over $19 billion in federal investments to support:

    - Health care system capacity;
    - Testing and contact tracing; and
    - Other social services to support Canadians.

- This Rapid Surge Capacity initiative is intended to support the needs of provinces and territories in responding to COVID-19 outbreaks and mitigating transmission in hot zones where they have exceeded their own capacity.

- It can strengthen existing services in areas where needs are most pressing, and most critical – including outbreak management, testing, and contact tracing.

IF PRESSED ON SUPPORT GIVEN TO PROVINCES/TERRITORIES …

- Provinces and territories will be responsible for prioritizing requests from their local jurisdictions.

- The Government of Canada will prioritize requests received based on the needs and capacity available at the time of the request.

- The Public Health Agency of Canada will coordinate the requests for surge capacity support and assistance.

- We are currently providing support to Ontario, Quebec, Manitoba and Alberta, and we are in discussions with all provinces and territories on their needs that could be addressed through this initiative.

- Our current support includes:

    - Approximately 150 Canadian Red Cross personnel deployed to outbreaks, from a roster of about 500 available personnel. This roster will increase over the coming months.
    - The establishment of two federal labs to supplement testing capacity, with an additional four labs in operation by December;

    - Processing about 2000 calls a day to assist with contact tracing, with the ability to assist many other provinces and territories; and

    - The commitment of $100 million for safe voluntary isolation sites across the country.

- In addition, the federal government has over 100 subject matter experts ready for rapid deployment to assist provinces and territories with assessing local outbreaks, and

has committed $35 million for the Canadian Red Cross to supplement testing.

- The Government of Canada is also continuously working to secure critical personal protective equipment, as well as medical equipment and supplies, and expedite the delivery of this equipment to our frontline healthcare workers.

BACKGROUND

Through the COVID-19 Federal Rapid Surge Capacity initiative, rapid response surge capacity is being offered for potential deployments across Canada, including rural and remote locations as well as Indigenous communities, and is available until March 31, 2021.

Under this initiative, the Government of Canada has developed seven fields to respond:

- Public Health Rapid Response Team;
- Outbreak Management;
- COVID-19 Patient Testing;
- Laboratory Services;
- Contact Tracing; and
- Safe Voluntary Isolation Sites.

The development of a seventh field, Provision of Testing Equipment is underway and will be captured under regular reporting in the coming weeks.

The initiative leverages federal resources as well as the existing Public Safety Canada contribution arrangement with the Canadian Red Cross (CRC).

Resource Management (as of November 4):

Services	Total Available Capacity	Committed Capacity
1. Public Health Rapid Response Team	108 individuals	Nil
2. Outbreak Management (CRC)	Rapid Assessment Team: 7 teams	ON: 2 teams deployed
	Full Support team: 492 individuals	QC: 106 personnel at long term care sites ON: 25 personnel at a long term care site
3. COVID-19 Patient Testing (CRC)	$35M from Sep 2020-Mar 2021 (~80 staff, 2 teams)	Nil Discussions pending with ON (Ottawa CHEO and Montfort hospitals)
4. Laboratory Services	2,000 tests per day	ON: 200 tests per day

		MB: 1,000 tests per day
5. Contact Tracing	14,580 calls per day	ON: 1,175 calls per day QC: 25 calls per day MB: 47 calls per day AB: 254 calls per day
6. Safe Voluntary Isolation Sites	$100M over 2 years	ON (Toronto): $13.9M over 12 months (Aug 2020-Aug 2021) Proposals from Peel and Ottawa awaiting approval

The Government of Canada is also continuously working to secure critical personal protective equipment (PPE), as well as medical equipment and supplies. Canada is receiving a steady supply of PPE with shipments arriving daily, and the inventory is rapidly allocated to the provinces and territories. More information on the Government's efforts in this area can be found in the "National Emergency Strategic Stockpile Management and Personal Protective Equipment and Medical Device Procurement" QP note.

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 rapid testing devices needed during the COVID-19 pandemic?

KEY MESSAGES

- Health Canada understands the need to have a variety of test kits available for use to meet different public health needs
- The Department has prioritized the review of all types of COVID-19 tests, including rapid and new innovative testing options and technologies.
- Health Canada is working as quickly as possible to approve rapid, point-of-care diagnostic and monitoring tests based on nucleic acid and antigen technologies to meet Canadian testing needs without compromising on standards for safety, effectiveness and quality.
- Health Canada has authorized 43 test kits through an expedited regulatory review process under the Interim Order for medical devices issued on March 18, 2020.
- As of October 26, Health Canada has authorized 3 antigen teststhe Abbott Panbio, the BD Veritor™, and the Quidel Sofia.
- On September 30, Health Canada authorized the Abbott ID NOW rapid PCR COVID-19 test kit to be used at the point-of-care.
- 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.
- As new tests become available and approved for use in Canada, the Public Health Agency of Canada works with

provincial public health laboratories to acquire and distribute them to increase our existing testing capacity.

IF PRESSED… on the authorization of "rapid tests"

- Health Canada is reviewing applications for many different technologies, including those that are able to return rapid results.
- Health Canada is reviewing applications for ~~six~~ antigen tests that are all indicated for use in point-of-care settings, such as the doctor's office or bedside.
- Health Canada is reviewing these applications as quickly as possible without compromising patient safety.

IF PRESSED… on the authorization of the Abbott Panbio test kit

- The test is intended for use in symptomatic individuals.
- This point-of-care test is carried out by a health care professional and can produce results within 20 minutes.

IF PRESSED… on the authorization of the BD Veritor™ System

- The test is intended for use for individuals who are suspected of COVID-19 by their healthcare provider, within the first seven days of the onset of symptoms.
- This point-of-care test can be carried out by medical professionals or trained operators, and can return results in 20 minutes.

IF PRESSED… on the authorization of the Quidel Sofia

- The test is intended for use for individuals who are suspected of COVID-19 by their healthcare provider, within the first five days of the onset of symptoms.
- This point-of-care test can be carried out by laboratory professionals or trained operators, and can return results in 15 minutes.

IF PRESSED… on the accuracy of the authorized antigen tests

- These tests provide preliminary test results only. There is the possibility of false-negative results, meaning that the patient may have COVID-19 even if the test result is negative.
- Negative results from this test are considered “presumptive”, which means that they cannot entirely rule out that the patient may be infected.
- Treatment decisions or the need for additional testing should be made in consultation with the patient’s healthcare provider and take into account whether symptoms are present or continue.

IF PRESSED… on the authorization of the Abbott ID NOW COVID-19 test kit

- The test is intended for use in symptomatic individuals, within seven days of the onset of symptoms.
- This point-of-care test can be carried out by medical professionals or trained operators, and can return results in 13 minutes or less.

IF PRESSED… on the accuracy of the Abbott ID NOW COVID-19 test:

- Health Canada was provided clinical evidence that demonstrated the sensitivity of the Abbott ID NOW is 92.9%.
- The labelling makes it clear under what conditions the tests should be used.
- The test is intended for use for individuals who are suspected of COVID-19 by their healthcare provider, within the first seven days of the onset of symptoms, and that swabs should be tested as soon as possible after collection or within one hour.
- The labelling is clear that negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions.
- These limitations and directions mitigate the risks of potential false negative results.

- Health Canada believes that the Abbott ID NOW COVID-19 test will perform adequately in the context of the urgent public health need for rapid diagnostic testing solutions.

IF PRESSED… on how tests are deployed

- Scientists at Canada's National Microbiology Laboratory (NML) are determining a national strategy to distribute point of care tests in the best way possible to meet the needs of those most at risk.
- The Public Health Agency of Canada (PHAC) distributes the testing devices based on a needs analysis—in coordination with provinces and territories and Indigenous Services Canada—to get devices to communities that are at greatest risk if there were to be an outbreak of COVID-19.
- As of October 7, 109 point-of-care testing devices and over 34,000 tests have been deployed across Canada to support in-community diagnostics.

IF PRESSED… on Health Canada's position on home testing for COVID-19:

- Health Canada is open to reviewing all testing solutions. This includes approaches that use self-collection or at-home test kits for screening purposes - to enable individuals with or without symptoms who wish to assess and monitor their own infection status.
- Health Canada has not yet received any applications for at-home test kits.

IF PRESSED… on Health Canada's position on saliva testing for COVID-19:

- Health Canada has authorized a number of accurate and reliable COVID-19 tests devices for use with various samples.
- At this time, Health Canada has not authorized the use of saliva samples with any authorized testing device.
- Health Canada is actively working with companies who have

filed their application for saliva based testing, and will prioritize the review of applications for test kits that use saliva samples in order to enable new testing options for Canadians.
- Health Canada welcomes applications from any manufacturer of a test kit that is validated for use with saliva samples.

IF PRESSED… on the authorization of the bCube

- On September 23, 2020, Health Canada has authorized the Hyris Global Diagnostics bKIT and bCUBE from Hyris Global Diagnostics, to be used at the point-of-care.
- We continue to work with companies developing innovative and new testing technologies in Canada and around the world to ensure Canadians get the tools they need to help reduce the spread of COVID-19.

IF PRESSED… on the British Columbia swish and spit lab tests:

- Health Canada and the Public Health Agency of Canada welcome all new technologies that will help in the fight and reduce the impact of COVID-19 on Canadians.
- Provincial/territorial laboratories can develop their own tests in-house and offer testing services. These tests and testing services are regulated under provincial or territorial jurisdiction.
- Laboratory developed tests and testing are not regulated by Health Canada - there is no sale of a device.
- Health Canada has not received any applications for a commercial swish and spit COVID-19 test.

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 authorization of Spartan test kits:

- Health Canada continues to work with Spartan in their efforts to produce the evidence required to demonstrate that their product functions appropriately.
- Health Canada has provided regulatory guidance to Spartan relating to the completion of clinical trials on their testing device and will prioritize the review of the application for authorization of the test when it is received.

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.

Health Canada has received applications for three types of testing devices:

1. Nucleic acid-based tests (detection of the viral genetic material)

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. A number of lab-based and point-of-care nucleic acid-based tests have been authorized for use in Canada, including the recent authorization of the Abbott ID NOW COVID-19 test on September 30, 2020. Health Canada has received two additional point-of-care nucleic acid-based tests which are being prioritized for review at this time. Health Canada has also received a very small number of applications for lab-based nucleic acid-based tests for use with saliva samples. These applications are also being prioritized for review at this time.

2. Antigen-based tests (detection of proteins on the surface of the virus)

Antigen tests are rapid tests that can be offered at the point of care in disposable formats. Health Canada has authorized the sale of 3 antigen tests as of October 26, the Abbott Panbio
the BD Veritor™ and the Quidel Sofia Antigen testing is one of several emerging technologies that can be used to determine if a person is infected with the COVID-19 virus.

3. 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.

TESTING CAPACITY

SYNOPSIS

Health Canada and the Public Health Agency of Canada are working closely with the provinces and territories to distribute the Abbott ID NOW and Abbott Panbio rapid tests, following the bulk procurement of these tests in late September/early October.

POTENTIAL QUESTION

- What is the Government of Canada doing to ensure that Canadians have access to effective COVID-19 testing?

KEY MESSAGES

- Our Government is working aggressively to procure tests to meet both current and future demand as testing continues to increase across the country.

- As part of this work, we purchased two rapid tests – the Abbott ID NOW and Abbott Panbio – and have worked with our provincial and territorial counterparts to allocate and distribute them.

- The first shipment of tests were sent last week. Shipments continued to provinces and territories this week and will continue each week as supply arrives in Canada.

- This means that we will have distributed over 200,000 ID NOW rapid tests and over 2 million Panbio antigen tests by November 7. These tests are being provided to provinces and territories at no cost to them.

- Provinces and territories will decide how to deploy these technologies, informed by the Pan-Canadian Testing and Screening Guidance that was released a few weeks ago.

- We have also put into place surge support for provinces and territories, including for contact tracing, testing sample collection, and test processing in federal laboratories.

- As our top priority, we will be continuing all efforts to support jurisdictions in their efforts to manage COVID-19.

IF PRESSED ON HOW CANADA IS INCREASING TESTING CAPACITY

- My department continues to work with colleagues in Public Services and Procurement Canada, Innovation, Science and Economic Development Canada, and the National Research Council to identify and support new and emerging testing and screening products and platforms.

- As emerging testing and screening 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.

BACKGROUND

Health Canada and the Public Health Agency of Canada work closely with provincial and territorial officials and laboratories in support of a coordinated approach and conducting laboratory testing for the virus that causes COVID-19. As of September 15, 2020, over 6,200,000 patients in Canada were tested for COVID-19. Over the last week, an average of more than 47,000 people were tested a day in Canada.

On July 27, 2020, the Government of Canada announced it will provide $4.28 billion, as part of over $19 billion announced by the Prime Minister on July 16, 2020 as part of the Safe Restart Agreement, to further expand testing and contact tracing capacity, and the associated data management and information sharing systems. The objective of the Safe Restart Agreement is to ensure that Canada has the resources and information it needs to reopen the economy safely.

As we move into the next phase of lifting some public health measures and re-opening some parts of the economy, cases of COVID-19 will still occur until the population has enough immunity or a vaccine is available to prevent the disease.

Testing will remain an important tool to detect and isolate new cases, follow up with close contacts, stop spread of the virus and prevent outbreaks in the community. In this next phase, testing will be critical for groups that are more vulnerable to complications from COVID-19. This testing will be an early warning for our healthcare system.

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.

ACCESS TO TREATMENTS FOR COVID-19

SYNOPSIS

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

POTENTIAL QUESTION

- What is Health Canada doing to help Canadians get access to treatments for COVID-19?

KEY MESSAGES

- Health Canada is expediting the review of all treatments for COVID-19 while continuing to ensure that these products meet standards for safety, effectiveness and quality.

- As of mid-October, 68 clinical trials had been authorized for the treatment or prevention of COVID-19. We have also authorized, with conditions, the drug remdesivir for the treatment of COVID-19.

- Additionally, I signed an interim order that creates a mechanism for the expedited review of treatments, while ensuring that we maintain a high level of scientific scrutiny.

- The Government of Canada continues to proactively engage with domestic and international companies to negotiate advance purchase agreements for the procurement of treatments to ensure timely access.

IF PRESSED ON TREATMENT AVAILABILITY

- Health Canada is closely monitoring global treatment development and is in active discussions with manufacturers and researchers to provide regulatory and scientific advice for clinical trials that may launch in Canada.
- While recognizing the urgent need for treatments, all products will undergo a rigorous scientific review to ensure they meet standards for safety, efficacy and quality before being authorized.

IF PRESSED ON INTERIM ORDER

- The Interim Order will allow Health Canada to expedite the review and authorization of drugs and vaccines for Canadians in four ways:
    - authorizing a brand new drug based on available evidence with more agile administrative and application requirements;
    - authorizing a new drug based on certain elements being approved by a trusted foreign regulatory authority;
    - allowing expanded use of an already-approved drug to include COVID-19-related indications that were not in the original authorization; and
    - permitting the Public Health Agency of Canada (PHAC) to arrange for the importation of promising COVID-19 drugs for placement (pre-positioning) in Canadian facilities prior to their authorization in Canada if the Government of Canada has entered into a contract for its procurement.

- Health Canada will ensure that these drugs are supported by sufficient evidence of safety, efficacy and quality.

- In addition, under the Interim Order, Health Canada can impose terms and conditions on the authorization, such as risk mitigation measures and periodic assessments of safety information.

- Health Canada will monitor the safety and effectiveness of these drugs and will take immediate action, including the suspension or cancellation of authorizations or establishment licences, if required, to protect the health and safety of Canadians.

IF PRESSED ON CLINICAL TRIALS AND POTENTIAL TREATMENTS

- Health Canada recommends that any potential treatments for COVID-19 be investigated through clinical trials. 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.

