COVID-19
EVERGREEN QUESTIONS AND ANSWERS

Questions and Answers

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SITUATION AU CANADA

Q1. What is Canada doing in response to the current pandemic situation?

Our top priority is the health and safety of Canadians. The Public Health Agency of Canada is actively monitoring the situation regarding the new coronavirus (COVID-19) and is continuously assessing the risks in order to adjust Canada's response accordingly.

The Government of Canada has created the necessary infrastructure to respond to the public health threats of the virus, and is well prepared to act—in collaboration with provincial and territorial governments and international partners—to minimize the health, economic, and social impacts of this rapidly evolving public health issue.

Canada's response is based on plans and guidance related to pandemic preparedness, with the following guiding principles:

- **Collaboration** – all levels of government and stakeholders need to work in partnership to produce an effective and coordinated response
- **Evidence-informed decision-making** – decisions should be based on the best available evidence
- **Proportionality** – the response to a pandemic should be appropriate to the level of the threat
- **Flexibility** – actions taken should be tailored to the situation and evolve as new information becomes available
- **A precautionary approach** – timely and reasonable preventive action should be proportional to the threat and informed by evidence to the extent possible
- **Use of established practices and systems** – well-practised strategies and processes can be rapidly ramped up to manage a pandemic
- **Ethical decision-making** – ethical principles and societal values should be explicit and embedded in all decision-making

These principles build on lessons learned from past events, particularly the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, which led to dedicated legislation, plans, infrastructure and resources to help ensure that the country would be well prepared to detect and respond to a pandemic outbreak. Examples include:

- The creation of the Public Health Agency of Canada, which monitors and responds to disease outbreaks that could endanger the health of Canadians.
- The appointment of a Chief Public Health Officer, who advises the Government of Canada and Canadians on the steps they should take to protect their health, working in close collaboration with the chief medical officers of health in provinces and territories.
- The development of the document entitled Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector, which sets out guidance to prepare for and respond to a pandemic.
- The enhancement of diagnostic capacity in the National Microbiology Laboratory.
- The strengthening of working relationships with the World Health Organization and other international partners, such as the United States Centers for Disease Control and Prevention.

While the Government of Canada has been focusing on containing the spread of COVID-19, it has also been undertaking coordinated planning to prepare for possible broader transmission of the virus, and to mitigate the impacts of a potential pandemic.

To support these efforts, the Prime Minister convened an **Incident Response Group on coronavirus**, which has been meeting since the end of January, and, on March 5, he created a **Cabinet Committee on the federal response to the coronavirus disease (COVID-19**). Chaired by the Deputy Prime Minister and vice-chaired by the President of the Treasury Board, the committee meets regularly to ensure whole-of-government leadership, coordination, and preparedness to limit the health, economic and social impacts of the virus.

Q2. Does Canada intend to base its plan for the re-opening of the economy and the borders on WHO guidelines?

Canada has a strong history of pandemic planning and is an international leader in this regard. The 2006 Pandemic Plan was published post-SARS and provided leverage for our reaction to the previous H1NI pandemic. Since the outbreak of the H1NI flu virus, the plan has been continually updated. One of the main lessons learned from the H1N1 flu is the need for a flexible and scalable approach to planning.

We are carefully reviewing the World Health Organization's updated COVID-19 strategy in consultation with our partners. In the meantime, our public health efforts will continue to focus on reducing the spread of the virus by quickly identifying cases, locating individuals who have had close contact with them, and using proven public health measures such as self-isolation and physical distancing.

We continually assess the impact of our public health measures on the number of reported cases and adapt them as necessary in collaboration with our provincial and territorial partners. Our response must be evidence-based because our understanding of the science of COVID-19 continues to grow.

INFORMING CANADIANS

Q3. What are Canada's projections for COVID-19?

For the most recent information, visit the Canada.ca coronavirus disease (COVID-19) site. You can also follow Dr. Theresa Tam, Chief Public Health Officer of Canada, on Twitter (@CPHO_Canada).

There is also a new toll-free phone number (1-833-784-4397) where Canadians can get answers to questions regarding the new 2019 coronavirus. The service is available from 7 a.m. to midnight.

Canadians travelling abroad should consult the travel guidelines on the travel.gc.ca site.

Q4. Why is the Government of Canada running a COVID-19 ad campaign?

The Government of Canada is implementing a comprehensive national public education campaign for COVID-19 that will provide Canadians with credible information on behaviours that will protect individuals and overall public health. The campaign will include advertising, social marketing, the development of information resources, the establishment of partnerships and targeted outreach to at-risk populations. This work will complement current Public Health

Agency of Canada outreach and communications activities such as the website for information on COVID-19 with a virtual assistant to help Canadians get the information they need more efficiently; a toll-free information line; a self-assessment tool; digital advertising; social media posts; and regular updates to media.

Public education plays a critical role in our response to COVID-19 as it helps to:

- increase awareness and understanding about symptoms and treatment
- provide information on preventive measures such as self-isolation
- address misinformation and public concerns

Advertisements are expected to appear on a number of ethnic radio stations and newspapers by the end of April 2020. However, given the current situation where some print media are closed and we need to find alternatives, we are unable to provide a list of media outlets or a specific timeline.

Virtual health tools

On Sunday, May 3, 2020, the Prime Minister announced $240.5 million for the development and rollout of virtual health tools to support Canadians.

Q5. **What, specifically, will the money be spent on?**

This funding will further enable the development and reach of:

- The **Canada-COVID-19 mobile app**, which provides Canadians with access to a symptom tracker, credible sources of information and resources, and a **self-assessment tool**

- The **Wellness Together Canada** portal, which makes it easy for Canadians to access self-directed tools and find credible information on mental health and substance use. It also connects Canadians to peer support workers, social workers, psychologists and other professionals for confidential chat sessions, phone calls and online counselling

- **Our artificial Intelligence capacity**, which will help us gain further insight and understanding concerning the emergence, spread and public health risks of COVID-19: Health Canada and the Public Health Agency of Canada have put in place contracts with BlueDot to enhance and expand upon existing expertise in this field.

In addition, the Government of Canada is working with the provinces and territories, and in collaboration with Canada Health Infoway, to support the use and adoption of virtual care services. This means that Canadians can continue to have their regular health needs met in a safe and secure manner, via telephone, text or video-conferencing, in addition to face-to-face visits.