- The Department is working tirelessly to facilitate and expedite as many clinical trials for COVID-19 in Canada as possible, without compromising their quality. To this end, in May I approved an Interim Order that supports clinical trials. Among its benefits, the Interim Order reduces the administrative burden for sponsors without compromising the safety of participants, and makes it easier to set up trials across Canada to facilitate access. As of September 17, 2020, Health Canada has authorized five clinical trials submitted under the Interim Order.

IF PRESSED ON POTENTIAL DRUG TREATMENTS AND UNAPPROVED PRODUCTS

- Results from large, well-designed clinical trials are needed to make any conclusions on the safety and efficacy of any treatments.

- Health Canada is expediting the review of clinical trials so that products can be studied and made available to Canadians as quickly as possible.

- As new data about these novel treatments becomes available, Health Canada will continue to take the appropriate steps to ensure the health and safety of Canadians.

IF PRESSED ON REMDESIVIR

- Health Canada has authorized the drug remdesivir (brand name Veklury) for the treatment of patients with severe symptoms of COVID-19 who have pneumonia and require extra oxygen to help them breathe. We approved this drug with conditions for the manufacturer to ensure its continued safety, efficacy and quality.

- We are aware that preliminary results from the WHO SOLIDARITY trial were somewhat inconsistent with results from the previous trial, which Health Canada had used to support the authorization with conditions of this drug.

- There are differences between the studies that make it difficult to compare the outcomes. However, no additional safety concerns have been identified in the available SOLIDARITY data.

- Health Canada will continue to evaluate the detailed results for these trials, as well as any other information that becomes available, and will take the appropriate steps to ensure the health and safety of Canadians.

IF PRESSED ON DEXAMETHASONE

- Treatment with dexamethasone has been shown to reduce the number of deaths for severely ill COVID-19 patients.

- Dexamethasone is a relatively inexpensive steroid drug that has been shown to reduce the number of deaths for some severely ill COVID-19 patients. It is available in Canada and can be used off-label by physicians to treat these patients.

- Health Canada is actively monitoring supplies of this drug in Canada and is in contact with the manufacturers to assess current supply levels. The Department will take action if needed, in collaboration with the provinces and territories, industry and key stakeholders, to help ensure continued supplies of dexamethasone in Canada.

IF PRESSED ON HYDROXYCHLOROQUINE

- Hydroxychloroquine is a malaria drug being investigated as a potential treatment for COVID-19 through clinical trials. Some trials have been discontinued but others are proceeding, depending on the purpose of the trial. Risks associated with this drug can be best managed through screening of trial candidates and close monitoring.
- Health Canada continues to closely monitor the safety and effectiveness of hydroxychloroquine and other drugs used in the treatment of COVID-19, and will take appropriate and timely action, including informing Canadians if and when any new health risks are identified.

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 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 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 THERAPEUTIC INVESTMENTS

- The Government of Canada is collaborating with academia and the private sector to advance research and development of therapeutics including pre-clinical research, bio-manufacturing and enhancing capacity for and access to clinical trials.

- The Government of Canada is closely monitoring and reviewing emerging evidence on possible COVID-19 treatments such as corticosteroids, antiviral drugs and antibody treatments.

- Health Canada and the Public Health Agency of Canada are working closely with provinces and territories to ensure rapid and equitable access to therapeutics.

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.

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 and treatments 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. 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 October 28, 2020, Health Canada has authorized 68 clinical trials for treatment or prevention of COVID-19, most of which are repurposing existing drugs.

Remdesivir

Health Canada has authorized with conditions the drug remdesivir (brand name Veklury) manufactured by Gilead Sciences Canada, Inc. for the treatment of patients with severe symptoms of COVID-19 who have pneumonia and require oxygenation. As a condition of authorization, the manufacturer will submit to Health Canada:

- post-market safety monitoring reports, as well as reports on all serious adverse drug reactions, annual pregnancy safety reports and any foreign regulatory actions related to the safety of remdesivir;
- any further data on the safety and efficacy of the drug, including final data from ongoing clinical trials and additional safety data on patients with liver and kidney disease; and
- further quality data confirming that the manufacturing processes and controls will consistently produce product of suitable quality for the intended use.

Remdesivir has also been granted emergency or conditional authorization in the U.S., Europe, Japan, Singapore, Switzerland and Australia. In Canada, the authorization included a full scientific review. There is no preset expiry date on the authorization. Two existing clinical trials authorized by Health Canada to evaluate the safety and effectiveness of remdesivir for use in Canada are ongoing. These clinical trials will continue to gather more data on the drug.

On October 2, 2020, the European Medicines Agency's safety committee (PRAC) initiated a review to assess reports of acute kidney injury in some patients with COVID-19 that were treated with remdesivir. This review is ongoing.

On October 15, interim results of the World Health Organization's SOLIDARITY trial for COVID-19 treatments were released. The trial comprised 11,266 hospitalized patients across 405 hospitals in 30 countries. As reported in the preprint, which has yet to be peer reviewed, and without accompanying detailed data, remdesivir appeared to have little or no effect on hospitalized COVID-19 patients, as indicated by overall mortality, initiation of ventilation and duration of hospital stay.

- The results of this pre-print are inconsistent with the results of the clinical trials led by Gilead and NIAID, which demonstrated a reduction in time to recovery.
- Currently available evidence indicates that the remdesivir treatment arm of the

SOLIDARITY trial will continue.

Dexamethasone

Clinical trial results announced in June 2020 showed that dexamethasone, used since the 1960s to reduce inflammation, cut death rates by around a third among the most severely ill COVID-19 patients admitted to hospital. As a result, the WHO has updated its guidelines on treating people with COVID-19. Although the dexamethasone study's results are preliminary, the researchers behind the project suggest the drug should immediately become standard care in severely ill patients.

The oral tablet format of dexamethasone was added to Health Canada's list of Tier 3 shortages on May 1, 2020 based on its current indications for use. Tier 3 shortages are those that have the greatest potential impact on Canada's drug supply and health care system. Drugs on this list are in high demand or in shortage. The IV format of dexamethasone has not been determined to be a Tier 3 shortage; a consensus determination was made to monitor the supply situation on a monthly basis.

Apotex and Pharmascience are the only two companies in Canada that market the Dexamethasone oral tablets. Apotex is reporting a shortage for the 0.5mg strength with an estimated end date of October 30, 2020. Apotex is not reporting any shortage for the 4mg strength. Pharmascience is reporting shortages for the 0.5mg strength with an estimated end dates of November 23, 2020 and for the 0.75mg, 2mg and 4mg strengths with an estimated end date of December 7, 2020. Health Canada continues to monitor the supply situation on a monthly basis. Health Canada is also monitoring the supply situation for dexamethasone alternatives, corticosteroids such as methylprednisolone, prednisolone and hydrocortisone.

Hydroxychloroquine

Hydroxychloroquine is an antiparasitic drug approved in Canada for the treatment of malaria, as well as autoimmune diseases such as rheumatoid arthritis and lupus. Health Canada has authorized clinical trials on the use of this drug in COVID-19, and is aware of other ongoing clinical trials across the world.

- An article in the May 22, 2020 edition of "The Lancet" features a study which showed increased mortality and cardiac arrhythmias in hospitalised patients taking chloroquine and hydroxychloroquine for the treatment of COVID-19. This paper was later retracted amid concerns with the validity of the data.
- On June 3, a Canadian-led study published their results in the New England Journal of Medicine, concluding that HCQ did not prevent infection when used as post-exposure prophylaxis within 4 days after exposure.
- On June 5, Investigators of the RECOVERY trial (the UK arm of the SOLIDARITY trial) issued their preliminary results and concluded that there is no

beneficial effect of HCQ in patients hospitalized with COVID-19. As such, they have decided to stop recruitment to the hydroxychloroquine arm of this trial.

- On June 17, 2020, the World Health Organization announced that hydroxychloroquine will no longer be part of its global SOLIDARITY trial. Their decision was based on the evidence that hydroxychloroquine in that trial did not result in the reduction of mortality of hospitalized COVID-19 patients, when compared with standard of care. This decision does not impact other ongoing clinical trials.

VACCINE RESEARCH AND TIMELINES

SYNOPSIS

The Government of Canada is committed to supporting the timely development of a COVID-19 vaccine and securing sufficient supply for Canadians.

KEY MESSAGES

- The Government of Canada is committed to securing promising COVID-19 vaccines for Canada.

- The Government of Canada has entered into seven agreements with AstraZeneca, Sanofi/GlaxoSmithKline, Johnson & Johnson, Novavax, Moderna, Medicago, and Pfizer to secure millions of doses of the leading COVID-19 vaccines.

- To complement these agreements, the Government of Canada has signed an optional purchase agreement with Gavi, committing approximately $220 million to procure roughly 15 million vaccine doses for Canadians from the COVAX Facility's diverse portfolio of candidates.

- An additional $220 million will be channeled through the COVAX Advance Market Commitment to purchase doses for low- and middle-income countries.

- The Government of Canada has also invested more than $1 billion in support of a national medical research strategy to fight COVID-19 that includes vaccine development, production of treatments, and tracking of the virus.

- In Canada, there are currently at least 30 candidate vaccines in early development and it is anticipated that several of these will advance to human clinical trials in the coming months.

- A Vaccine Task Force has been convened to provide advice

to the Government of Canada on how best to support domestic vaccine research and help ensure Canadian leadership in vaccine development, related bio-manufacturing and international partnerships.

IF PRESSED…

- Through our $1 billion investment, the Government of Canada is supporting multiple organizations who are working at unprecedented speed to develop candidate vaccines.

- On July 14, Medicago, a biopharmaceutical company headquartered in Quebec City, began a Phase 1 clinical trial, marking the launch of the first Canadian clinical trial of a COVID-19 vaccine candidate.

- 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.

- Advance purchase agreements with suppliers are an investment in the promise of vaccines.

- Novel vaccines often fail during development, which is why Canada has purchased more supply than is needed for the entire population.

- A diverse portfolio of vaccine candidates will give Canada the greatest chance of earliest access to safe and effective vaccines.

- Canada is exploring opportunities to donate any potential surplus vaccine doses, should it have more than is needed

for Canadians.

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. As of October 5, 2020, there are over 120 COVID-19 candidate vaccines in different stages of development by academia and industry globally, with 64 vaccines in clinical trials (51 vaccines in Phase 1 and/or 2 and 13 vaccines in Phase 3). Phase 3 clinical trials, which are designed to measure how well a vaccine will prevent COVID-19, have been registered in the UK, the US, Brazil, South Africa, Pakistan, Russia and the UAE with results expected this fall or early next year.

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.

Through the first round of its COVID-19 Rapid Research Funding Opportunities, Canadian Institutes of Health Research (CIHR) invested over $16 million in14 vaccine-related projects, including ones focused on identifying candidate vaccines through different animal models, which could be suitable for future clinical trials in humans. These projects targeted a range of vaccine strategies and, in some cases, involved industry partnerships (e.g., Medicago; Inovio) or were supported by the Public Health Agency of Canada (PHAC). Research included, for example, a focus on vertical transmission (mother to child), immune enhancement, and nanoparticle-based vaccine. One such example of a research project is from Dr. Denis Leclerc and his team from Université Laval who were awarded $717,645 in February 2020, through CIHR's first Rapid Response competition to develop the most robust vaccine that will prevent COVID-19. The team has already developed a nanoparticle that has the potential to bond with the virus and trigger a general immune response that aims to motivate the immune system to attack the virus before it can infect cells. Another prominent example of a project is the one by a renowned expert in the field, Dr. Ève Dubé of Université Laval, who received a $499,089 grant to research online discourses related to COVID-19 in Canada (tweets and comments on news media reports) and to describe individual and community understanding of disease, priorities, fears, etc., including public health messaging that may impact the acceptance of measures to limit the spread of COVID-19. Her research will also identify interventions that will help build public trust in authorities responsible for disease transmission tracking and management, while dispelling unfounded rumours and xenophobic discourse.

CIHR also funds the Canadian Immunization Research Network (CIRN), a national network that undertakes coordinated, collaborative, and multi-disciplinary vaccine and

immunization-related research. This includes examining various biomedical research questions and aspects of the vaccine life cycle including safety, short- and long-term effectiveness and protection, as well as social issues like hesitancy and uptake. CIRN has established capacity for timely evaluation of vaccines for a variety of infectious diseases, seeks to continue to improve immunization programs and coverage nationwide, and has built strong links between the research community and key decision makers. On April 7, CIHR and PHAC provided $1 million to CIRN's Serious Outcomes Surveillance Network to gather data related to COVID-19 symptoms, as well as possible treatments and risk factors, to inform Canada's public health response to COVID-19.
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, a global pledging initiative that raised more than $17.9 billion (USD) to accelerate the development of and equitable access to new diagnostic capabilities, therapeutics, and vaccines, including through support to the World Health Organization's Access to COVID-19 Tools Accelerator (ACT-A).

Within ACT-A, Gavi, the Vaccine Alliance, has teamed up with the Coalition for Epidemic Preparedness Innovations (CEPI) and the World Health Organization, to create a pooled procurement mechanism for the purchase of COVID-19 vaccines called the COVAX Facility. This will pool the resources of economies to make advanced purchase agreements for a number of promising vaccine candidates. The Facility will include both low- and lower-middle income countries, whose purchases will be financed by official development assistance through the COVAX Advanced Market Commitment (AMC), and upper-middle and high-income countries who will self-finance their own purchase of vaccine doses for domestic use through the Facility. The Facility is a strong multilateral mechanism that will support timely access to vaccines for all participating economies.

On September 18, Canada signed a binding commitment with the Gavi Alliance to participate in the Facility through an optional purchase agreement that could see Canada acquire vaccine doses through the Facility for upwards of 20% of the Canadian population. An additional $220 million will be channeled through the COVAX Advance Market Commitment to purchase doses for low- and middle-income countries. By

joining, Canada is contributing to collective efforts towards a safe, effective, and affordable COVID-19 vaccine, in line with the Prime Minister's commitment to help ensure that once a vaccine is developed, it will be produced at a scale and cost accessible to all countries. As of September 25, 67 high-income economies have formally joined the Facility along with 92 lower-income countries that are expected to participate in the Advance Market Commitment.

As of October 1, 2020, the Government of Canada has secured access to seven leading vaccine candidates for Canadians through agreements with Pfizer/BioNTech, Moderna, Janssen/Johnson & Johnson, Novavax, Sanofi/GlaxoSmithKline, Medicago, and AstraZeneca. Pfizer/BioNTech will supply a minimum of 20 million doses of its BNT162 mRNA-based vaccine candidate, while Moderna will provide up to 56 million doses of its mRNA-1273 vaccine candidate. Agreements in principle have been struck with Janssen/Johnson & Johnson to supply up to 38 million doses of its Ad26.COV2.S vaccine candidate; Novavax to supply up to 76 million doses of its NVX-CoV2373 vaccine; Sanofi/GlaxoSmithKline to supply up to 72 million of doses of their protein subunit vaccine candidate; Medicago up to 76 million doses of its recombinant plant-derived COVID-19 vaccine; and, AstraZeneca to supply up to 20 million doses of its viral vector vaccine candidate. Active negotiations with other potential vaccine suppliers are also under way.

The development of a diverse portfolio of promising candidate technologies, based on expert advice, will mitigate the risk of vaccines failing to reach market. Should Canada find itself in the enviable position of procuring more vaccine than needed for the Canadian population, the government could stockpile excess supply for future use or donate unneeded doses to countries in need.

Vaccine research and development in Canada

As of October 5, 2020, of the 100+ global candidates noted above, at least 30 organizations in Canada are developing vaccines (some are developing multiple vaccine strategies) using 7 novel and existing vaccine platforms. Two vaccine candidates (CanSino and Medicago) obtained regulatory authorization to initiate clinical trials in Canada and several others could advance to Phase 1 clinical trials in the coming months.