Q6. Do you have a breakdown of the how the money will be spent?

Our government is committed to working collaboratively with the provinces and territories to determine priorities for this investment. Health Canada is already engaging with the provinces and territories, as well as with Canada Health Infoway, to identify where additional support is needed in terms of virtual care technology and infrastructure.

The majority of this funding ($200 million) will be used to improve Canadians' access to the health services they need through virtual tools and approaches. We are working with the provinces and territories to map out where virtual tools are needed most so that Canadians can continue to receive the high-quality care they expect from Canada's health systems.

The remaining balance of this funding ($40.5 million) is supporting a growing suite of digital solutions and tools, including Wellness Together Canada and the Canada COVID-19 app.

Q7. Will a contact tracing app be part of this funding announcement? If so, how will the Government of Canada ensure Canadians' data is protected?

Rigorous contact tracing by provincial and territorial public health authorities continues to be an important part of Canada's COVID-19 response. Recognizing the importance of tracking the virus and preventing future flare-ups, the Government of Canada's National Volunteer Recruitment Campaign included a call-out for volunteers to help provincial and territorial authorities with case tracking and contact tracing for COVID-19.

Our government is aware that many contact tracing tools are being developed to help digitize the contact tracing process, including through mobile apps, and is monitoring these developments closely. It is important that such apps protect the privacy and security of users. Privacy considerations will continue to be front and centre at every stage of any initiative undertaken by the Government of Canada.

Q8. There are vulnerable populations in Canada who are being affected by COVID-19. Will any of this funding address their unique needs?

Health Canada is exploring ways to support a variety of populations in the deployment of virtual health services. Community partners could potentially use virtual technologies, particularly secure messaging and videoconferencing, in a way that addresses unique needs of vulnerable populations. However, important discussions are needed with provincial and territorial partners on the implementation of these tools.

The Canada COVID-19 mobile app

Q9. How do I access the Canada COVID-19 app

The app is accessible as a free mobile app for modern Apple iOS and Android smartphones and tablets, but is also available as a web application that can be accessed through any modern laptop or desktop computer browser.

Q10. How does it work?

The app is simple to use and designed to provide users with information and recommendations based on their personal risk. It also provides users with the ability to track their symptoms.

It includes educational information related to COVID-19 on subjects like physical distancing, handwashing, food safety, pets and other common questions, as well as links to reliable and up-to-date public health information sources.

The Canada COVID-19 app will help Canadians access the information they need, whether through email, app or online service. In addition, we are putting in place other tools to further enhance the ability of Canadians to easily receive reliable and up-to-date information on COVID-19.

Q11. How does this app fit in with resources already available in some provinces?

The app builds on what provinces and territories are doing and provides another valuable resource for Canadians. This mobile platform was based on a mobile app launched by BC and developed by Thrive Health.

On the national platform, where a province or territory opts in to this mobile app, users will be directed to a province-specific module that will contain jurisdiction-specific information.

Q12. What are the results of the self-assessment tool?

Canadians using the tool are able to get the information and guidance they need, and this is resulting in a reduction calls to 811 and telehealth lines, as well as in-person services such as family doctor visits, walk-in visits, and urgent care centres.

The new Canada COVID-19 app will further support Canadians to ensure they have evidence-based recommendations, up-to-date information and resources.

EXPERT ADVICE AND RESEARCH

Q13. Do we have a team of scientific advisors in the event of an emergency, similar to the U.K.'s Scientific Advisory Group for Emergencies, to advise ministers or Cabinet on the coronavirus? If not, do we obtain all our scientific advice from the Public Health Agency of Canada?

In January, the federal, provincial and territorial governments agreed to set up the Special Advisory Committee (SAC) on the Novel Coronavirus (2019- nCoV) to advise Deputy Ministers of Health across Canada on coordination, public health policy, and technical content related to the COVID-19 outbreak. The SAC is made up of representatives of various federal departments and agencies, as well as members of the Pan-Canadian Public Health Network Council and the Council of Chief Medical Officers of Health of Canada.

The Committee is supported by three expert groups that bring together senior federal-provincial-territorial officials and public health experts: the Technical Advisory Committee, the Logistics Advisory Committee and the Public Health Network Communications Group.

Since January, the Minister of Health has held weekly Health Ministers' calls with her provincial and territorial counterparts, as has the Deputy Minister of Health Canada, to understand the situation in each jurisdiction and accelerate collaboration to meet common needs.

In March, as part of the Government of Canada's more than $1 billion COVID-19 Response Fund, the Prime Minister announced $275 million in funding for coronavirus research and medical countermeasures, including potential vaccines and treatments, to combat COVID-19.

The Chief Science Advisor of Canada (CSA) has assembled a multidisciplinary science expert panel to advise her on the latest scientific developments relating to COVID-19. The group is further broken down into sub-groups that will focus on health systems and modelling methods. This information will assist the CSA in providing current, cross-disciplinary and independent advice to the Prime Minister and government. The expert group is composed of distinguished Canadian scientists and will be meeting on a regular basis to discuss available science and evidence from disease modelling, risk perception, diagnoses and clinical research. The first meeting took place in March.

As was announced by the Prime Minister on April 23, 2020, the Government of Canada will invest in new medical countermeasures to allow it to gain a better understanding of COVID-19 and set up the necessary infrastructure to combat the virus in Canada. These measures include:

- The establishment of the COVID-19 Immunity Task Force, to be headed up by Dr. David Naylor (co-chair), Dr. Catherine Hankins (co-chair), Dr. Tim Evans, Dr. Theresa Tam and Dr. Mona Nemer. The Task Force will set priorities and oversee the coordination of a series of blood test samples from across the country that will indicate the extent of the spread of the virus in Canada, and will allow for a reliable assessment of the immunity and potential vulnerabilities of Canadians.

Q14. **What is CanCOVID?**

Canada's Chief Science Advisor has collaborated with the Government of Canada's departmental science advisors, the U15 Group of Canadian Research Universities, Compute Ontario and the University of Toronto to launch CanCOVID, a new Canada-wide network of health, science and policy researchers to facilitate COVID-19 research collaboration.