Medicago is the only vaccine developer that is actively conducting vaccine clinical trials in Canada. On July 14, 2020, Medicago launched its COVID-19 vaccine candidate's Phase 1 clinical trial in healthy adults. Their candidate, a virus-like-particle produced in plants, is to be tested in Quebec in combination with proprietary adjuvants developed by collaborators – GSK and Dynavax. Medicago is also planning a Phase 2/3 trial to beinitiated in December 2020.

On May 15, 2020, Health Canada authorized CanSino Biologics Inc. (CanSinoBio) vaccine candidate for a Phase 1/2 clinical trial in healthy adults in Canada. However, this research initiative has since been cancelled, as CanSino could not secure Chinese government approval to ship the vaccine clinical trial lots to Canada.

To facilitate impactful clinical trial research in Canada, government and experts are convening a series of COVID-19 Vaccine Clinical Trials Discussion Forums. Further, a COVID-19 Vaccine Task Force provides advice to the Government of Canada on investments in vaccine development and bio-manufacturing for COVID-19. Task force members include vaccine experts, as well as industry leaders with proven ability in developing and commercializing vaccines. The co-Chairs of the task force are Joanne Langley, Head of Infectious Diseases at the IWK Health Centre in Halifax and Professor in the Department of Community Health and Epidemiology at Dalhousie University, and J. Mark Lievonen, former President of Sanofi Pasteur Limited.

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. For example, the Government of Canada is monitoring international regulators' reviews of safety signals detected during trials of the AstraZeneca vaccine candidate.

On October 1, 2020, Health Canada received its first submission for authorization for a COVID-19 vaccine from AstraZeneca. AstraZeneca is seeking authorization under Health Canada's Interim Order on drugs and vaccines, which allows companies to submit data on the vaccine as it becomes available. This will allow the Health Canada to start its review right away, while information continues to come in, so that the Health Canada can speed up the review process.

Preparing provinces and territories for COVID-19 vaccine deployment

Provincial and territorial governments deliver vaccination programs and determine public health requirements in their jurisdictions, while considering national vaccine expert advice. Planning is underway and will take into account guidance from Canada's National Advisory Committee on Immunization (NACI), to prepare for vaccine availability and administration through public immunization programs.

NACI is formalizing national guidance that will inform administration and usage of approved COVID-19 vaccines. This fall, based on what is known of the burden of illness of COVID-19, NACI will identify key populations for early COVID-19 vaccination and priority vaccine program strategies. NACI guidance on use of specific vaccines will be formed as more is known about vaccine characteristics (e.g. efficacy, safety, dosing

schedule), how well the candidate vaccines work in different populations (e.g. elderly), and until it is determined which vaccines reach market in Canada.

While the Vaccine Task Force will focus on strategic investments in vaccine research, development, and domestic manufacturing, NACI will focus on recommendations for vaccine roll-out to targeted groups, and optimal use of vaccines that are authorised by Health Canada.
In addition, we are working with provinces and territories to ensure that the health care system is prepared to roll out a national vaccination program when a COVID-19 vaccine becomes available, including ensuring that we have sufficient supplies such as needles and syringes, for vaccination clinics.

ACCESS TO VACCINES FOR COVID-19

SYNOPSIS

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

POTENTIAL QUESTION

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

KEY MESSAGES

- The COVID-19 pandemic is unlike anything we have seen in recent history and, in response, we are seeing global vaccine candidates being developed.

- Since the start of the pandemic, Health Canada has worked closely with other departments, including Innovation, Science and Economic Development, the National Research Council, Public Services and Procurement Canada, and the Public Health Agency of Canada, along with the Vaccine Task Force, to develop and implement Canada's vaccine strategy.

- As the regulator, Health Canada has played a critical role in approving clinical trials and will be fundamental in the eventual authorization of vaccines for use in Canada.

- I issued an Interim Order to expedite the review of drugs and vaccines by allowing companies to submit safety and efficacy data as soon as it becomes available.

- As of November 3, Health Canada has three COVID-19 vaccines under review for authorization: those being developed by AstraZeneca, Pfizer, and Moderna.

- While recognizing the urgent need for vaccines, Health Canada will conduct a rigorous scientific review to ensure vaccines are safe, effective and of high quality, before being authorized.

IF PRESSED ON THE TIMING OF APPROVAL

- The vaccines are being reviewed as rolling submissions under the Interim Order signed in September, meaning that the evidence required to support their potential approval will be provided to Health Canada as it becomes available.

- Each manufacturer is filing a detailed plan that lays out the timing and content of the subsequent data and information submissions to Health Canada to support the rolling reviews.

- Timing for the completion of the rolling submission will depend on the outcomes of the companies' ongoing clinical trials.

IF PRESSED ON PRE-POSITIONING

- The Interim Order allows for pre-positioning of unapproved therapies (drugs and vaccines) for COVID-19.

- Health Canada can consider allowing pre-positioning of these unapproved therapies when there has been a filing in Canada or in another trusted regulator, and where requested by the Chief Public Health Officer so that the product can be positioned within Canada and can be readily deployed upon a market approval.

- Decisions on pre-positioning will be made on a case by case basis in order to meet public health needs.

IF PRESSED ON THE RECENT PAUSES TO VACCINE CLINICAL TRIALS IN THE U.S.

- Temporary pauses to clinical trials can be expected, and show that the safety monitoring system is functioning effectively. Any safety issues are being carefully assessed by regulators and independent safety monitoring boards, before decisions are made about trials resuming.

- All available safety data will be assessed by Health Canada as part of the vaccine submission review.

IF PRESSED ON VACCINE AVAILABILITY

- Health Canada is closely monitoring global vaccine and treatment development and is in active discussions with several vaccine manufacturers and researchers to provide regulatory and scientific advice for vaccine clinical trials that may launch in Canada.
- While recognizing the urgent need for vaccines, all products will undergo a rigorous scientific review to ensure they meet standards for safety, efficacy and quality before being authorized.

IF PRESSED ON INTERIM ORDER

- The Interim Order will allow Health Canada to expedite the review and authorization of drugs and vaccines for Canadians in four ways:
    - authorizing a brand new drug based on available evidence with more agile administrative and application requirements;

    - authorizing a new drug based on certain elements being approved by a trusted foreign regulatory authority;
    - allowing expanded use of an already-approved drug to include COVID-19-related indications that were not in the original authorization; and
    - permitting the Public Health Agency of Canada (PHAC) to arrange for the importation of promising COVID-19 drugs for placement (pre-positioning) in Canadian facilities prior to their authorization in Canada if the Government of Canada has entered into a contract for its procurement.
- Health Canada will ensure that these drugs are supported by sufficient evidence of safety, efficacy and quality.
- In addition, under the Interim Order, Health Canada can impose terms and conditions on the authorization, such as risk mitigation measures and periodic assessments of safety information.
- Health Canada will monitor the safety and effectiveness of these drugs and will take immediate action, including the suspension or cancellation of authorizations or establishment licenses, if required, to protect the health and safety of Canadians.

IF PRESSED ON CLINICAL TRIALS

- All vaccines must first be tested in clinical trials to assess their safety and efficacy. 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.

- The Department is working hard to facilitate and expedite as many clinical trials for COVID-19 in Canada as possible, without compromising their quality. To this end, in May I approved an Interim Order that supports clinical trials. Among its benefits, the Interim Order reduces the administrative burden for sponsors without compromising the safety of participants, and makes it easier to set up trials across Canada to facilitate access. As of November 3, 2020, Health Canada has authorized 13 clinical trials submitted under the Interim Order.

IF PRESSED ON UNAPPROVED PRODUCTS

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

- Health Canada is expediting the review of clinical trials so that products can be studied and made available to Canadians as quickly as possible.

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 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.

BACKGROUND

Advance Purchase Agreements

- The Government has announced agreements to secure millions of doses of seven leading vaccine candidates, including those being developed by AstraZeneca, Sanofi/GlaxoSmithKline, Johnson & Johnson, Novavax, Moderna, Pfizer, and Medicago.
- The supply of any of these vaccines is dependent on it successfully completing clinical trials and authorization by Health Canada.

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 working with the manufacturers of the vaccine candidates recommended by the Vaccines Task Force. While regulatory approvals are separate from the procurement process, Health Canada is prepared to receive and expedite vaccine drug submissions.

Clinical Trials

Health Canada is facilitating clinical trials related to COVID-19 in Canada. Clinical trials

are conducted to determine whether new vaccine are both safe and effective in human beings. Clinical trial applications will be reviewed and approved by Health Canada in under 15 days.

Virtual Care

SYNOPSIS

In response to the COVID-19 pandemic, on May 3, 2020 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. Of this, $200M will go to support work in health systems to support expanded deployment of virtual care.

POTENTIAL QUESTION

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

KEY MESSAGES

- The Government of Canada is working closely with provinces and territories, vendors and stakeholders to expand virtual health services so that Canadians can continue to access the care they need during the pandemic.

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

- Of this, $200M will support virtual care services so that Canadians can safely engage with providers through telephone, text or video-conferencing.

- This investment will help Canadians continue to have their health needs met in a safe and secure manner, while reducing pressure on health systems.

IF PRESSED ON THE NATURE OF FEDERAL SUPPORT

- We are negotiating bilateral agreements with provinces and territories to flow $150M this year to help them accelerate their work on virtual care, with a focus on secure messaging and file transfer, secure videoconferencing, remote patient

monitoring, and patient online access to test results, along with needed infrastructure for their existing digital systems in this regard.

- In addition, we are providing up to $50M to Canada Health Infoway to develop pan-Canadian standards for these priorities and to provide support to provinces and territories to implement virtual care initiatives under the bilateral agreements.

BACKGROUND

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. Of this funding, $150M will flow to PTs through bilateral agreements for enhancements to virtual services focused on secure messaging and file transfer, secure videoconferencing, remote patient monitoring, patient online access to test results, and backend supports to integrate these tools within existing digital systems.

In addition, Canada Health Infoway will receive up to $50M to develop pan-Canadian standards on secure messaging and videoconferencing and support PTs as they implement new initiatives pursuant to the bilateral agreements.

Health Canada is working with provinces and territories to begin to identify where support is needed most on virtual care and supporting infrastructure. As part of this work, Health Canada is also supporting work to evaluate the benefit of virtual care in terms of better quality and patient outcomes as well as more sustainable care.

VIRUS LIVING ON SURFACES

SYNOPSIS

Early evidence suggests the COVID-19 virus can remain viable on different objects and surfaces from a few hours to days. The survival time appears to vary with surface type and environmental conditions.

POTENTIAL QUESTION

Are Canadians at risk for contracting COVID-19 if they touch a surface that could potentially be contaminated?

KEY MESSAGES

- Scientific information on COVID-19 continues to be produced rapidly and we continue to evaluate new evidence as it becomes available to inform our intervention and mitigation strategies.

- Though evolving evidence suggests the virus causing COVID-19 can survive on objects and surfaces from a few hours to days, the type of material, and environmental conditions like temperature and humidity, can have an impact.

- We have learned that the virus is easily inactivated by using simple disinfectants such as store-bought disinfectants, which supports the importance of adhering to recommended strategies to prevent infection.

BACKGROUND

Scientific information on COVID-19 continues to be produced rapidly and PHAC continues to evaluate new evidence as it becomes available to inform our intervention and mitigation strategies.

Early on in the pandemic, PHAC was aware that in simulated (laboratory) settings, COVID-19 viruses could survive on surfaces from several hours to days depending on several factors and varied under different circumstances, such as surface type and relative temperature or humidity of the environment.

We have learned that the virus is easily inactivated by using simple disinfectants such as store-bought disinfectants or a diluted bleach solution prepared daily.

Studies on the stability of the virus in laboratory and healthcare settings provide important knowledge on how long the virus may survive on objects and surfaces, and this supports the importance of adhering to recommended strategies to prevent infection. PHAC continues to review new evidence that relates to transmission in healthcare settings, and will update infection prevention and control guidance for healthcare settings, as appropriate.

While important knowledge was gained on how long the virus survives on objects and surfaces commonly found in healthcare settings, additional studies are required to understand whether these findings are the same for surfaces and materials commonly found in other community settings. The infectiousness (i.e., ability to cause infection) of virus particles isolated from various surfaces is also largely unknown.

CANADA HEALTH ACT – ABORTION SERVICES

SYNOPSIS

In New Brunswick (NB), Regulation 84-20 of the NB *Medical Services Payment Act* limits coverage of surgical abortion services to approved hospitals (three NB hospitals currently offer the service – two in Moncton and one in Bathurst). This means that individuals who received these services at Clinic 554 in Fredericton were required to pay out-of-pocket. Patient charges for abortion services received in private clinics are considered extra-billing and user charges under the *Canada Health Act*. Even with the announced closure of Clinic 554, the exclusionary nature of this regulation poses comprehensiveness and accessibility concerns under the Act**.** The NB Health Ministry has repeatedly stated publicly that the government has no intention of changing its position on the issue**.**

Evidence continues to indicate that a number of abortion clinics in Ontario (ON) may be charging patients, contrary to the *Canada Health Act* and provincial legislation. Discussions between Health Canada and the province are ongoing on this matter.

POTENTIAL QUESTIONS

Will the Minister enforce the *Canada Health Act* and penalize provinces (such as NB and ON) where patients face charges when they attempt to access to abortion services?

KEY MESSAGES

- Our Government believes that Canadians should have access to the full range of reproductive health services, including abortion services.

- Individuals should not face charges when seeking these insured services regardless of where the services are provided.

- The Act is clear: where there is evidence of patient charges, a mandatory deduction to federal health transfer payments to the province or territory must be taken.

- This Government will uphold the *Canada Health Act* to help ensure that patients do not face barriers when accessing medically necessary health care.

BACKGROUND

In New Brunswick, Regulation 84-20 of the NB *Medical Services Payment Act* limits coverage of surgical abortion services to approved hospitals (three NB hospitals currently offer the service – two in Moncton and one in Bathurst). This means that individuals who receive these services at the private clinic in Fredericton are required to pay out-of-pocket. New Brunswick is the last province with a private abortion clinic that refuses to provide coverage for services delivered there. Patient charges for abortion services received in private clinics are considered extra-billing and user charges under the *Canada Health Act* and raise concerns under the accessibility and comprehensiveness criteria of the Act. The lack of coverage for abortions performed in private clinics has been discussed bilaterally with NB since 1995, without resolution.

The Morgentaler Clinic in Fredericton closed in July 2014. Clinic officials indicated New Brunswick regulations preventing coverage of abortion services provided in private clinics made the clinic financially unviable. A crowd-sourcing effort subsequently raised sufficient funds and in January 2015, it reopened as Clinic 554. The clinic's web-site indicates abortion services cost between $700 and $850, depending on the stage of pregnancy. It also indicates financial assistance may be available from the National Abortion Federation and provides contact information. The clinic also offers primary health care services and services to the LGBT community, all of which are covered under the provincial health insurance plan, according to the clinic director. It claims a roster of 3,000 patients.

Clinic 554, which was the only facility in the area providing surgical abortion services, closed in fall 2020 due to the lack of public funding for these services. In early July 2019, former Minister Petitpas Taylor met with the NB Health Minister to discuss the accessibility and comprehensive concerns related to this issue, including the patient charges being levied by the clinic for the abortion services. These concerns were reiterated by Minister Petitpas Taylor, and then by the Prime Minister and Minister Hajdu, in late 2019. During the recent election in NB, Premier Higgs maintained the province provides sufficient access to abortion services and does not intend to fund abortion services in private clinics. He said this was consistent with the *Canada Health Act*.

On October 14, 2020, the Canadian Civil Liberties Association notified the NB government of its intention to launch legal proceedings to compel the province to eliminate the preclusion for coverage under Regulation 84-20 of clinic abortions, if the province does not take immediate action to do so, on its own.