Q15. **Can you explain the importance of Dr. Francesco Marchetti's response to the review of OECD test guideline 488?**

Revisions to OECD Guideline 488 focus on updating the recommended protocols for germ cell mutagenicity testing. The original guideline included some protocols that were found to be ineffective in detecting germ cell mutagenicity and which, if used to test agents for regulatory submission, could have led to erroneous conclusions. Germ cell mutations are associated with a

variety of hereditary diseases, and it is important to appropriately classify chemicals as germ cell mutagens under the Globally Harmonized System of Classification and Labelling. The revised guideline provides recommendations that should generate more robust data on the potential for chemicals to cause germ cell mutations. In addition, it provides a common sampling time for the simultaneous assessment of mutagenicity in somatic tissues and germ cells, which significantly reduces the number of animals required for testing.

Health Canada led the OECD expert group tasked with revising the germ cell portion of the 488 test guideline. These revisions were ratified after lengthy deliberations among several member countries. This consensus was largely based on two publications of the germ cell working group of the Genetic Toxicology Technical Committee of the Health and Environmental Sciences Institute, chaired by Health Canada.

FUNDING

Q16. **How much did the Public Health Agency of Canada receive for COVID-19? What proportion of this amount went towards funding COVID-19 testing across Canada? What proportion was used for public health surveillance? How much was spent on contact tracing?**

Approximately $230 million of the projected funding was awarded to the Public Health Agency of Canada (PHAC).

Of this amount, the following was set aside:

a) $25.7 million for COVID-19 testing (this funding is used to support lab tests at the PHAC's National Microbiology Laboratory)
b) $23.1 million for public health surveillance

Funding for contract tracing was not included in this envelope, as contract tracing is conducted locally by the provinces and territories.

Q17. **Can you confirm what the Public Health Agency will do with the $50 million allocated for COVID-19 public health information work?**

The funding will support the development and implementation of a comprehensive national public education campaign for COVID-19 that will provide Canadians with credible information that promotes behaviours that will protect individuals and overall public health. This will include advertising, social marketing, the development of information resources, the establishment of partnerships and targeted outreach to at-risk populations. This work will complement current Public Health Agency of Canada outreach and communications activities such as the website for information on COVID-19, a toll-free information line, digital advertising, and regular updates to media.

Public education plays a critical role in our response to COVID-19 as it helps to:

- increase awareness and understanding about symptoms and treatment
- provide information on preventive measures such as self-isolation
- address misinformation and public concerns

Q18. What, specifically, will the $240.5 million investment in mental health tools during the COVID-19 pandemic be used for?

More than ever, Canadians need to have tools and resources—including easily accessible mental health information and support, alerts and tracing tools—to support their mental health and well-being. The $240.5 million in funding announced today will help Canadians access reliable health information and support access to health services through virtual tools and approaches.

This funding will further enable the development and reach of the following:

- The Canada COVID-19 app, which includes a symptom tracker tool, access to credible information and resources, and a self-assessment tool

- The Wellness Together Canada portal, which makes it easy for Canadians to access self-directed tools and find credible information on mental health and substance use. This portal also connects Canadians to peer support workers, social workers, psychologists and other professionals for confidential chat sessions, phone calls and online counselling

- Enhanced analytical capacity, to better understand the emergence, spread and public health risks of COVID-19: Health Canada and the Public Health Agency of Canada have put in place contracts with BlueDot Inc. to enhance and expand upon existing expertise in this field

In addition, the Government of Canada is working with the provinces and territories, and in collaboration with Canada Health Infoway, to support initiatives involving the development of virtual care services so that Canadians can continue to have their regular health needs met in a safe and secure manner, via telephone, text or video-conferencing, in addition to face-to-face visits. Our government is committed to working collaboratively with all jurisdiction to determine priorities for this investment and to identify areas where additional support is needed in terms of virtual care technology and infrastructure.

The majority of this funding ($200 million) will be used to help Canadians gain better access to the health services they need through virtual tools and approaches. The remaining balance of this funding ($40.5 million) is supporting a growing suite of digital solutions and tools, including Wellness Together Canada and the Canada COVID-19 app.

As part of the rollout of virtual health services, Health Canada is looking into ways of serving various population groups. Community partners could potentially use the virtual technology, notably secure messaging and video-conferencing, to meet the specific needs of vulnerable populations. However, the implementation of such tools requires significant discussion with provincial and territorial partners.

Q19. Are Spotify ads promoting COVID-19 included in this $30 million campaign?

Government of Canada ads featured on Spotify make up part of the $30 million campaign. Since we have yet to receive the final invoices, we cannot provide any information regarding spending.

Q20. Which organizations funded by the $30-million COVID advertising campaign were not Canadian outlets? How much money was paid to non-Canadian companies for this advertising?

A variety of media and platforms are being considered, including print, television, radio and digital platforms, to reach a wide range of audiences. The majority of platforms have facilities in Canada; however, exceptions have been made for some digital platforms that are effective in reaching some of our specific target audiences in Canada, including Facebook and YouTube. We do not yet have the final costs of the media buy as the campaign is ongoing and final invoices have not yet been received.

Q21. How much did the government (PSPC) contract with Cossette cost? How much is Cossette receiving for this work?

The total cost of Cossette's contract with the Government of Canada for ongoing services (Public Services and Procurement Canada) is currently $813,600 (including tax) over a three-year period.

The other services are provided upon request and are paid according to the work done (Task Authorizations), as per the contract basis of payment, including the contractor's fees and rates. Cossette's fees and rates are confidential.

MENTAL HEALTH SUPPORT FOR CANADIANS

Launch of the Wellness Together Canada portal

Q22. How do I access the Wellness Together Canada portal?

The portal can be found at https://ca.portal.gs/ and in the Canada COVID-19 app, along with other virtual COVID-19 tools from Health Canada.

Q23. Does the government plan to make other digital COVID-19 tools and resources available to Canadians?

The portal makes up part of a series of virtual products supported or funded by Health Canada that aim to provide Canadians with information and support during the COVID-19 pandemic. The Self-Assessment Tool and the Canada COVID-19 app have already been launched.

We will continue to work with all our partners to ensure that Canadians have access to the latest COVID-19 tools, information and resources.

Q24. How does the portal work?