In Summer 2019, media reports indicated that individuals in Ontario were encountering patient charges for abortion services when they sought insured services in certain private clinics in the GTA. Surgical abortions are an insured service under the Ontario Health Insurance Plan. In Ontario, these services are provided in hospitals and two types of private facilities: licensed Independent Health Facilities (IHF), and non-IHF clinics. The Ministry of Health only funds facility costs at the four clinics licensed as IHFs. Health Canada has signaled to Ontario that patient charges being levied in non-IHF clinics are user charges under the CHA. Discussions between Health Canada and the province are ongoing on this matter.

DECISION IN CAMBIE SURGERIES CORP V BC (ATTORNEY GENERAL)

SYNOPSIS

- On September 10, 2020, the Supreme Court of British Columbia released its decision in Cambie Surgeries Corp v. BC (Attorney General), which dismissed a constitutional challenge to provisions of British Columbia's *Medicare Protection Act* and upheld the province's ban on patient charges and the purchase of private insurance for publicly insured health care services.

POTENTIAL QUESTIONS

- What is the federal government's position on the Court's decision?

KEY MESSAGES

- Our Government fully welcomes the Court's decision and commends the Government of BC for its successful defense of universally accessible health care.

- This decision validates Canada's single-payor public health care system and the fundamental principle that access to medically necessary health services should be based on health need and not on the ability or willingness to pay.

- Patient charges – whether they take the form of charges at the point of service or payment for private insurance – undermine the principles of fairness and equity.

- These values are more important than ever as we continue to respond to the unprecedented challenges presented by the COVID-19 outbreak, and the Government of Canada will continue to defend universally accessible health care for all Canadians.

BACKGROUND

- On September 10, 2020, Justice Steeves of the Supreme Court of British Columbia released his decision *Cambie Surgeries Corp v. BC (Attorney General),* which dismissed a constitutional challenge to provisions of British Columbia's *Medicare Protection Act* and upheld the province's ban on patient charges and the purchase of private insurance for publicly insured health care services.
- Launched in 2009, the plaintiffs in this case (two private health facilities, founded and co-owned by Dr. Brian Day, and four individual patients who paid privately to obtain publicly insured health care services), argued that in light of long waits for care in BC's publicly funded system, provisions of the *Medicare Protection Act* (MPA) that place limits on a patient's ability to access more timely, privately paid medical care violate section 7 (right to life, liberty and security of person) of the Canadian Charter of Rights and Freedoms (Charter). They also argued that exclusions under the MPA, which allow some BC residents (e.g., Workers' Compensation claimants) unobstructed access to timely care in the private system, violate section 15 (equality rights) of the Charter. The trial began on September 6, 2016, and after numerous delays concluded on February 28, 2020.
- During the course of the proceedings the plaintiffs were also granted an injunction that prevented the BC government from enforcing new penalty provisions (e.g., large fines) to deter providers from charging patients for insured services. The injunction expired on September 10, 2020, with the release of the decision.
- On September 12, 2020, the plaintiffs filed their notice to appeal the decision to the BC Court of Appeal, in an attempt to overturn Justice Steeves' decision. Both BC and Canada will participate in the appeal, which will be heard over five days during the week of June 14, 2021. Regardless of the outcome of this appeal (i.e., whether it is successful, in part or in whole, or unsuccessful), it is expected that the decision will ultimately be appealed to the Supreme Court of Canada.
- On October 16, 2020, the plaintiffs also filed a new injunction application (to replace the injunction that expired on September 10, 2020). The new injunction seeks to further delay BC's enforcement of provisions to deter providers from charging patients for insured services, as well as block BC's injunctive authority to restrain providers from levying these patient charges. If successful, the injunction would apply to privately paid insured services provided in private surgical clinics, and be in place until the appeal of the Cambie decision has been adjudicated. Canada is not participating in these proceedings but will provide assistance to BC, as required. The injunction hearing will take place on November 17-18, 2020.

While the *Canada Health Act* was not under direct challenge in this case, Canada joined these proceedings playing a supporting role to British Columbia in defending the constitutional validity of provisions of the MPA, which reflect the CHA's objective of ensuring universal access to insured health services based on need and not on the ability to pay.

- Given the significance of the plaintiffs' challenges to Canadian Medicare, Canada will continue to advocate for the principles of universally accessible publicly financed health care, including support for BC for the duration of any appeals process.

DENTAL CARE

SYNOPSIS

- The Government of Canada is committed to working with Parliament on its study of national dental care.

POTENTIAL QUESTION

- What is the Government of Canada doing to address the unmet dental care needs of Canadians?

KEY MESSAGES

- While most Canadians have dental coverage through their employment health plans, we know there are unmet dental care needs in Canada.

- My mandate letter highlights this Government's desire to work with Parliament to study and analyze the possibility of national dental care.

- Dental care is only one aspect of our commitment to improving health care for Canadians. The recent Speech from the Throne committed to work with provinces and territories to address health needs arising from the pandemic, but also to improve access to primary care, set standards for long-term care, address the opioid epidemic and implement pharmacare for Canadians.

BACKGROUND (FOR PUBLIC USE)

- The 2019 Speech from the Throne and the mandate letter for the Minister of Health both committed the Government to work with Parliament to study and analyze the possibility of national dental care.

- In February 2020, the House of Commons Standing Committee on Health agreed to undertake a study on the development of a national dental care program, although the study never began during the last session. On October 26, 2020, NDP Member of Parliament Don Davies introduced a motion that HESA undertake a study on the development of a national dental care program as an insured service for Canadians. The motion is yet to be voted on. Health Canada remains ready to support a study by the Committee, should it decide again to undertake that work.

- In October 2020, the Parliamentary Budget Officer published a cost estimate of a federal dental care program for uninsured Canadians with a total household income below $90,000. It is estimated that this program would cost close to $11 billion over five years (a one-time upfront cost of around $3 billion to clear accumulated care needs, plus ongoing program costs of around $1.5 billion annually through 2024-25). The program was estimated to benefit close to 6.5 million Canadians in the first year, and decrease to 6.3 million by 2025 due to changes in population and labour market conditions.

- During the 2019 election campaign, the New Democratic Party (NDP) identified inequality and wasted spending related to dental care as an issue, citing that care avoidance due to cost results in preventable oral health emergency room spending. The NDP planned to address this issue through a national, income-based "Denticare" plan that would have provided free care for households earning under $70,000 annually, and a sliding co-payment scale for those earning between $70,000 and $90,000.

Current Dental Care Programs in Canada

- According to the Canadian Institute for Health Information, $15.5 billion was spent on dental services in 2017: 54% was covered through private insurance; 40% was paid out-of-pocket; and 6% was publicly funded. About two-thirds of Canadians receive dental coverage through employment-based private health insurance plans.

- Provinces and territories (PTs) provide emergency, in-hospital medically necessary dental care for all residents. Additional PT programs vary in eligibility and coverage, and are limited to select services for groups such as those with low incomes, people with disabilities, children, and seniors.

- Federal support for dental care includes:
  - The federal government provides First Nations and Inuit with dental coverage for services not available under other FPT programs. The Government also provides dental services to Canadian Armed Forces personnel, inmates in federal penitentiaries, and some veterans and refugee claimants.
  - Federal public servants are provided with dental coverage through the Government of Canada's employee benefits program.
  - The Canada Health Transfer is providing $41.9 billion to the provinces and territories in 2020-21, which is used to support health services (including PT dental programs if they choose).
  - The federal government supports Canadians with private health insurance by not including the value of these insurance plans in the taxable income of employees. In addition, the income tax system provides assistance through the Medical Expenses Tax Credit, and through a refundable medical expenses supplement available for working individuals with low-incomes and high medical expenses.

- Comprehensive data does not exist on unmet dental care needs at a national level in Canada. The Canadian Association of Public Health Dentistry suggests that 1 in 5

people (6 million Canadians) are not receiving needed dental care due to cost, and that only Canadians with financial resources or insurance can experience good oral health.

DIABETES

SYNOPSIS

Diabetes is a chronic disease that occurs when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Diabetes can lead to serious complications and premature death. Some Canadians with diabetes may be at greater risk of severe COVID-19 outcomes because of pre-existing health conditions. Those who have diabetes can take steps to control the disease and lower the risk of complications.

KEY MESSAGES

- Our top priority is to protect the health and safety of Canadians and our Government recognizes the impact diabetes has on the health of Canadians during and following the COVID-19 pandemic. Almost 3.2 million Canadians are living with diabetes and 200,000 new cases are diagnosed each year.

- We contribute to the Government of Canada's coordinated response to the COVID-19 pandemic, which includes investments in research, prevention and early detection of diabetes. In 2018–2019 alone, our Government invested over $48 million in diabetes research through the Canadian Institutes of Health Research.

- With physical distancing and self-isolation restrictions, promoting healthy living and preventing diabetes continues to be a priority. The prevalence of physical inactivity and other factors that put some Canadians more at risk of chronic diseases, including diabetes, are increasing, and will likely remain high following the pandemic.

BACKGROUND

The Public Health Agency of Canada (PHAC) undertakes data collection and analysis of chronic diseases and their risk and protective factors; strengthens collaborations to better track disease trends and risks; supports the development of prevention guidelines for primary care; and shares knowledge of best practices and effective interventions. PHAC also leads the Pan-Canadian Health Inequalities Reporting Initiative, which monitors over 100 indicators of health outcomes and determinants, including several

related to diabetes, disaggregated across a range of population groups at the national, provincial, and territorial levels.

PHAC is supporting community-based initiatives that encourage behaviour changes that will improve the health of Canadians and reduce health inequalities among sub-groups of the population. In particular, PHAC's *Healthy Living and Chronic Disease Prevention - Multi-Sectoral Partnerships* (MSP) program invests approximately $20 million annually and leverages additional non-governmental funding to support projects that address the common risk factors, including physical inactivity, unhealthy eating and tobacco use, associated with major chronic diseases such as cancer, diabetes, and cardiovascular disease. Examples of projects funded by the MSP program include:

- ***Canadian Diabetes Prevention Program*** – In partnership with Diabetes Canada, LMC Prevention Ltd. is implementing a 12-month lifestyle intervention program to reduce the risk of type 2 diabetes in Canada by supporting behaviour changes and weight loss. The program targets individuals at risk of developing diabetes and those diagnosed with prediabetes.
- ***Hockey Fans in Training (Hockey FIT)*** – University of Western Ontario is implementing a project to increase physical activity and healthy eating behaviours among middle-aged overweight and obese men at risk of chronic disease, including diabetes. The program targets men from urban and rural communities, Indigenous communities, different cultures (e.g., new Canadian immigrant communities), and individuals across the socioeconomic spectrum.

Projects funded by the MSP program are adapting to continue to reach those in need during COVID-19.

To help Canadians identify their risk of diabetes and how they can reduce it, PHAC developed CANRISK, the Canadian diabetes risk questionnaire. CANRISK is accessible to Canadians through partnerships with Diabetes Canada, Shoppers Drug Mart, Pharmasave, Rexall, Loblaws and others.

From 2014-15 to 2018-19, the Government of Canada, through the Canadian Institutes of Health Research (CIHR), invested approximately $229 million in diabetes research, including $48 million in 2018-2019 alone. CIHR also funds research in areas such as obesity, kidney disease and cardiovascular disease that impact on diabetes prevention and management of the complications of diabetes. Key strategic diabetes-related research activities are included in the Pathways to Health Equity for Aboriginal Peoples Initiative, Canada's Strategy for Patient-Oriented Research, and a new Partnership to Defeat Diabetes with the Juvenile Diabetes Research Foundation. CIHR recently launched an initiative with key partners, including Diabetes Canada and JDRF Canada, to celebrate the 100th anniversary of the discovery of insulin to be marked in 2021 (*100 Years of Insulin: Accelerating Canadian Discoveries to Defeat Diabetes*).
Some Canadians may be at greater risk for severe COVID-19 outcomes because of pre-existing health conditions, such as diabetes.

Parliament

On April 10, 2019, the Standing Committee on Health released its report on its study of diabetes strategies, which had 11 recommendations in seven thematic areas: (1) a national diabetes strategy for Canada, (2) research funding, (3) disability tax credit, (4) provincial/territorial coverage of diabetes-related medications, supplies and equipment (5) cost of insulin, (6) access to health services including in rural and remote communities, and (7) diabetes-related education and training for health care professionals. The government response was prepared, but not tabled due to the 2019 Federal Election. Once re-constituted, HESA may choose to readopt the report.

In June 2019, the House of Commons passed a motion (M-173) designating the month of November as Diabetes Awareness Month.

On February 27, 2020, Member of Parliament Sonia Sidhu (Liberal – Ontario) introduced Bill C-237, which calls on the Minister of Health, in consultation with the representatives of the provincial governments responsible for health, Indigenous groups and with other relevant stakeholders, to develop a national framework designed to support improved access to diabetes prevention and treatment to ensure better health outcomes for Canadians.

Both JDRF and Diabetes Canada submitted a brief for the Pre-budget Consultations in Advance of the 2021 Budget of the Standing Committee on Finance. On September 10, the All-Party Juvenile Diabetes Caucus wrote Minister Freeland to express its support for the pre-budget recommendations submitted by the JDRF, citing it as an opportunity for the Government of Canada to renew its investment of $15 million in the JDRF-CIHR Partnership.

Diabetes Canada
Diabetes Canada publicly expressed disappointment about not received funding in Budget 2018 and 2019 for their national strategy to address diabetes as outlined in their Diabetes 360° report.

Missing Doc.

Blood Donor Deferral Policy and Related Research – Men Who Have Sex with Men (MSM)

SYNOPSIS

Health Canada funds research that could inform future changes to blood donation policies. This funding supports blood operators to generate the scientific data required to support a submission to Health Canada for regulatory authorization. Canada's blood system is internationally recognized for its high safety standards. It is, and will continue to be, one of the safest blood systems in the world.

POTENTIAL QUESTION

KEY MESSAGES

- Canada has one of the safest blood systems in the world.
- I'm proud that our government has been working on reducing barriers preventing MSM from donating blood by:
    - authorizing Canadian Blood Services' and Héma-Québec's proposals to reduce the deferral period for donation from five years to 3 months;
    - committing $3 million to Canadian Blood Services, starting in 2016, and in collaboration with Héma-Québec, to further advance research on this issue, and
    - providing a further $2.4 million over three years, starting in 2019–20, for additional research specific to reducing barriers to the donation of plasma.
- Health Canada remains open to assessing future changes to the MSM donor deferral policy, including its elimination, provided that submissions are received from the blood operators and are supported by scientific evidence.

IF PRESSED…

- Health Canada and the provinces and territories cannot mandate a policy change to donor screening requirements.

- Canadian Blood Services and Héma-Québec must make submissions to Health Canada demonstrating the change's potential benefit and safety based on up-to-date scientific data. Without this evidence, the current screening policies cannot be changed.

If pressed on the Karas' Human Rights complaint:

- This matter is presently before the court and further details of Canada's legal position will be provided to the court.

- Cette affaire est actuellement devant le tribunal et des détails supplémentaires sur la position juridique du Canada seront communiqués au tribunal.

BACKGROUND

In Canada:

There are no regulations prohibiting MSM and other groups from donating blood. Donor deferrals are policy decisions of the blood operators. However, under Canada's *Blood Regulations*, CBS and H-Q are required to make submissions to HC for any changes to their processes. HC must evaluate and authorize any changes before they can be implemented. HC has no authority to mandate that a donor screening criterion be changed due to perceived discriminatory aspects.

The first MSM deferral in 1984 prohibited a man who had engaged in sex with another man even once since 1977 from donating blood. On May 22, 2013, HC authorized a request from CBS and H-Q to change its MSM deferral criteria to a five-year deferral period and on June 16, 2016 HC authorized subsequent proposals from CBS and H-Q, to change the blood donor deferral period for MSM from a five-year to a one-year deferral period. On April 30, 2019, HC authorized a submission from CBS and H-Q to further reduce the MSM deferral period to three-months.