The portal will provide Canadians with much-needed mental health and substance use support in the context of the current COVID-19 pandemic. It will provide them with various levels of support depending on their needs—from information and self-assessment tools to the opportunity to talk with peer support workers and other professionals. Discussions may include a limited number of face-to-face telephone sessions.

The portal is offered by a consortium of organizations dedicated to mental health and substance use. It is managed by Stepped Care Solutions. Partner organizations include Kids Help Phone and Homewood Health, as well as Bell Canada Enterprises, the Mental Health Commission of Canada, the Canadian Psychological Association and Facebook Canada.

Q25. Will information I share on this portal be protected?

Crisis support links, as well as a number of different resources, are accessible directly through the portal without registration. You can register in order to obtain additional support and resources. The resources and services included in the portal are provided by licensed professionals. All information provided will remain strictly confidential.

Q26. How many Canadians are expected to be able to use the Wellness Together Canada portal? What is the portal's current capacity?

The portal provides Canadians in all provinces and territories, 24 hours a day, seven days a week, with free access to evidence-based tools and resources that will help meet their mental health and substance use support needs. In addition, Canadians can access the services of more than 6,000 Homewood Health and Kids Help Phone employees through the portal.

Following the SARS outbreak, it was found that more than 40% of Canadians had reported increased stress levels at home and at work during the outbreak, and 16% showed signs of traumatic stress. Based on these estimates and other considerations specific to the COVID-19 pandemic, some 11 million or so Canadians are expected to experience high levels of stress at home and at work, and nearly 2 million will show signs of traumatic stress. For this reason, access to the portal will be closely monitored in order to tailor services to meet the demands of Canadians.

Q27. How many psychologists, social workers, peer support workers and "other professionals" has the government hired to date, and how many does it intend to hire overall? How many of these employees are available full-time?

The series of tools on the Wellness Together Canada portal will provide Canadians with different levels of support depending on their needs, ranging from information and self-assessment tools to the ability to chat with peer support workers and other mental health professionals. Homewood Health and Kids Help Phone will have more than 6,000 employees available to provide psychosocial support services for Canadians via text and telephone.

While the exact mix of care providers is not available at this time, they represent a range of health care professions, including social work and psychology, and have diverse backgrounds in counselling psychology, clinical social work, rehabilitation, crisis management, child psychology and neuropsychology, sexuality, adolescent problems, marital and family therapy and addiction. The vast majority of these service providers are certified mental health and addiction professionals.

Q28. Will the federal government pay the psychologists that Canadians will be consulting via the mental wellness portal?

The Wellness Together Canada portal makes up part of a series of virtual products supported or funded by Health Canada that aim to provide Canadians with information and support during the COVID-19 pandemic. Portal funding is awarded to a consortium of organizations, including Stepped Care Solutions, Kids Help Phone and Homewood Health. The psychosocial support services to which Canadians are referred through the portal are provided by mental health professionals trained and employed by Kids Help Phone and Homewood Health. These services are paid for by Health Canada from funding that also serves to pay for the portal.

Q29. Will the Government of Canada make additional investments in mental health and suicide prevention?

With school closures and reduced access to community resources, Kids Help Phone is experiencing increased demand for its confidential, 24-hour crisis support services available online, as well as by phone and text messaging. In response, the Government of Canada has provided Kids Help Phone with $7.5 million to help it meet this increased demand and provide young people with the mental health support they need during this difficult time.

This additional funding will make it possible to provide electronic mental health services in English and French for children and youth across Canada who are experiencing the social and financial effects of the COVID-19 pandemic. This will help vulnerable Canadian children and youth find the help they need when they need it most.

Q30. Does the portal take the specific needs of First Nations into account?

During the funding process for this initiative, Health Canada requested that the portal take cultural safety and trauma into consideration. The portal is for all Canadians.

Q31. Can people who do not have Internet access use the portal?

The portal is a digital tool accessible on the Internet only. If you require mental health or substance use support and do not have access to the Internet, we invite you to contact your local health authority or self-help hotline. Thanks to the growing number of organizations that mobilize every day, there are many services available to help Canadians in these difficult times.

Q32. What is the situation regarding the Pan-Canadian Suicide Prevention Service?

In the 2019 Budget, the Government announced that it would invest $25 million over five years, and $5 million annually thereafter, to implement and sustain a fully operational pan-Canadian suicide prevention service. This service will give Canadians across the country access to a bilingual crisis support service, using the technology of their choice (telephone, text messaging or chat), that will be available 24/7 and will be staffed by trained professionals.

In July 2019, the Public Health Agency of Canada issued a call for funding requests from organizations interested in developing a pan-Canadian suicide prevention service. This process closed on October 31, 2019 and a decision is expected shortly.

Q33. What is the government doing to prevent overdose deaths from increasing during the COVID-19 pandemic?

The Government of Canada is taking action to help community health service providers and all levels of government respond to the COVID-19 pandemic. The government is funding harm reduction, treatment and housing services, etc., for drug users. It is committed to ensuring that the provinces and territories have the necessary tools to address the combined effects of the opioid overdose crisis and the COVID-19 pandemic on their populations.

- On March 19, 2020, Health Canada issued a six-month exemption for prescriptions of controlled substances (such as narcotics) under the *Controlled Drugs and Substances Act* and its regulations. This temporary exemption allows practitioners to orally prescribe controlled substances; makes it easier for pharmacists to extend or refill prescriptions and transfer prescriptions to other pharmacies; and allows for drugs to be delivered or picked up by another person.

  This means that people with a substance use disorder who are on opioid agonist therapy will be able to continue getting their medication while maintaining physical distancing guidelines.

- On April 6, 2020, Health Canada granted class exemptions allowing the provinces and territories to establish new, urgently-needed public health sites (also known as temporary overdose prevention centres) within existing supervised consumption sites, shelters and other sites, as needed, to help people avoid overdoses while practising physical isolation and self-isolation.

  Health Canada will also allow health service providers in the community to ensure that existing supervised consumption sites can quickly adapt their operations to meet public health recommendations within the context of COVID-19. This can be done without the need to notify or seek additional authorization from Health Canada. Changes to

operations could include, but are not limited to, new measures regarding how people move around the premises and changes to hours of operation or the number of booths.