There are two main blood donor deferral strategies used internationally to address the risk of HIV and other disease transmission. The first and most common is a time-based deferral based on the higher-risk activities of specific populations, such as the MSM deferral currently applied in Canada. The second is an individual-based deferral that looks at higher-risk activities on a donor-by-donor basis. This is often referred to as a behaviour-based deferral and usually includes questions on new partners or multiple partners of either sex.

In 2016, the Government allocated $3.0 million for research to strengthen the evidence base supporting a non-discriminatory approach to blood donations. Results of these

research projects are expected to be available in 2021, to inform future blood donation policies. Budget 2019 further provided $2.4 million over three years, starting in 2019–20, for additional research specific to reducing barriers to the donation of blood plasma. Among the funded studies, alternative donor eligibility questions and criteria are under evaluation for MSM.

International trends:
There is no international scientific consensus regarding donor deferral periods for MSM. Some countries, such as Austria and the Ukraine, maintain indefinite deferral periods, while other countries, including France and Australia, have one-year deferral periods. Others have adopted a 3-month deferral including England, Scotland, Wales, and United States. Some countries, such as Spain and Italy, do not have MSM-specific deferral periods. For example, in Italy the donor screening includes a face-to-face interview in a private and confidential location by a trained physician who is responsible for donor selection.

HIGH COST DRUGS FOR RARE DISEASES

SYNOPSIS

- Rare diseases are life-threatening, seriously debilitating and sometimes chronic in nature. With few or no treatment options, available treatments can command high prices which pose significant challenges to patients, caregivers, and the health care system, including the sustainability of public and private drug plans that pay for these drugs.
- Budget 2019 proposed to invest up to $1 billion over two years, starting in 2022-23, with up to $500 million per year ongoing. As reaffirmed in the September 2020 Speech from the Throne, this includes working with willing provinces, territories and stakeholders to establish a national strategy for high cost drugs for rare diseases.

POTENTIAL QUESTION

- The September 2020 Speech from the Throne referenced a rare diseases strategy, which was previously included as a commitment in Budget 2019. Why has the Government not delivered on this strategy while Canadians with rare diseases desparately wait?

KEY MESSAGES

- We recognize that for many Canadians who require prescription drugs to treat rare diseases, the cost of these medications can be astronomically high.

- To help Canadians get better access to effective treatments, we are working with provinces, territories and other partners willing to move forward to develop a national strategy for high cost drugs for rare diseases.

- *Budget 2019* proposed to invest up to $1 billion over two years, starting in 2022-2023, with up to $500 million per year ongoing, to help Canadians with rare diseases access the drugs they need. The recent Speech from the Throne highlights the Government's continued commitment in developing a national strategy.

- Our Government has also been working with key stakeholders to improve access by encouraging the development and availability of drugs for rare diseases for Canadians. In 2019, 16 of the 35 new drugs Health Canada approved were drugs for rare diseases.

IF PRESSED ON THE STATUS OF THE NATIONAL STRATEGY…

- Despite the global pandemic, our Government recognizes the pressing need to improve access and affordability of treatments for rare diseases.

- In collaboration with willing provinces, territories and other partners, we intend to continue to work toward delivering a national strategy by 2022-2023.

IF PRESSED ON THE SPECIAL ACCESS PROGRAM…

- Our Government recognizes the importance of Canadians having access to the treatments they need.

- Health Canada's Special Access Program considers requests for access to drugs that are unavailable for sale in Canada. There have been approximately 150 drugs accessed through the program for the treatment of rare diseases.

IF PRESSED ON RESEARCH…

- Our Government recognizes that supporting research is another important aspect of addressing rare diseases. Through the Canadian Institutes of Health Research (CIHR), Canada is playing an important role, both at the national and international levels, to tackle rare diseases.

- For example, Canada, through CIHR, is a founding member of the International Rare Diseases Research Consortium and is also engaged in E-Rare, the European Union's main instrument for funding research in areas related to rare diseases.

BACKGROUND

CANADIANS LIVING WITH RARE DISEASES

- Rare diseases are life-threatening, seriously debilitating and sometimes chronic in nature. They are often genetic conditions, with onset either at birth or early childhood.

- More than 7,000 rare diseases (cancer and non-cancer) have been identified to date. Despite the number of rare diseases, each disease affects a relatively small number of patients (e.g., less than 5 in 10,000; typically closer to 1 in 100,000).

- Patients generally have reduced quality of life and shortened life span, and are high-end users of the public health care system.

HIGH COST DRUGS FOR RARE DISEASES

- Patients with rare diseases generally have few treatment options, resulting in unmet clinical need. Accordingly, treatments are in high demand and can command high prices. The pharmaceutical treatments for rare diseases are often referred to as orphan drugs, or expensive drugs for rare diseases, or high cost drugs for rare diseases.

- High prices are often attributed to factors such as the high cost of research, limited number of patients, small market size, and lack of competitors.

- The Government of Canada is 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.

- In August 2019, the Government modernized the Patented Medicines Regulations to ensure the Patented Medicine Prices Review Board (PMPRB) has the tools and information to protect consumers from excessive patented medicine prices. It is estimated that the amendments will result in savings for governments and private payers of approximately $13.2 billion over 10 years. However, the brand-name pharmaceutical industry and some patient groups have expressed concerns that the amendments could result in reduced pharmaceutical investments and access to medicines.

ACCESS TO HIGH COST DRUGS FOR RARE DISEASES

- Canadians have been able to gain access to drugs for rare diseases through participation in clinical trials, or as drugs are approved under Division 8 of the *Food and Drug Regulations*. In cases where criteria are met, Health Canada's Special Access Program (SAP) considers requests for access to drugs that are unavailable for sale in Canada. About 150 of the drugs accessed through the SAP are for the treatment of rare diseases.

IMPACT OF COVID-19 ON HIGH COST DRUGS FOR RARE DISEASES

- Despite the pandemic, attention continues to be focused on high cost drugs for rare diseases, including on new drugs for specific patient cases, and general calls emphasizing the need for a national strategy.

- To date, private drug plans have reported minimal changes to the coverage status of patients taking high cost drugs for rare diseases, but it is unknown if this will change over time.

STAKEHOLDER PERSPECTIVES ON HIGH COST DRUGS FOR RARE DISEASES

- There is broad consensus amongst political parties, PT governments, private insurers and other health system partners for federal funding for high cost drugs for rare diseases.

- Reaching an agreement on the scope/details of the strategy – and the balance of access vs. affordability vs. appropriate use – will require a comprehensive engagement approach. This will also help manage expectations around the limits of federal funding.

- Engagement efforts will be carried out virtually and are expected to commence in this fall. Key stakeholders will include PTs, patients and patient groups, clinicians, health technology assessment organizations, pharmaceutical manufacturers, private payers, and international jurisdictions.

INVESTMENT IN RESEARCH

- Through the Canadian Institutes of Health Research (CIHR), the Government is supporting research on rare diseases and has taken a leadership role by joining important international research initiatives, such as the International Rare Disease Research Consortium, which aims to accelerate medical breakthroughs for people affected by rare diseases and includes 58 organizations from 22 countries.

- As of 2017, this international Consortium has yielded 279 new medicinal products and therapies for rare diseases.

LYME DISEASE

SYNOPSIS

Lyme disease continues to draw public, political and media attention with particular scrutiny on the number of human cases, risks, diagnosis and treatment in Canada. In particular, the risk of transmission from mother to baby during pregnancy is an issue of concern to some advocacy groups.

KEY MESSAGES

- Our Government recognizes that Lyme disease is increasing in Canada, due in part to climate change.
- We are committed to working with stakeholders to help protect Canadians.
- We are raising public awareness of Lyme disease and making sure health care providers have the information they need to recognize the symptoms.
- We are funding research on the diagnosis and treatment of Lyme disease to support early detection and care.

IF PRESSED on LYME DISEASE DURING PREGNANCY …

- Our Government recognizes that further research is required to better understand if there may be adverse effects of Lyme disease during pregnancy.
- Our Government will continue to support research to help address the significant knowledge gaps that exist on this topic.

IF PRESSED on CHANGES TO CDC WEBSITE LANGUAGE …

- The Public Health Agency of Canada is aware of the recent revisions to the United States' Centers for Disease Control and Prevention website regarding Lyme disease and pregnancy.
- The Public Health Agency of Canada will continue to monitor

new evidence as it becomes available, and is committed to providing Canadians with up-to-date information on Lyme disease so that they can take measures to protect their health.

BACKGROUND

Caused by the bite of an infected blacklegged tick, Lyme disease can cause serious symptoms such as long-term neurological problems, chronic pain and fatigue. However, if diagnosed early, it can be effectively treated with antibiotics. The number of regions with established blacklegged ticks continues to increase across Canada. The provinces reported 2,025 cases of Lyme disease in 2017, compared to 1,487 cases in 2018. Although total cases were down in 2018, there has been variation in case numbers from year to year. The overall trend over the past 10 years indicates that incidence of Lyme disease is increasing in many areas of Canada, in part due to climate warming and associated expansion of tick habitats.

Federal Role:

The Public Health Agency of Canada (PHAC) monitors Lyme disease in Canada. PHAC provides national information on the number of cases reported and identifies where Lyme disease is present and emerging in Canada. Addressing Lyme disease is a shared responsibility. In partnership with public health authorities at other levels of government, the Government of Canada is raising awareness through public education; supporting surveillance activities and national reporting; conducting and supporting laboratory diagnostic testing; engaging with international and domestic organizations; and funding research. Provinces and territories (P/Ts) provide healthcare services to Lyme disease patients and coordinate prevention and control activities.

Federal Framework on Lyme Disease

The *Federal Framework on Lyme Disease Act* came into force on May 30, 2017. The effectiveness of the Framework must be reviewed in five years, and a report on these findings must also be tabled in each House of Parliament (2022). The Framework includes an Action Plan with three pillars:

- Surveillance : Coordination of national surveillance to monitor and report on human cases of Lyme disease and the geographic distribution of ticks;
- Education and Awareness: Increasing awareness of Lyme disease among health professionals and the general public; and,
- Guidelines and Best Practices: Supporting medical professionals and provincial laboratories in the diagnosis of Lyme disease and work to improve laboratory diagnostic testing.

There is no dedicated long-term funding for the implementation of the Federal Framework on Lyme disease.

Research Network on Lyme disease
Between 2014-15 and 2018-19, the Canadian Institutes of Health Research (CIHR) invested approximately $2.6 million in Lyme disease research. This includes approximately $1.1 million in 2018-19.

In October 2018, CIHR and PHAC invested $4million over 4 years in the Canadian Lyme Disease Research Network, led by Dr. Kieran Moore from Queen's University. Dr. Moore and his research team are working with Lyme disease stakeholders, including researchers, clinicians and patients, in order to facilitate national collaboration and to generate new knowledge to improve the diagnosis, treatment, and health outcomes for people with Lyme disease.

Infectious Diseases and Climate Change Fund
PHAC's Infectious Disease and Climate Change (IDCC) Fund provides $2 million annually over 11 years (2017-2028) to help Canadians, communities and health professionals have the information they need to better understand their risks and take measures to protect themselves from climate-driven infectious diseases. As of November 2020, more than $4 million in funding has been invested to support fourteen new Lyme disease projects focussed on enhancing surveillance and monitoring efforts, and developing new education and awareness resources and tools for the public and health professionals.

Current Issues: Lyme Disease and Pregnancy

Revisions to U.S. Centers for Disease Control and Prevention (CDC) Website Language
On January 27, 2020, the U.S. CDC revised their website (cdc.gov/lyme) to include revised language regarding transmission of Lyme disease during pregnancy. The revised language states "untreated Lyme disease during pregnancy can lead to infection of the placenta. Spread from mother to fetus is possible but rare." As the source of evidence for the updated language, CDC cites a 1997 review article of early case reports and epidemiologic studies from 1983 to 1997. The change in language on the CDC website has prompted an immediate response from media and stakeholder groups, who are calling for the Canadian government to follow U.S. recognition of mother-to-fetus Lyme disease transmission.

Federal Initiatives and Investments
PHAC and the CDC conducted a systematic review to assess the literature on Lyme disease and its effect on pregnancy and the fetus, which was published in a peer-reviewed journal in November 2018. The review concludes that, while maternal-fetal transmission is biologically plausible, more research is needed to determine whether maternal-fetal transmission occurs, and if so, whether there is any association with poor outcomes for the baby. The PHAC review is consistent with the April 2018 review done by the UK National Institute for Health and Care Excellence, both of which have indicated that there is no conclusive evidence of maternal-fetal transmission of Lyme disease.

Through the IDCC Fund, PHAC provided funding of $525,274 to the Society of Obstetricians and Gynecologists of Canada (SOGC) to review the current evidence on the effects of Lyme disease and other tick-borne diseases on pregnancy and pregnancy outcomes. In May 2020, SOGC published the Committee Opinion No. 399: Management of Tick Bites and Lyme Disease During Pregnancy. The research concluded that while currently there are no conclusive data to support transplacental transmission of Lyme disease, more research is needed to address the gaps in knowledge around Lyme disease in pregnancy and potential congenital infection. Lyme disease and other tick-borne diseases represent an evolving field. The guidance provided in SOGC's committee opinion is based on the best available evidence. The funding provided to SOGC also supports the development of resources that will equip health care providers and women with evidence-based information and tools on Lyme disease and other tick-borne diseases during pregnancy. It is expected that they will complete this work in the coming months.

PHAC will continue to monitor new evidence as it becomes available and is committed to providing Canadians with up-to-date information on Lyme disease so that they can take measures to protect their health.

MEDICAL ASSISTANCE IN DYING (MAID) – DEBATE ON BILL C-7

SYNOPSIS

Bill C-7 was reintroduced on October 5, 2020 and responds to the Superior Court of Quebec decision in *Truchon*, which struck down the eligibility requirement of a reasonably foreseeable natural death (RFND). Bill C-7 was originally tabled on February 24, 2020 and was terminated with the prorogation of Parliament.

The Quebec court originally suspended its judgment until March 11, 2020. In light of COVID-19, the deadline was extended to December 18, 2020. If legislative changes are not passed prior to this date, there will be a difference in eligibility for MAID between Quebec and the rest of Canada.

The original MAID legislation required a Parliamentary Review of its provisions and of the state of palliative care in Canada. It was originally anticipated that this review would be initiated in June 2020 but this was delayed due to the pandemic.

POTENTIAL QUESTION

- What is the status of the government's amendments to the MAID legislation and the parliamentary review as required in the original MAID legislation?

KEY MESSAGES

- Bill C-7 was reintroduced in Parliament on October 5, 2020. It responds to the *Truchon* decision, while also addressing areas where there is strong provider and public support for improvement in the medical assistance in dying law.

- We are working with Parliamentarians to meet the deadline of December 18, 2020 set by the Quebec Court in order to provide a consistent legal framework for MAID for all Canadians.

- Our Government recognizes the importance of the Parliamentary Review which will provide an opportunity to address complex issues not addressed in Bill C-7. It is up to Parliament to determine the scope and timing of this review.

BACKGROUND

BILL C-7, AN ACT TO AMEND THE CRIMINAL CODE (MEDICAL ASSISTANCE IN DYING)

On September 11, 2019, the Superior Court of Quebec ruled in favour of two plaintiffs (Jean Truchon and Nicole Gladu) who had challenged the Criminal Code eligibility requirement that an individual's natural death be reasonably foreseeable and the more stringent provincial requirement for a person to be at the end of life. The governments of Canada and Quebec did not appeal the decision.

On February 24, 2020, the federal government tabled proposed amendments to the 2016 *Criminal Code* provisions on MAID (Bill C-7) in response to *Truchon*. These proposed amendments were:

- remove the RFND eligibility requirement (those suffering solely from mental illness would not be eligible);
- introduce two-tracks of safeguards (RFND and non-RFND);
- allow "waiving of final consent" for eligible persons in the RFND category who may lose capacity to consent before MAID is provided; and
- expand data collection to provide a more complete picture of MAID in Canada

The original Bill was terminated with the prorogation of Parliament. Bill C-7 was re-introduced on October 5, 2020; its content was unchanged.

The Quebec court originally suspended its judgement until March 11, 2020. At the request of the Government of Canada, the date of invalidity was extended to July 11, 2020, and then again to December 18, 2020 in light of disruptions to parliamentary business during the pandemic. During the period of suspension, Quebec residents who meet all eligibility requirements (other than RFND) are able to make an application to a court for an individual exemption to have their request for MAID considered.

As of late October, 2020, eleven Quebec residents have applied for exemptions. Ten of these requests have been approved, with one request still pending. Two people have received MAID through an individual exemption, including Jean Truchon.

MAID DELIVERY DURING THE PANDEMIC

While MAID delivery continues, provinces and territories have experienced challenges during the pandemic. Key concerns include:

- Obtaining individuals to act as witnesses to a MAID request and practitioner access to the individual requesting MAID, either due to institutional policies limiting visitors or limited supply of personal protective equipment (PPE) available to facilitate a safe encounter.
- Residents of faith-based institutions with restrictive MAID policies unable to move to another location to receive MAID due to cancelled or limited transfers.
- Availability of drug supply used in MAID provision because the same drugs are also used as sedatives for the ventilation of COVID-19 patients.

In response to correspondence from the Canadian Association of MAID Assessors and Providers encouraging use of virtual witnessing/assessment, Minister Lametti confirmed that provisions in the *Criminal Code* do not pose a barrier to the use of electronic tools to facilitate assessing or witnessing a MAID request. Many provincial governments and health professional regulatory bodies have released pandemic-adapted guidelines/policies such as supporting the use of virtual witnessing/assessments and preserving back-up MAID kits to prevent disposal of unused drugs.

Some practitioners have reported increased MAID inquiries from individuals concerned about

their options in the context of COVID. The authors of an April 2020 Canadian Medical Association Journal article state that palliative sedation is preferable for COVID positive patients with a poor prognosis, given the procedural requirements for MAID. This view has been reiterated by Dying With Dignity Canada.

MAID STATISTICS AND MONITORING REGIME

The *Regulations for the Monitoring of MAID* require the federal Minister of Health to produce an annual report of MAID data. The first report, released on July 24, 2020, covers data collected under the new reporting regime for the 2019 calendar year.

This report found that, in 2019, there were 5,631 reported cases of MAID, accounting for 2.0% of all deaths (this percentage is in line with that of other permissive jurisdictions). This represents an increase of 26.1% over 2018 numbers, with all provinces experiencing a steady year over year growth in the number of MAID cases since 2016. When all data sources are considered, the total of number of medically assisted deaths reported in Canada since the enactment of federal legislation is 13,946.

Importantly, it also found that the majority of individuals receiving MAID (82.1%) were reported to have received palliative care services. Of those MAID recipients who did not access palliative care services before receiving MAID, the majority (89.6%) would have had access to these services according to the reporting practitioner. Similarly, 89.9% of persons receiving MAID deemed to require disability support services received them.

The regulations came into force in November 2018 and set out reporting requirements for participating physicians, nurse practitioners and pharmacists. Under this new reporting regime, data is now being collected on all written requests for MAID and its provision. The regulations will need to be updated to reflect the changes to the legislation proposed in the amendments.

PARLIAMENTARY REVIEW OF MAID LEGISLATION

As outlined in the current legislation, the 2016 law was to be referred to one or more Parliamentary Committees by June 2020. The parliamentary review will provide an opportunity to undertake a comprehensive review of the MAID legislation as well as the state of palliative care in Canada. The timing and scope of the review will be determined by Parliamentarians.

ORGAN DONATION

SYNOPSIS

- Every year, hundreds of Canadians die while waiting for an organ transplant. Data from the Canadian Institute for Health Information shows that deceased donor rates in Canada increased by 42% between 2009 and 2018. However, Canada's donation rates lag behind higher donor countries such as Spain, United States and United Kingdom.
- Due to the COVID-19 pandemic, data from Canadian Blood Services shows that there has been a 28% decrease in deceased donation and living donation has decreased by 44% compared to 2019. Although rates are not at previous levels, donation rates are rising again.

POTENTIAL QUESTION

- What is the Government of Canada doing to improve organ donation and transplantation in the country?

KEY MESSAGES

- Our Government recognizes the value of organ and tissue donation and transplantation, and has an important role to play in protecting the health and safety of Canadians who need transplants as well as those who are living donors.

- Budget 2019 committed $36.5 million over five years, to improve consistency and quality in data to ensure Canadians have timely and effective access to organ transplant care.

- This investment will support the development of a pan-Canadian data and performance system for organ donation and transplantation, in collaboration with provinces and territories, leading to more donors and recipients being effectively matched.

IF PRESSED ON DETAILS OF THE ORGAN DONATION AND TRANSPLANTATION COLLABROATIVE …

- Our Government recognizes that too many Canadians are on organ waitlists. Since 2018, we have led a joint initiative, the Organ Donation and Transplantation Collaborative, in

collaboration with the provinces and territories (except Quebec), Canadian Blood Services and other stakeholders to identify opportunities to improve the organ donation and transplantation system for the benefit of Canadians. Transplant Quebec participates as an observer.

- An additional $5 million over three years was allocated to stakeholder organizations to support several major projects arising from this collaboration that are aimed at improving the accessibility, quality, sustainability and accountability of Canada's organ donation and transplantation system. One of these projects will evaluate the impact of new "opt-out" legislation in Nova Scotia, the *Nova Scotia Human Organ and Tissue Donation Act*, which takes effect January 2021.

- By working together, we are identifying ways to continue to improve the organ and tissue donation and transplantation ecosystem and we will keep the House informed as this process unfolds.

IF PRESSED ON FEDERAL INVOLVEMENT…

- Health Canada also regulates the safety of the system through a national regulatory compliance and enforcement program for human cells, tissues and organs for transplantation. Serious adverse reactions to transplants are also monitored.

BACKGROUND

Canadian Blood Services (CBS) is a not-for-profit charitable organization that is financed by provinces and territories. Its primary mission is to manage the blood and blood products supply for Canadians in every province but Quebec, where Héma-Quebec has this responsibility. CBS also has roles in plasma, stem cells, and organs and tissues.

the Organ Donation and Transplantation Collaborative (ODTC) was launched in early 2018 in collaboration with Canadian Blood Services, various stakeholders, and provinces and territories (Transplant Quebec participates as an observer). The

purpose of the ODTC is to inform thinking and facilitate action and collaboration on improving Canada's organ donation and transplantation system performance. The priorities of the ODTC are based on comprehensive stakeholder engagement.. Membership aims to reflect the spectrum of functional (clinical, administrative, research, patient advocacy), jurisdictional, and geographic stakeholders.

Between 2014-15 and 2018-19, the Canadian Institutes of Health Research (CIHR) invested close to $105 million in transplantation research, with over $20 million invested in 2018-19 alone. In June 2018, an additional $3.3 million was invested by CIHR and its partners ($2.4 million from CIHR) to support for the Canadian Donation and Transplantation Research Program.

Budget 2019 provided Health Canada with $36.5 million over five years, starting in 2019–20, with $5 million per year ongoing, to develop a pan-Canadian data and performance system for organ donation and transplantation, in collaboration with provincial and territorial partners.

According to the Canadian Institute for Health Information (CIHI), in 2018 a total of 2,782 transplants were performed in Canada (including Quebec), there were 4351 patients on organ waitlists, and 223 patients died while waiting for a transplant. Kidneys are the core of the organ donation and transplantation system. In 2018, 59% of all organs transplanted were kidneys.

CIHI (2019). Annual Statistics on Organ Replacement in Canada: Dialysis, Transplantation and Donation, 2009 to 2018. https://www.cihi.ca/sites/default/files/document/corr-snapshot-2019-en.pdf.

PHARMACARE

SYNOPSIS

- Last session, the NDP introduced Private Member's Bill C-231 to implement single-payer universal pharmacare, as well as a motion that passed with Government support in March.

- In Budget 2019, the Government announced steps toward the implementation of national pharmacare, including the creation of a Canadian Drug Agency, a national formulary and a national strategy for high-cost drugs for rare diseases.

POTENTIAL QUESTION

- When does the Government intend to implement a national pharmacare program?

KEY MESSAGES

- No Canadian should have to choose between paying for prescription drugs and putting food on the table.

- The Government of Canada is committed to working with provinces, territories and stakeholders to implement national universal pharmacare so that Canadians have the drug coverage they need.

- As committed in Budget 2019, this important work will include establishing a Canadian Drug Agency, a national formulary and a national strategy for high-cost drugs for rare diseases.

- We have already taken action to improve access and affordability of medicines. Last year, we modernized the way patented drug prices will be regulated in Canada, which will save Canadians billions over the next decade.

BACKGROUND

Private Member's Bill on Pharmacare

- On February 24, 2020, NDP MP Peter Julian tabled Private Member's Bill C-213, *An Act to Enact the Canada Pharmacare Act*, in the House of Commons. This bill would provide for a legislative framework for a public single-payer drug coverage system in Canada.

Opposition Motion on Pharmacare

- On March 13, 2020, the House of Commons unanimously adopted a motion from NDP MP Don Davies (Vancouver Kingsway, BC) that called on the government to negotiate with the PTs to establish a dedicated fiscal transfer for universal, single-payer, public pharmacare. The motion was passed with the Government's support.

Text of the motion:

(a) acknowledge the government's intention to introduce and implement national pharmacare;

(b) call on the government to implement the full recommendations of the final report of the Hoskins Advisory Council on the Implementation of National Pharmacare, commencing with the immediate initiation of multilateral negotiations with the provinces and territories to establish a new, dedicated fiscal transfer to support universal, single-payer, public pharmacare that will be long term, predictable, fair and acceptable to provinces and territories;

(c) urge the government to reject the U.S.-style private patchwork approach to drug coverage, which protects the profits of big pharmaceutical and insurance companies, but costs more to Canadians; and

(d) recognize that investing in national pharmacare would help stimulate the economy while making life more affordable for everyone and strengthening our health care system.

Advisory Council on the Implementation of National Pharmacare

- In Budget 2018, the Government announced the creation of the Advisory Council on the Implementation of National Pharmacare, chaired by Dr. Eric Hoskins. The Council engaged with Canadians, patients, provincial, territorial and Indigenous leaders, health care experts, and stakeholders through regional roundtables, town halls, an online questionnaire, and written submissions. On June 12, 2019, the Council's final report was tabled in Parliament, recommending the implementation of national universal pharmacare over several years.

Budget 2019 Commitments

- Guided by the recommendations of the Advisory Council, Budget 2019 announced federal investments to move forward on three foundational elements of national pharmacare:
    - Creation of a **Canadian Drug Agency** to take a coordinated approach towards assessing effectiveness and negotiating drug prices;

    - As part of the work of the Agency, development of a **national formulary** to promote more consistent coverage across the country; and,
    - Creation of a **national strategy for high-cost drugs for rare diseases** to help Canadians get better access to the effective treatments they need.
- Budget 2019 announced $35 million over four years, starting in 2019-20, to establish a **Transition Office** to support the creation of a Canada Drug Agency and national formulary. It also announced an investment of up to $1 billion over two years, starting in 2022-23, with up to $500 million per year ongoing, to help Canadians with rare diseases access the drugs they need.

Modernization of the Patented Medicines Regulations

- In August 2019, the Government modernized the *Patented Medicines Regulations* to ensure the Patented Medicine Prices Review Board (PMPRB) has the tools and information to fulfill its mandate to protect consumers from excessive patented medicine prices. It is estimated that the amendments will result in savings for governments and private payers of approximately $13.2 billion over 10 years. However, the brand-name pharmaceutical industry and some patient groups have expressed concerns that the amendments could result in reduced pharmaceutical investments and access to medicines.
- On June 29, 2020, the Federal Court issued a ruling in *IMC v Canada* that maintained most of the regulatory amendments, but struck down the collection of confidential rebate information.

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 prices of patented medicines. On October 23, 2020, the PMPRB published its final Guidelines to operationalize the amendments, which will come-into-force on January 1, 2021.

- 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 June 29, 2020, the Federal Court issued a ruling that maintained most of the regulatory amendments, but struck down the collection of confidential rebate information.

POTENTIAL QUESTION

- Why does the Government insist on continuing with the amendments to the *Patented Medicines Regulations* when it impacts Canadians' access to new medicines?

KEY MESSAGES

- Our Government remains committed to increasing the affordability and accessibility of prescription drugs, including patented medicines, to improve the health of Canadians and better meet health care system needs.

- Canada has among the highest patented medicine prices in the world, and these high prices negatively affect the ability of patients to access new 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 the Coming-into-Force Date

- The amendments were scheduled to come into force on July 1, 2020.

- The COVID-19 pandemic has increased demands on the pharmaceutical industry. For that reason, the Government delayed the coming into force of the amendments by six months—until January 1, 2021.

- This delay allowed manufacturers of patented drugs additional time to make any necessary adjustments to comply with the new regulatory regime.

If Pressed on the Access to COVID-19 Patented Medicines (Drugs and Vaccines):

- Our Government is committed to ensuring that Canadians have access to the drugs, vaccines and medical devices that are urgently needed in response to COVID-19.

- On September 17, 2020, the PMPRB issued a policy notice stating that special consideration would be given to specified patented medicines authorized for use in COVID-19. This policy notice was adopted as part of a government-wide effort to ease the regulatory pathway for drugs and medical devices urgently needed for COVID-19 diagnosis, treatment, mitigation or prevention.

- In this policy notice, the PMPRB indicated that certain patented medicines on lists published by Health Canada would not be subject to review or investigation unless a pricing complaint is received from myself or any of my provincial or territorial counterparts.

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.

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 strengthened intellectual property protection in recent trade agreements.

If pressed on recent litigation

- There are ongoing proceedings before the Federal Court of Appeal and the Superior Court of Québec.

- The PMPRB is aware of these proceedings and will take any decisions into account.

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 made revisions to the final Guidelines in response to the significant stakeholder feedback it received.

- The PMPRB published its final Guidelines on October 23, 2020.

BACKGROUND

- As an arm's-length organization of the government, the Patented Medicine Prices Review Board (PMPRB) reviews the prices patentees charge for patented medicines on the Canadian market. The PMPRB can work with patentees to achieve voluntary price reductions, or hold public hearings to determine whether a price is excessive, and (if so) order price reductions or the offset of excess revenues.

- The Minister of Health has the authority under the *Patent Act* to direct the PMPRB to inquire into any matter regarding patented medicine prices and report its findings back to the Minister. Additionally, the Minister is responsible for making recommendations to Cabinet on changes to the *Patented Medicines Regulations*, which inform how the PMPRB fulfills its mandate.

- On August 9, 2019, the Government of Canada announced the final amendments to the *Patentend Medicines Regulations* which were then published

on August 21, 2019 in *Canada Gazette, Part II*. At that time, the amendments were scheduled to take effect on July 1, 2020.

- The most significant reforms to the *Patentend Medicines Regulations* since their introduction in 1987, these amendments lay the groundwork for national pharmacare by giving the PMPRB the tools and information to protect Canadians from excessive prices of patented medicines.

- 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); and,
    - **Revising the "basket" of comparator countries**, to include markets with comparable consumer protection priorities, economic wealth and medicine markets as Canada.

- 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*. The hearing started on September 28, 2020 but following three days of hearing, the court was adjourned and will resume on November 17, 2020.

- 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 June 29, 2020, the Federal Court issued a ruling in *IMC v Canada* that maintained most of the regulatory amendments, but struck down the collection of confidential rebate information. Either party can initiate an appeal in a split ruling, and on September 10, 2020, a Notice of Appeal was filed by IMC and a Notice of Cross-Appeal was filed by the Crown on September 21, 2020.

- 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's consultation included numerous opportunities for stakeholder engagement and extended the consultation window to allow constructive engagements to continue.