Q34. What are the current statistics on downloads of the Canada COVID-19 app or the number of clicks on the mental health portal? How many Canadians have accessed mental health services through these tools?

As on April 26, the Canada COVID-19 app had been downloaded 471,015 times; as on April 21, 70,000 Canadians had visited the mental health portal. Q35.

Q35. What other resources are available to Canadians?

The COVID-19 pandemic is new and unexpected. This situation can be unsettling and can cause a sense of loss of control. It is normal for people and communities to feel sad, stressed, confused, scared or worried.

The Government of Canada is working with the provinces and territories to expand and scale-up digital platforms that can help governments in their response to COVID-19, through education, information, mental health supports, alerts and tracing tools.

We will continue to work with all of our partners to ensure that Canadians have access to up-to-date COVID-19 information, tools and resources.

There are a number of resources available to help people in crisis, including:

Kids Help Phone – 1-800-668-6868 or text CONNECT to 686868 (available to young Canadians between 5-29 years old seeking 24-hour confidential and anonymous care from professional psychological counsellors)

Hope for Wellness Help Line – Call the toll-free Help Line at 1-855-242-3310 or connect to the online chat (available to all Indigenous peoples across Canada who are seeking immediate crisis intervention)

Crisis Services Canada
1-833-456-4566 (available to all Canadians seeking support)

GUIDELINES

Long-term care facilities

Q36. Why do you recommend that personal support workers and essential visitors and volunteers wear personal protective equipment when there is a shortage?

Personal support workers are an integral part of the health care system. Personal support workers provide close, direct care to patients. Every person entering a long-term care home, including essential visitors and volunteers, has a responsibility to prevent infections among residents of these facilities, who are at high risk of severe illness and death from COVID-19.

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

Q37. Why are you telling workers to not to have multiple jobs when they may need to have multiple jobs to survive?

We know that seniors are more at risk of developing severe complications from COVID-19 because of their underlying medical conditions and age.

For seniors living in long-term care homes or assisted-living facilities, there is an even greater risk of infection and transmission of the virus owing to proximity. The movement of workers from one facility to another increases the risk of spread of infection, which ultimately puts seniors more at risk of contracting the virus. We need to protect seniors in these challenging times

Therefore, the guidelines recommend identifying staff who work in more than one location and ensuring efforts are made to prevent this where possible

Q38. How would residents' needs be met if there is a further restriction on the availability of personal support workers?

The administration of long-term care is the responsibility of provincial and territorial governments. They have put in place a number of measures to support continued quality care to residents during this crisis. For example, actions undertaken have included introducing flexibility in staffing policies and approaches, and working with third-party providers to deliver short-term care support.

The Government of Canada is working with provincial and territorial governments to respond to COVID-19. A national recruitment campaign has been developed, seeking volunteers, including individuals with health care experience, to help conduct case tracking functions and support health system surge capacity. An inventory of volunteers is being maintained from which provincial and territorial governments can draw as needed

More information is available at: https://emploisfp-psjobs.cfp-psc.gc.ca/psrs-srfp/applicant/page1800?toggleLanguage=en&poster=1437722.

Q39. What is the Government doing to support low wage workers?

The Government of Canada is taking strong and quick action to protect our economy, and the health, safety, and jobs of all Canadians during the COVID-19 pandemic.

The new Canada Emergency Response Benefit will support Canadian workers, whether employed or self-employed, who have stopped working and lost their income because of COVID-19. It will provide eligible workers $2,000 a month for up to 4 months to help them pay the bills.

The Government of Canada's priority is to ensure that Canadians receive the money they are entitled to as quickly as possible. We have launched a portal to provide information and to help workers apply for the new benefit.

Q40. What is the Government of Canada doing to protect seniors' financial security?

The Government of Canada is taking measures to ensure that the Canada Pension Plan and Old Age Security benefits that seniors rely on will continue to be paid without delay, and that new applications for these benefits will be processed in a timely fashion.

The Old Age Security pension is intended to provide a minimum income guarantee to all seniors. Therefore, the Old Age Security pension is based on age and residence and not on employment history or investment income, and it continues to be paid to seniors monthly.

The income-tested Guaranteed Income Supplement is provided to all low-income seniors. Old Age Security pensioners who experience a drop in income as a result of the pandemic may be eligible to receive this additional support.

To further protect seniors' financial security, we are introducing several new measures. For low- and modest-income Canadians, including seniors, starting April 9, 2020, the Government began providing a one-time special payment through the Goods and Services Tax (GST) credit. This will provide close to $400 to low-income single individuals and close to $600 to low-income couples.

We are also reducing required minimum withdrawals from Registered Retirement Income Funds (RRIFs) by 25% for 2020. This will provide flexibility to seniors and help preserve RRIF assets during a volatile market.

Furthermore, we are extending the deadline to file your income taxes to June 1, 2020, and allowing any new balances due, or instalments, to be deferred until September 1, 2020, without incurring interest or penalties.

Q41. What is the Government doing to protect seniors' pensions?

Budget 2019 introduced new measures to enhance the security of workplace pensions in the event of corporate insolvency.

Measures to make insolvency proceedings fairer, more transparent and more accessible for pensioners and workers are now in force.

Higher expectations and better oversight have also been set for corporate behaviour:

- Federally incorporated businesses are now explicitly permitted to consider pensioner and worker interests when acting in the best interests of the corporation.
- Publicly traded, federally incorporated firms will be required to disclose their policies pertaining to workers and pensioners' well-being and executive compensation, or explain why such policies are not in place.

Finally, measures protect Canadians' hard-earned benefits by clarifying that, in accordance with federal pension legislation, pension plan members are entitled to the same pension benefits when a plan is wound up as when it was ongoing.

Q42. What is the Government doing to protect seniors from elder abuse?

The Government of Canada is committed to protecting the safety and well-being of seniors in Canada and recognizes the devastating impact of elder abuse on seniors and their families.

We continue to provide information, resources and tools to help seniors, caregivers, service providers and the general public identify elder abuse and respond appropriately.

We will continue to work collaboratively with the provinces and territories, as well as with community organizations, to implement measures to help improve the lives of seniors and their families.

Q43. What is the Government doing to protect seniors from COVID-19 related fraud and scams?

The Government of Canada is working to implement measures to help improve the lives of seniors and their families and is taking the issue of financial exploitation of seniors very seriously. Indeed, fraud and theft are offences under the *Criminal Code*.