- On March 29, 2020, stakeholders were informed that the coming-into-force of the regulatory amendments would be delayed by six months. The delay responds to the circumstances of COVID-19, including increased demands on industry stakeholders. It also resulted in additional time for stakeholders to engage with

the PMPRB through its Guidelines consultation process, which was also disrupted by COVID-19. The amendments will now come-into-force on January 1, 2021.

- On June 19, 2020, the PMPRB released revised draft Guidelines, which operationalize the regulatory amendments, and undertook further consultations.

- The PMPRB published its final Guidelines on October 23, 2020.

- The PMPRB has indicated that patented medicines appearing on either the *List of Drugs for Exceptional Importation and Sale* or any list associated with other COVID-19 Interim Orders will not be subject to review or an investigation unless a complaint is received from either the federal Minister of Health or any of her provincial or territorial counterparts.

SEASONAL INFLUENZA

SYNOPSIS

The flu season in Canada usually runs from mid-November to mid-May. In a typical year in Canada, seasonal influenza leads to an estimated 12,200 hospitalizations and 3,500 deaths. The flu shot, recommended for all Canadians six months of age and older, is the most effective way to prevent the flu and flu-related complications, such as pneumonia. The flu shot is especially important this year because of the ongoing pandemic.

KEY MESSAGES

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

- Vaccination is the best defense against the flu. That is why we work with the provinces and territories to provide flu vaccine to Canadians every year during flu season. The Government of Canada supports provinces and territories by bulk procurement of flu vaccine, based on vaccine orders placed by jurisdictions.

- All provincial and territorial flu vaccine orders have been filled. In addition, we have a reserve that is available to them, and we are accessing more supply from vaccine manufacturers expected for mid-December.

- This year, because of the COVID-19 pandemic, we are ensuring that residents in long-term care are protected from the flu. We have purchased high-dose flu vaccine (FluZone) for long-term care residents 65 and older in all provinces and territories.

- Demand for the flu vaccine is high, but not necessarily higher than what is typically seen at the start of program launch.

- It may take longer than normal to get the vaccine due to physical distancing and other safety measures in place during the COVID-19 pandemic.

- We are raising public awareness of the benefits of vaccination for individuals, families, and communities. We are giving Canadians the information they need to prevent illness.

BACKGROUND

Seasonal influenza epidemics occur in Canada every year. Canada's flu season typically runs from mid-November to mid-May and peaks during the winter months. The best time to get the influenza vaccine is between October and December; however, the vaccine can still be effective even when received during later winter months. Each year in Canada, seasonal influenza leads to an estimated 12,200 hospitalizations and 3,500 deaths. The flu shot, recommended for all Canadians six months of age and older, is the most effective way to prevent the flu and flu-related complications, such as pneumonia.

In light of the upcoming flu season, the Public Health Agency of Canada (PHAC) is planning for the potential co-circulation of both the flu and COVID-19 in Canada. While the symptoms of the flu and COVID-19 can appear to be similar, it reinforces the importance of getting the annual flu shot and then if you feel sick, getting tested for COVID-19 and staying home.

Vaccine Effectiveness (VE) & Coverage

The Canadian Sentinel Practitioner Surveillance Network has published estimates of influenza vaccine effectiveness against primary care visits for influenza. Based on data from the early part of the 2019-20 influenza season up to February 1, 2020, vaccine effectiveness was estimated to be 58% against influenza, 44% for A(H1N1), 62% for A(H3N2), and 69% for influenza B.

Substantial protection was observed among children 1 to 19 years of age against both influenza A and B. A good level of protection was also observed among working age adults (20-64) across all influenza types. VE among adults 65 years and older, although imprecise due to small numbers, was lower at 18%.

The 2019-2020 influenza season vaccine coverage was similar to the 2018-2019 season. 34% of adults aged 18 to 64 years and 70% of seniors (aged 65 years and older) received their annual seasonal influenza vaccine.

2020-21 Influenza Surveillance

Canada participates in national and international activities to detect and monitor the spread of influenza in humans and animals. PHAC maintains FluWatch, Canada's national surveillance system that monitors circulating flu viruses, activity levels, outbreaks, and hospitalizations.

Testing for influenza continues at elevated levels; however, influenza activity remains

below average for this time of year.

In week 43 ((October 18 to October 24) 7715 tests for influenza were performed at reporting laboratories, which is 2 times the average for this period over the past 6 seasons. Additionally, one outbreak of laboratory-confirmed influenza was reported in a long-term care facility (LTCF). No other influenza or influenza-like-illness (ILI) outbreaks were reported in any other settings.

Also during this reporting period two laboratory detections of influenza were reported and two jurisdictions reported influenza activity. To date, no influenza-associated hospitalizations were reported by participating provinces and territories.

Global situation summary

Globally, influenza activity remains at **lower levels than expected for this time of the year,** although sporadic detections have been reported in some countries. Influenza activity in temperate regions of the Southern Hemisphere remained low or below baseline during the 2020 season.

As in Canada, changes in public behaviour, healthcare service delivery, and the adaptation or initiation of surveillance programs for COVID-19 may affect the comparability of influenza surveillance data with previous years, as well as the timing, duration and intensity of the season. However, numerous studies have documented reductions in influenza and other respiratory virus circulation because of public health measures to reduce transmission of COVID-19.

Influenza Vaccine Development and Supply

The World Health Organization (WHO) issues recommendations each year on the composition of the influenza vaccines for the southern and northern hemispheres. These recommendations are used by national vaccine regulatory agencies and pharmaceutical companies to develop, produce and license seasonal influenza vaccines. WHO has released the recommended composition of the influenza vaccine for use in the 2020-2021 northern hemisphere influenza season. The recommended strain was changed for each of the A(H1N1), A(H3N2) and B/Victoria components compared to the 2019-20 vaccine.

The P/Ts and some federal departments (Correctional Service of Canada, Royal Canadian Mounted Police, and Department of National Defence) order the majority of their influenza vaccine through Public Services and Procurement Canada's Bulk Procurement Program. The P/Ts use their discretion to make decisions regarding their influenza vaccination programs, including eligible populations, vaccine types and quantities.

Provincial and territorial governments have increased their vaccine orders for this year's influenza season in expectation of increased demand. Orders have been placed with

suppliers for more than 14 million doses of vaccine for 2020-21. In addition, this year the Government of Canada has created a small reserve of additional doses that will be made available to provinces and territories if needed. Approximately 300,000 additional doses are now available and have been equitably allocated to PTs who can now order it as needed. Efforts are underway to secure an additional (approximately) 1.3M doses, with the majority of these doses available in mid-December. Final quantity for this later supplier is still to be fully confirmed.
To date, most of the provincial and territorial orders have been released and manufacturers are distributing additional doses from reserve supplies.

As a one-time initiative to help protect one of Canada's most vulnerable populations in the event of the co-circulation of both COVID-19 and influenza this fall and winter, the federal government is purchasing Fluzone® High-Dose vaccine for long-term care residents in all provinces and territories. This initiative includes purchasing Fluzone® High-Dose vaccine for those provinces and territories that don't regularly cover it as part of their public immunization programs, and purchase costs in provinces and territories that do already offer Fluzone® High Dose vaccine to long-term care residents 65 and older as part of their program.

Recommendations for Influenza Vaccination

The National Advisory Committee on Immunization (NACI), an expert advisory body to PHAC, annually reviews available scientific evidence to provide recommendations for vaccinating Canadians with seasonal flu vaccine. NACI recommends that everyone 6 months and older, without contraindications, receive an annual flu shot.

The influenza vaccine remains the best line of defense against influenza and is especially important for those at high risk of severe illness from influenza. Evidence suggests that the influenza vaccine protects pregnant women and their newborns. NACI notes that seasonal influenza vaccination provides benefits to health care workers and to the patients for whom they care. NACI considers the provision of influenza vaccination to be an essential component of the standard of care for all health care workers for the protection of their patients.

Additional guidance has been developed to support the operation of influenza vaccine programs during the COVID-19 pandemic. PHAC has published guidance on the delivery of influenza vaccine in clinics and other vaccination settings for this fall. This includes advice on infection prevention and control measures, physical distancing, alternate delivery models (e.g. drive-through clinics), and personal protective equipment needs for staff, volunteers, and vaccine recipients. Guidance has also been developed on who should receive the influenza vaccine this fall, and what to do if someone seeking vaccination is showing symptoms.

Concerns have been raised regarding the potential for influenza vaccine to worsen COVID-19 symptoms. Based on international and Canadian studies, experts agree that this concern is not supported by the currently available evidence base. Everyone who is eligible should receive the influenza vaccine.

NACI also recently developed guidance recommending the usual wait time of at least 15 minutes after receiving the influenza vaccine be maintained in most circumstances. The usual wait time could potentially be reduced after vaccination to limit the spread of COVID-19 in clinics during times when proper physical distancing cannot be maintained, due to a surge in people seeking vaccination.

NACI is also examining evidence related to the effectiveness of different influenza vaccine doses, in the rare event that there is a significant shortage of influenza vaccine. There is no shortage expected at this time.

Smoking and Tobacco Use in Canada

SYNOPSIS

- Cigarette smoking is the leading cause of preventable disease and premature death in this country, killing more than 47,000 Canadians each year. Smoking has negative effects on many systems in the body. Smoking compromises the immune system and increases the risk for pulmonary infections, as well as negatively affecting the functioning of the lungs and causing chronic lung disease, cancer and cardiovascular diseases.

- Almost 5 million Canadians still smoke cigarettes – about 15% of the population over the age of 15.

- The Government has an ambitious target to reduce tobacco use in Canada to less than 5% by 2035. Canada's Tobacco Strategy is a comprehensive and integrated approach to increase cessation rates and protect youth and non-smokers from nicotine addiction, with a $330M investment over five years, starting in May 2018.

- The Strategy includes funding for enhanced scientific and surveillance activities; grants and contributions programming directed at increasing the reach and effectiveness of prevention and cessation programming; public education; collaborative activities with the provinces and territories; and partnership and engagement with domestic, international and multi-sector stakeholders.

- The emergence of COVID-19 has raised concern about the potential of increased risks posed by smoking. Cigarette smoking has negative effects on many systems in the body that are also affected by COVID-19. Smoking negatively affects the function of the lungs, causing inflammation and impairing the ability of the lungs to clear mucus. In addition, smoking can increase the spread of COVID-19 as hand-to-mouth behaviour creates an opportunity for the virus to enter the body.

POTENTIAL QUESTION

- What is the Government of Canada doing to address smoking and tobacco use in Canada?

KEY MESSAGES

- Cigarette smoking is the leading cause of preventable disease and premature death in this country. The Government is committed to helping Canadians quit using tobacco and to protecting the health of young people and non-smokers. Through Canada's Tobacco Strategy, we are

working to drive down tobacco use in Canada to less than 5% by 2035.

- Canada has a long history in tobacco control. We are a global leader in the regulation of tobacco products and have implemented many internationally-recognized practices in tobacco control.*The Tobacco and Vaping Products Act* (TVPA) regulates the manufacture, sale, labelling and promotion of both tobacco and vaping products. The TVPA includes significant restrictions to prevent the uptake of tobacco and vaping products by youth and adults who do not use these products.
- Building on the strong foundation provided by the TVPA, we will continue to strengthen regulations to prevent youth and non-smokers from becoming addicted to nicotine and to provide Canadians with health information on tobacco use.
- We are engaged with our provincial and territorial partners to find new and innovative ways to increase quit attempts and make it easier for Canadians currently using cigarettes to access the support and resources they need to quit and reduce the harms to their health.
- We are continuing work to prevent the appeal and access of tobacco products to youth and supporting specific initiatives for populations that face higher rates of tobacco use.
- We continue to invest in research, science and surveillance to support evidence-based decision-making while also increasing investments to better understand and combat the illicit tobacco market.

IF PRESSED ON SMOKING AND COVID-19…

- The Government of Canada is investing in research and international partnerships to understand the health effects of COVID-19. We are aware of reports in the media on the impacts that smoking may have on contracting or experiencing a COVID-19 infection.
- New findings are being published every day and our researchers are actively engaged in interpreting that data as it evolves. Smoking is a leading cause of heart disease, cancer and many respiratory illnesses. As COVID-19 is a respiratory disease, there is some evidence that smokers may be at greater risk of developing more severe symptoms of the disease. In addition, smoking can increase the spread of COVID-19 as hand-to-mouth behaviour creates an opportunity for the virus to enter the body.
- People should avoid or reduce exposure to any substance that might impair the normal function of the lungs and immune system, including the use of cigarettes. This is a stressful time, but if you currently smoke, now is an excellent time to consider quitting.
- The Government of Canada recommends that you do not share cigarettes with anyone, and that you wash your hands frequently with soap and water, for at least 20 seconds each time. For the latest information on COVID-19, how it spreads, and how to protect yourself, we encourage Canadians to visit www.canada.ca/coronavirus.

IF PRESSED ON HELP FOR SMOKERS…

- The Government of Canada is concerned with the risks posed to Canadians by smoking.
- We urge Canadians to consider quitting smoking. We know that when you give up cigarettes, your body starts to renew itself as early as the first day of quitting. Quitting will improve your life in ways you will see and feel, both now and later,

including reducing your chance of developing heart disease, cancer, breathing problems, and infections.

- Quitting smoking can be difficult, but it is possible. The Government of Canada has many resources to help Canadians quit and reduce the harms of smoking.
- We urge Canadians to contact the pan-Canadian toll-free quitline where trained specialists can help them develop a quit smoking plan, answer questions, and provide referrals to programs and services in their community where available. The quitline can be reached by phone at 1-866-366-3667 or online at http://www.gosmokefree.gc.ca/quit.

IF PRESSED ON NEW AND PLANNED REGULATORY MEASURES FOR TOBACCO

- In 2019, the Government of Canada implemented the Tobacco Products Regulations (Plain and Standardized Appearance) to standardize the appearance of tobacco packages and tobacco products.
- Tobacco packages and the products they contain are powerful promotional vehicles. Evidence shows that plain packaging is perceived as less appealing, particularly among young people.
- These Regulations apply to all tobacco packages and products. The measures include requiring a standard colour, font, and font size on all tobacco packages, and removing distinctive and attractive features such as the use of logos, graphics and promotional information on packages. Cigarette packaging will be standardized to a slide-and-shell format, and the appearance of cigarettes and other tobacco products will be standardized as well.
- We are also working to finalize new regulations that update and expand requirements for Health Warning messages for tobacco products to ensure that these labels remain

noticeable, memorable and engaging. These new labels will enhance public awareness of the hazards of all tobacco products while also providing information to Canadians who currently use tobacco about information and resources they can access to help them quit.

- In October 2018, Health Canada sought feedback on options for new health labelling for tobacco products including labelling on cigarettes. Comments received through this consultation are being carefully considered as Health Canada continues to develop new health-related labelling for tobacco products.

IF PRESSED ON WORK WITH INDIGENOUS COMMUNITIES…

- The rates of use of commercial tobacco for Indigenous peoples are two to five times higher than the overall Canadian rate. The Government is committed to working with First Nations, Inuit, and Métis organizations to co-develop distinct and high quality approaches to address high rates of commercial tobacco use.

- Indigenous Services Canada and Crown-Indigenous Relations and Northern Affairs are investing $45M over five years to support community-based tobacco use programming and the co-development process.

BACKGROUND (NOT FOR PUBLIC USE)

Tobacco use in Canada

Data released on August 5, 2020 from the 2019 Canadian Community Health Survey (CCHS) shows a continued downward trend in smoking over the past three decades for Canadians 12 years of age and older. Smoking declined to 14.8% (4,684,400) from 15.8% (4,926,800 Canadians) in 2018 and from 17.7% (5,344,100 Canadians) in 2015. Daily smoking also declined to 10.0% (3,160,100) from 10.9% (3,392,700 Canadians) in 2018 and from 12.6% (3,809,500 Canadians) in 2015. Daily smoking for youth aged 12-17 is less than 1% (10,300). While the recent declines are positive, millions of Canadians are still smoking, reminding us that, despite decades of effort to deter smoking, tobacco use remains a significant public health problem in Canada. Tobacco

use is still the leading cause of premature death in Canada, killing half of all long-term daily smokers. Furthermore, prevalence rates for on-reserve First Nations and Inuit are up to four times higher than that of other Canadians.