Employment and Social Development Canada has been sharing anti-fraud content from other government departments in real time on its Seniors Facebook page, as well as other departmental channels.

In the longer term, the Government will move forward with a national definition of elder abuse, invest in better data collection and law enforcement, and establish new penalties in the *Criminal Code* relating to elder abuse.

This builds on work under way, such as the National Seniors Council's examination of the issue of financial abuse of seniors and funding for community groups under the New Horizons for Seniors Program to help reduce elder abuse.

Q44. Why did the PHAC take so long to publish its long-term care guidelines?

One of our priorities is to protect residents and staff in long-term care facilities, which is why the PHAC is working with provincial and territorial governments on all aspects of the response to the COVID-19 pandemic that affect them. To develop the information necessary to protect residents and staff, as set out in the document entitled *Infection Prevention and Control for COVID-19: Interim Guidance for Long-Term Care Homes*, the PHAC consulted the governments involved, as well as other experts across the country. Scientific knowledge on the transmission of COVID-19 is evolving rapidly; this document, therefore, is a synthesis of the latest findings regarding the transmission of COVID-19.

The document illustrates the careful, evidence-based work required to provide the greatest possible protection for residents and staff in long-term care facilities in Canada.

Q45. How many deaths have there been in long-term care facilities?

The Public Health Agency of Canada reports daily on the number of cases and deaths. As on May 6, 2020, 3,429 of the 4,232 deaths in Canada (81%) were linked to long-term care facilities.

It should be noted that these figures reflect public reports by the provinces and territories.

Q46. Does the Public Health Agency of Canada compile data on COVID-19 outbreaks in long-term care facilities?

The Public Health Agency of Canada (PHAC) is monitoring the impact of COVID-19 on our most vulnerable populations, including residents of long-term care homes. Data collection is done through daily communication between federal, provincial and territorial epidemiologists who work together to collect and share information. Data on cases is collected from the provinces and territories (P/Ts) using a reporting form that includes a field to report residence in a long-term care facility. This information is supplemented by publicly available data sources. Local public health authorities submit data on outbreaks in long-term care facilities to their provincial and territorial public health counterparts, who synthesize the information, make it public and implement control measures. We are currently working on a standardized data set for long-term care facilities. PHAC also publishes information on its website about possible exposure to the virus, such as in long-term care facilities.

Additional guidance for persons with disabilities in Canada

Q47. What factors could make persons with disabilities more vulnerable to COVID-19?

In the case of persons with disabilities, certain factors could increase their risk of contracting COVID-19 or developing serious symptoms. These include:

- the nature of their disability (for example, people who have difficulty washing their hands, or the visually impaired, who need to touch objects for support or to obtain information)
- communal living, due to proximity to others
- having to interact with multiple care providers and support workers, which increases the risk of exposure
- barriers to accessing public communications about COVID-19, as well as response services and programs
- treatment of unrelated health conditions in the health care system
- the loss of community services and support (jobs, access to therapy, schools), which could lead to regression for some persons with disabilities

Q48. What specific measures should persons with disabilities take to protect themselves?

To protect themselves from COVID-19 and to avoid spreading the disease to the people who are taking care of them, persons with disabilities should:

- Stay home and only go outside your home for necessary activities like doctor appointments or getting groceries
- Ask family, a neighbour or friend to help with essential errands

- Wash your hands frequently, or get someone to help you do so
- Immediately notify or have others notify your family / care providers /friends

Q49. What should caregivers do to meet the needs of persons with disabilities?

Caregivers should consider accommodating persons with disabilities and the people who take care of them to ensure access to their services.

Persons with disabilities must have the right to be accompanied at all times by an essential support person. This may be a paid employee, friend or family member.

There are special provisions for health care workers with disabilities, as well as essential supports for persons with disabilities (work arrangements, financial resources, mental health resources and other policies and procedures).

Personal protective equipment, such as a face shield, is a good alternative to a mask for people with hearing or visual impairments and those with cognitive or intellectual disabilities, as long as their support person does not have COVID-19.

Q50. What should assessment centres do to meet the needs of persons with disabilities?

It is important that persons with disabilities have access to the services of designated COVID-19 assessment centres. Specifically, assessment centres must ensure accessibility (e.g., ramps and accessible parking spots) and accommodation for people who suffer from anxiety or who have a cognitive or intellectual disability. This might also include allowing individuals to avoid line-ups, providing a private room, accommodating sensitivity to noise and light, or providing alternatives to in-car swabs.

COVID-19 assessment centres should also allow essential attendants (caregivers, support persons, sighted guides, interpreters or friends) to remain with the person while at the assessment centre, and must ensure that information is provided in multiple languages and in a functionally and culturally appropriate manner.

Assessment centres should ensure that test results are communicated to the person with a disability or his or her support network. Communication should be in multiple languages and in a functionally and culturally appropriate manner.

ISOLATION, QUARANTINE (SELF-ISOLATION) AND PHYSICAL DISTANCING

Q51. Should a certain percentage of the population be tested to allow for the easing of social distancing restrictions?

We are continuing COVID-19 testing on a massive scale; in fact, Canada has one of the highest testing rates in the world. We know that testing is key to detecting new cases and identifying and interrupting the chains of transmission. We are now testing 20,000 people a day, almost double the number of tests we were doing earlier this month, and the number continues to grow.

We do not have a precise figure for the number of tests that need to be performed each day to allow us to ease social distancing measures. This number will vary from one jurisdiction to the

next. However, increasing the number of tests performed helps us quickly detect new cases and their contacts in order to prevent or reduce the spread of COVID-19.

Canada has maintained a positive test result rate of approximately 6–7%, which is within the effective detection range to accurately target the circulation of the disease. We want to get the most accurate picture possible of what is happening in our communities. This shows that we have a very sensitive screening system. We are continuing to increase the capacity of our labs so as to ensure that this continues to be the case.

The main goal is to test people who are symptomatic, people in high-risk situations such as long-term care facilities and correctional facilities, and health care workers and COVID-19 support personnel, regardless of the setting.

Our priorities continue to be accessing testing reagents, evaluating rapid point-of-care tests and accessing authorized test kits so that provinces and territories are equipped to ramp up testing according to their requirements.

Q52. Can people who are asymptomatic go outside for walks, as long as they maintain physical distancing?

For all Canadians, you can go for a walk if you:

- Have not been diagnosed with COVID-9
- Do not have symptoms of COVID-19
- Have not travelled outside of Canada in the past 14 days

If you go out for a walk, do not congregate and always practise physical (social) distancing by keeping at least two metres from others at all times.

For travellers entering Canada, during their 14-day period of isolation or quarantine:

- For those in mandatory isolation, stay inside your home.
- For those in quarantine (self-isolation), you may go outside for fresh air in a private place like your yard or on a balcony; however, you must stay on your property and not go into community settings.

BORDER MEASURES

ArriveCAN mobile app

Q53. How do I access the ArriveCAN app?

The mobile app is currently available in the Google Play Store or the Apple App Store.

It can be downloaded and installed for free on:

- iPhones running iOS 12 or above
- Android phones and tablets running OS 6 and above

ArriveCAN is also available as a Web application that can be accessed through the browser on a laptop or desktop computer.

Q54. How does it work?

The ArriveCAN app is simple to use and is designed to collect basic contact and travel information from travellers, as well as their location for mandatory isolation. The app also asks yes or no questions related to symptoms and self-isolation plans.

Q55. Is the Government planning to make other COVID-19 digital tools and resources available to Canadians?

The Government of Canada is working with the provinces and territories to make available additional digital platforms that can help with the response to COVID-19, including education, information, mental health and substance use supports, alerts, and screening tools.

On March 31, 2020, the Government of Canada launched the Canada COVID-19 mobile platform. The platform provides users with:

- information and recommendations based on their personal risk
- the ability to track their symptoms
- links to reliable and up-to-date public health information sources
- educational information related to COVID-19 on subjects such as:
  - physical distancing
  - handwashing
  - food safety
  - pets

ArriveCAN is a free mobile application for Apple iOS and Android smartphones and tablets. It is also available as a web application that can be accessed through any laptop or desktop computer.

We will continue to work with all of our partners to ensure that Canadians have access to up-to-date information, tools and resources on COVID-19.

Q56. Why not just use the paper contact form instead of a mobile app?

The app allows for the seamless transition of contact information from the traveller to the border services officer upon entry to Canada.

Travellers are encouraged to use the ArriveCAN app as an alternative to paper forms. It enable faster processing at the border for travellers returning to Canada.

This electronic collection method also limits physical contact between travellers and border services and quarantine officers.

Q57. What is the difference between the app and the Web version of the form

The Web version of the form can be accessed using the Web browser on any laptop, tablet or smartphone that is connected to the internet. The Web version requires entering a local token that travellers can obtain at the port of entry into Canada.

The ArriveCAN app can be downloaded directly on a mobile phone, and travellers can enter their information, without the need for a token, prior to their arrival at the port of entry. The token provided at the port of entry into Canada is only required to submit the information after it has first been entered in the app.

The ArriveCAN app allows all travellers arriving in Canada to make their declarations quickly, easily and securely.

Q58. Will this app be used to track travellers?

The ArriveCAN app will not be used to automatically track the user's position through their phone or GPS, nor is it a surveillance tool. The protection of Canadians' personal information is a priority for the Government of Canada, and any tool used to collect personal information has to undergo a rigorous privacy assessment.

Q59. We know that the provinces and territories are planning and developing mobile case monitoring apps. Is the ArriveCAN app a case monitoring app?

The ArriveCAN app is not a case monitoring app and does not overlap with any current digital or mobile solutions. In accordance with the emergency orders issued under the *Quarantine Act*, all travellers arriving in Canada must provide the Government of Canada with their essential contact information and an established quarantine plan. The app is designed to collect essential information that supports compliance and enforcement of the mandatory 14-day quarantine or self-isolation measures.

The ArriveCAN app is a digital solution that facilitates the collection of essential information and simplifies the submission of traveler responses. The app also supports physical distancing measures by limiting contact between travellers and border services personnel, since the required information can be easily and securely captured on mobile devices. Travellers can download the mobile app at any time, including prior to their departure, and enter their information, thus making things easier and faster for them when they come back into Canada.

Q60. What type of information does the app collect?

The information collected in the ArriveCAN app (as well as the on the paper and online forms) is required under the *Quarantine Act* and includes the following:

- name, date of birth, flight number and destination details
- self-assessment on symptoms (yes or no question on whether traveller is showing signs of a cough, difficulty breathing, or fever)
- self-isolation plan (yes or no question on whether a plan is in place)

Q61. What is the difference between the ArriveCAN app and the Canada COVID-19 app?

The Canada COVID-19 app provides all Canadians with general information and resources on COVID-19. The ArriveCAN app is only designed for travellers entering Canada who need to provide essential information in support of PHAC's mandate to ensure compliance with regulations and the enforcement of emergency orders under the *Quarantine Act*.

Q62. How will the information be protected?

Personal information under the control of the federal government is subject to the *Privacy Act*. Information is collected, used, disclosed, retained and disposed of in accordance with this Act.

Q63. How will the information be used?

The collected information will be used for three activities under subsection 15(1) of the *Quarantine Act*:

1. To monitor, verify or enforce compliance with mandatory isolation orders
2. To provide information to help travellers comply with mandatory isolation orders
3. For public health monitoring purposes

Compliance and enforcement officers may use the information provided to contact travellers during their mandatory isolation period to ensure they are respecting the requirement to stay in their place of isolation. The information will not be used for surveillance or tracking purposes.

Upon entry into Canada, travellers are informed of the compliance monitoring and verification activities, the possible consequences of non-compliance, and the enforcement actions and penalties they could face.

The Public Health Agency of Canada is working with the Royal Canadian Mounted Police and provincial law enforcement agencies to verify returning travellers' compliance with mandatory isolation orders, using a risk-based approach based on the information provided by the travellers at the border.

Q64. Which statute gives the government the power to request personal information?

Personal information can be requested under subsection 15(1) of the *Quarantine Act*:

> ***15 (1)*** *Every traveller shall answer any relevant questions asked by a screening officer or* ***quarantine*** *officer and provide to the officer any information or record in their possession that the officer may reasonably require in the performance of a duty under this* ***Act****.*

Q65. Why does the ArriveCAN app ask for more information than the paper or online forms?