In July 2020, the Canadian Centre on Substance Use and Addiction released a report entitled “Canadian Substance Use Costs and Harms 2015 – 2017”. The report identifies the enormous burden tobacco use places on all Canadians. The report found that in 2017 the total cost of tobacco use to society was approximately $12.3 billion or $336 for every Canadian. Tobacco use was identified as the deadliest substance by far accounting for over 47,000 premature deaths in 2017 (over 128 deaths per day or 17% of all deaths).

Canada’s Tobacco Strategy

Canada’s Tobacco Strategy represents the Government of Canada’s plan to address tobacco use. It is led by Health Canada, in partnership with the Canada Border Services Agency, the Canada Revenue Agency, Indigenous Services Canada, Crown-Indigenous Relations and Northern Affairs Canada, the Public Health Agency of Canada, Public Safety Canada, and the Royal Canadian Mounted Police.

SUICIDE PREVENTION IN CANADA

SYNOPSIS

Suicide is a significant public health issue that affects people of all ages and backgrounds across Canada. The Public Health Agency of Canada (PHAC) is supporting the implementation of a fully operational pan-Canadian suicide prevention service, which is providing 24/7 toll-free crisis support.

KEY MESSAGES

- The Government recognizes the impact suicide has on families and communities.
- That is why we are investing $21 million over 5 years for the Centre for Addiction and Mental Health and its partners to implement a fully operational pan-Canadian suicide prevention service.
- Recognizing that supporting the mental health of Canadians is fundamental to suicide prevention, the Government of Canada has also provided provinces and territories with $5 billion over 10 years to improve access to mental health and addiction services.

IF PRESSED ON MENTAL HEALTH SUPPORTS FOR COVID-19

- On March 29, 2020, the Prime Minister announced an investment of $7.5 million to Kids Help Phone to expand crisis supports for children and youth during the COVID-19 pandemic.
- The Public Health Agency of Canada is also providing additional funding for the Canada Suicide Prevention Service to support the increased demand for crisis support at this time.
- The Canadian Institutes of Health Research is currently leading a COVID-19 and Mental Health Research Initiative that is providing new knowledge to inform policy making and innovative services for mental health in the pandemic context.

BACKGROUND

Approximately, 10 people die by suicide every day in Canada. There were over 3,800 deaths by suicide in Canada in 2018. Suicide was the 9th leading cause of death among all Canadians in 2018, and the 2nd leading cause of death among individuals aged 15 to 34, behind unintentional injuries (Statistics Canada). There is no single cause that fully explains or predicts suicide; a combination of factors are associated with suicide, such as mental illness, physical health, personal issues and loss, childhood abuse and neglect, and exposure to trauma.

The Public Health Agency of Canada (PHAC) has provided proof of concept funding to **Crisis Services Canada (CSC)** in the amount of $5.46 million over five years (2015/16 to 2020/21) to support the development of the **Canada Suicide Prevention Service (CSPS),** a national phone, text and chat suicide prevention service that links existing telephone and distress and crisis infrastructures throughout Canada. Quebec is serving its residents through its provincial suicide prevention line: 1-866-APPELLE.

PHAC is providing $21 million over five years, starting in 2020-21, to the **Centre for Addiction and Mental Health (CAMH)** to implement and sustain a fully operational pan-Canadian suicide prevention service. CAMH will lead this initiative in partnership with the Canadian Mental Health Association (CMHA) and Crisis Services Canada (CSC). This service will provide people across Canada with access to 24/7/365 bilingual crisis support from trained responders, using the technology of their choice (voice, text or chat).

The **Federal Framework for Suicide Prevention** was made publicly available November 2016. It focuses on raising public awareness, reducing stigma, disseminating information and data, and promoting the use of research and evidence-based practices. Progress Reports on the Framework were released in December 2016 and December 2018 on Canada.ca, with the next report planned for release in December 2020.

Artificial Intelligence to Improve Understanding of Suicide-Related Verbalization
In 2018, PHAC funded a feasibility study that uses artificial intelligence to collect social media (i.e., Twitter) data on suicide-related verbalization. Initial results suggest that this could be a possible complementary data source that could provide timely information among diverse populations to enhance suicide prevention efforts. This project will not be able to predict suicides by individuals or include any interaction with people on social media.

Survey on COVID-19 and Mental Health (SCMH) and Survey of Mental Health and Stressful Events
PHAC is currently conducting surveillance to understand the unintended consequences of COVID-19 on suicide and self-harm. The analysis will seek to estimate the prevalence of suicide ideation among the population in Canada during the COVID-19 pandemic and compare this to pre-pandemic prevalence, while also identifying those groups that may potentially have a higher risk of suicide than the general population.

Motion 174 – A National Suicide Prevention Action Plan
In April 2018, MP Charlie Angus (NDP, Timmins-James Bay) sponsored motion M-174, calling for the Government of Canada to establish a national suicide prevention action plan. On May 8, 2019, parliamentarians voted unanimously in favour of M-174, though it is non-binding. Some of the proposed actions in the plan are already being addressed in the *Federal Framework*. PHAC will facilitate the coordination and collaboration on elements of the action plan with relevant departments, agencies and key stakeholders through its convening role on the Federal Framework for Suicide Prevention. An update on M-174 will be included under the next Framework progress report (December 2020).

3-Digit Suicide Prevention National Telephone Line – 9-8-8 Campaign in Canada
In line with the efforts of the U.S. and the U.K. to designate memorable 3-digit numbers for their suicide prevention national lines, Ms. Kathleen Finlay of the Zer0Now Campaign recently launched an online and social media campaign calling for the introduction of 9-8-8 in Canada. Senator Denise Batters (Conservative, Saskatchewan) has actively championed the campaign online. More recently, Member of Parliament, Todd Doherty, has also highlight this issue via a written question and Opposition Day motion. PHAC will work with the new funding recipient leading the pan-Canadian Suicide Prevention Service to develop an approach to introduce a 3-digit number in the future.

COVID-19 Mental Health Crisis Supports
Demand for crisis support has increased significantly since the start of the COVID-19 outbreak.
On March 29, 2020, the Prime Minister announced an investment of $7.5 million to Kids Help Phone to expand crisis supports for children and youth during the COVID-19 pandemic. The Public Health Agency of Canada provided $750,000 in additional funding for the Canada Suicide Prevention Service to support the increased demand for crisis support.

The Government of Canada recently launched Wellness Together Canada, a new portal dedicated to mental wellness and substance use issues. The portal connects Canadians to peer support workers, social workers, psychologists and other professionals for confidential chat sessions or phone calls.

Through its's **COVID-19 and Mental Health Research Initiative**, the Canadian Institutes of Health Research is currently supporting more than 100 research projects on COVID-19 and Mental Health, including problematic substance use ($13.5M from CIHR and partners). These important projects will look at mental health during and after the pandemic and will generate new evidence to inform the Mental Health response to the pandemic. Ultimately, they will help offer new evidence-based treatments and services to all Canadians, especially for priority populations that may be experiencing acute mental health concerns associated with COVID-19.

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, at an annual cost of over $300,000 USD. Although Health Canada has not received a new drug submission for Trikafta, as of October 2020, 151 patients in Canada have accessed this drug through the Special Access Program (SAP). The Department has received many letters from patients and their supporters expressing their desire to have this drug made available in Canada, and media interest is high, particularly because of its use in the pediatric population.

POTENTIAL QUESTION

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

KEY MESSAGES

- Health Canada recognizes the importance of patient access to new therapies for serious or life-threatening conditions. We are aware of the many steps involved in the approval and coverage of drugs in Canada, and that this can be frustrating for families who are trying to gain access to treatments for their loved ones as quickly as possible.

- To date, the manufacturer of Trikafta has not submitted an application to market this product in Canada. While Health Canada encourages manufacturers to submit applications, it is the manufacturer's decision whether to do so.

- 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 October 2020, 151 patients in Canada have accessed Trikafta through this program.

- 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 expanding drug coverage for patients with rare diseases, through federal support.

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 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.

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

- While Health Canada encourages manufacturers to submit applications, it is the manufacturer’s decision whether to do so.

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.

A study published in the "Journal of Cystic Fibrosis" on August 24, 2020, predicted benefits that will be lost by cystic fibrosis patients should the drug not be available to them by 2021. Access to the drug by next year would result in a 60% decrease in severe cases, 19% decrease in hospitalization, fewer lung transplantations and a 9-year increase in survival. Such results would have a significant impact not only on the personal health of these patients but also on the health care system.
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 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)

(Tikafta contains ivacaftor, tezacaftor and elexacaftor)

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 October 28, 2020, 151 patients in Canada have accessed Trikafta through SAP.

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. They will come into force in January 2021.

Youth Vaping

SYNOPSIS

- Youth vaping rates in Canada have doubled over the last two years. Furthermore, youth are also vaping more frequently. There has been significant media coverage and concerns expressed by parents, educators, health professionals and non-government organizations.

- The Government of Canada has implemented a comprehensive suite of measures to address youth vaping, including enhanced public education, increased compliance and enforcement of existing rules and advancing regulations to put in place more controls.

- Health Canada's national public education campaign "*Consider the Consequences of Vaping*" informs youth and their parents about the risks and harms associated with vaping through advertising, interactive learning tours in schools and online. Health Canada quadrupled the investment in advertising and the campaign last fiscal year to $8.8 million (more than $12 million over 3 years).

- Enforcing the strong set of controls already established under the *Tobacco and Vaping Products Act* remains an important part of the Government's efforts. In the last six months of 2019, Health Canada inspected 3,000 retailers, including speciality stores and convenience stores, and seized more than 80,000 units of non-compliant vaping products.

- The new *Vaping Products Promotion Regulations* came into force on August 7, 2020. These regulations prohibit any vaping product promotions in locations or media visible to youth. Additionally, the regulations require all remaining permitted ads to include clear health warnings to increase awareness of the risks of these products.

- In addition, the new *Vaping Product Labeling and Packaging Regulations* came into force on July 1, 2020. These regulations require that vaping products containing nicotine display a standardized nicotine concentration statement and a health warning about the addictiveness of nicotine as well as a toxicity warning to further increase awareness of the risks.

- Building on consultations in 2019, additional measures with respect to nicotine concentration limits and flavour restrictions are being examined, based on the best available evidence.

POTENTIAL QUESTION

- What is the Government doing to address the increased use and appeal of vaping products to youth?

KEY MESSAGES

- Our Government is concerned by the rapid rise in youth vaping, and is taking comprehensive action to address it.

- New regulations now prohibit the promotion and advertising of vaping products anywhere they can be seen or heard by youth. This means that young Canadians should no longer see advertising for vaping products in public spaces, in convenience stores or online.

- These regulations also require health warnings on any remaining permitted advertisements and join new labelling requirements for vaping products that require warning labels, an ingredients list and nicotine concentration on vaping products and their packaging to further enhance awareness of potential health hazards.

- Health Canada is also looking at additional measures to reduce youth access and the appeal of vaping products. These include measures regarding nicotine concentration limits and flavour restrictions, using the best available evidence.
- We increased investments in our national public education campaign to inform youth and their parents about the risks and harms of vaping, and created funding opportunities to engage partners and stakeholders in a collaborative response.

- My department also intensified enforcement of the strong set of controls that Parliament has established under the *Tobacco and Vaping Products Act* and will continue these efforts to ensure that the vaping industry is compliant with our new regulations.

IF PRESSED ON THE YOUTH-ORIENTED PUBLIC EDUCATION CAMPAIGN…

- In early 2019, Health Canada launched the *Consider the Consequences of Vaping* prevention campaign to inform youth and parents of the risks and harms associated with vaping.

- The campaign included digital advertising on social media and television, advertising in malls, cinemas and on transit and print and online resources. It also included an interactive learning tour in schools and community venues. In June 2020, the tour transitioned to an online format in response to COVID-19.

- Vaping awareness kits were also provided to all middle and high schools across Canada. Information resources were also sent to health care professionals to share in their offices.

- An evaluation of the advertising campaign found that 26% of teens who saw the ads, report that they decided not to vape as result of the ads.

IF PRESSED ON COMPLIANCE AND ENFORCEMENT OF CURRENT MEASURES…

- The *Tobacco and Vaping Products Act* has significant restrictions in place to limit youth access to vaping products and vaping product promotions. For example, it is prohibited to furnish a vaping product to anyone under 18 in Canada, and lifestyle advertising of vaping products is strictly

prohibited under the *Act*.

- Health Canada has taken actions that have led companies to remove:
  - lifestyle advertising or advertisements from television and in-store displays; and,
  - online content from social media influencers that encouraged youth vaping.

- In the last year, Health Canada inspected more than 3,000 retailers of vaping products and seized more than 80,000 units of non-compliant vaping products.

IF PRESSED ON THE RISKS OF VAPING AND COVID-19…

- Doctors and scientists are in the early stages of understanding COVID-19 and the factors that might make the symptoms of COVID-19 more severe for some people.

- We are aware of one study to date that found associations between vaping and testing positive for COVID-19. While concerning, caution should be exercised given the limitations in this study. Additional research is needed but we do know that vaping can expose users to harmful chemicals that can have negative effects on the lungs and airways.

- Youth and non-smokers should not vape. Vaping is a less harmful option than smoking for Canadians who currently use combustible tobacco products and are unable to quit - switching completely to vaping will reduce their exposure to many toxic chemicals found in tobacco smoke.

- We are advising Canadians not share vaping products with anyone, and to wash their hands frequently with soap and water, for at least 20 seconds each time after they vape.

BACKGROUND

There is a rapidly growing consumer market for vaping products in Canada. Smoking is the leading preventable cause of premature death and disease in Canada. Smoking-related disease is caused by the toxic and carcinogenic chemicals in smoke. Vaping products expose users to far fewer toxic chemicals and substances than conventional cigarettes, and are marketed, sold and used as less harmful alternatives to tobacco products.

However, vaping is not harmless. Vaping nicotine can lead to addiction and physical dependence and youth are especially susceptible to the negative effects of nicotine. In addition, for those who do not smoke, vaping can also cause lung damage and can increase exposure to harmful chemicals. The long-term health effects of vaping are unknown.

The most recent Canadian Student Tobacco, Alcohol and Drugs Survey (CSTADS) results from 2018-2019, released in December 2019, indicate e-cigarette prevalence rates have doubled among students since the last survey with 20% of students reporting having used an e-cigarette in the past 30 days, an increase from 10% in 2016-2017. These students are also reporting using vaping products more frequently. Health Canada has not seen a corresponding increase in student smoking rates; these rates continue to be at all-time lows. Results showed the prevalence of current daily smoking decreased among students in Grades 7 to 12 to 0.9% in 2018-2019, down from 1.3% in 2016-2017. High youth vaping rates have also been observed in other recent national survey data, including the 2019 Canadian Tobacco and Nicotine Survey and the 2019 Canadian Community Health Survey, further confirming the upward trend.

The *Tobacco and Vaping Products Act* (TVPA) became law on May 23, 2018 and regulates the manufacture, sale, labelling and promotion of both tobacco and vaping products. The TVPA includes significant prohibitions and restrictions intended to prevent access to, and uptake of, tobacco and vaping products by youth, including:

- prohibiting the furnishing (including online) to persons under 18;
- prohibiting the sale and promotion of products with design features that make the product appealing to youth (e.g., a vaping device that is shaped like a toy);
- prohibiting the sale and promotion of products using flavour names appealing to youth (e.g., flavour names such as cotton candy or crème brûlée); and
- restricting the promotion of tobacco and vaping products.