The app can collect all the information needed to administer and enforce the *Minimizing the Risk of Exposure to COVID-19 in Canada Order (Mandatory Isolation) No. 2*. In addition to the information gathered by the current paper and online forms, the app asks travellers for flight or border crossing information and whether they are exhibiting COVID-19 symptoms and have a self-isolation plan.

Even though some information is not requested on the paper and online forms, every traveller entering the country is asked about exhibiting symptoms and having a self-isolation plan by a border services officer, who records their answers.

Eventually, the mobile app and the paper and online coronavirus forms will all request the same information. PHAC is currently working with the Operations Team on aligning the information collected from incoming travellers for it to be the same in all three formats.

Q66. What does the online from on ArriveCAN look like for travellers arriving in Canada?

Travellers arriving in Canada by air or land must provide basic information using the Traveller Contact Information Form, available through the ArriveCAN mobile app or a paper or online form. Access to the online form is limited and can be gained by obtaining an invitation code at the airport. Please see the Traveller Form in English and French.

Upon their arrival in Canada, travellers are informed that they will be monitored and their compliance verified, what potential consequences of non-compliance will be and what enforcement measures and sanctions they may be subject to. People who do not comply with mandatory self-isolation or quarantine requirements may be subject to a range of measures enforcing the *Quarantine Act*, including verbal and written warnings as well arrest and detention.

The Government of Alberta is introducing enhanced screening measures at border crossings and ports of entry

Q67. Why does the Government of Canada not take travellers' temperatures at all ports of entry?

The Government of Canada continues to take measures that have been found effective based on the most recent scientific data and assessments of the situation. At this time, border services officers do not take travellers' temperature at ports of entry. In the past, thermal imaging at Canadian ports of entry did not prove effective in detecting communicable diseases in travellers. For example, during the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, thermal imaging did not help us detect cases of the disease among the 2.3 million travellers who were thoroughly screened.

Each province and territory of Canada examines different situations and develops risk-based assessments and approaches based on what is happening within its boundaries.

Q68. If the Government of Canada considers that checking temperatures is not a reliable means of reducing the spread of COVID-19 by incoming travellers, why is it allowing the Government of Alberta to introduce this measure?

The Government of Canada is working closely with provincial and territorial governments to ensure their support for the measures it approves. Since the epidemiology of COVID-19 is not the same in all provinces and territories, provincial and territorial governments will continue to develop their own risk-based assessments and approaches.

Q69. Why is the question "Do you think you have a fever?" part of the current Government of Canada border measures if no temperature checks are conducted?

Border services officers are required to screen people arriving at ports of entry into Canada to determine whether they have symptoms associated with COVID-19. The question regarding having a fever is one among many others travellers must answer to help officers determine whether a quarantine or self-isolation is necessary. Alberta's recent decision to check temperatures at airports is an additional heath screening measure based on an assessment of the situation in that province.

Order 10 – Emergency Order – Mandatory Isolation

Q70. What is the new federal Emergency Order made under the *Quarantine Act* and why did the Government of Canada implement it?

Effective April 15, 2020, the Government of Canada has implemented a federal Emergency Order under the *Quarantine Act*, requiring anyone entering Canada, whether by air, land or sea, to isolate for 14 days if they have symptoms of COVID-19 or, if not exempted, to quarantine themselves for 14 days if they do not have symptoms, in order to limit the introduction and spread of COVID-19.

The Order applies to anyone who enters Canada, with few exceptions, whether they have symptoms of COVID-19 or not.

These measures will help protect the health of the individuals in question, those they may be in close contact with and Canadians in general, including people who are vulnerable such as adults aged 65 years or over and people with pre-existing medical conditions, who are at the greatest risk of severe health impacts from COVID-19.

Q71. How is the new Order different from the first Order imposing mandatory isolation?

Based on new scientific evidence that asymptomatic individuals can spread the disease, all travellers entering Canada, whether they have symptoms (symptomatic) or not (asymptomatic), are required to wear non-medical masks or face coverings when travelling to their self-isolation location (if symptomatic) or quarantine location (if asymptomatic).

In the past, only symptomatic individuals were prohibited from isolating in a location where a vulnerable person would be exposed.

This order extends that directive to asymptomatic people as well. Thus, asymptomatic individuals may not quarantine in a place where they would be in contact with vulnerable persons, such as adults aged 65 and over and those of all ages with compromised immune systems or underlying medical conditions, which makes them susceptible to complications relating to COVID-19.

If an asymptomatic person is unable to quarantine themselves in a suitable location, they will be transferred to a quarantine facility chosen by the Chief Public Health Officer of Canada.

In addition, the 14-day quarantine period is reset if the person develops any signs or symptoms of COVID-19 or if they are exposed to someone who is subject to the Order and exhibits signs and symptoms after entering Canada.

Q72. How will travellers be informed of protocols applicable to this type of situation upon their entry into Canada?

Upon their entry into Canada, travellers must answer questions regarding their health status and their symptoms, which they are required to disclose to a screening officer or quarantine officer. They must also acknowledge that, under the *Quarantine Act*, they are required to self-isolate or to quarantine for a period of 14 days, starting on the day of their entry into Canada.

Travellers will receive a document informing them that they are subject to the Order, describing the Order's requirements and providing general public health advice and a link to canada.ca/coronavirus for more information.

People who enter Canada are invited to consult their provincial or territorial public health authority to find out about other measures and restrictions concerning mandatory self-isolation or quarantine.

Q73. What does the Order issued under the *Quarantine Act* require of travellers returning to Canada? For travellers returning to Canada. what is the difference between what they can do at home if they have symptoms and if they do not?

Anyone returning to Canada must answer relevant questions at the border and provide any information or records required that they have in their possession. Travellers are also required to wear a non-medical mask or face covering upon their arrival and while travelling to their isolation or quarantine location.

In addition, the Order requires everyone who enters Canada and is not exempt to be added to one of the following categories: asymptomatic (who have no symptoms) or symptomatic (who have symptoms).

Asymptomatic

People entering Canada who have no signs or symptoms of COVID-19 are subject to the Order and must **quarantine** for 14 days as soon as they arrive in Canada because they may develop symptoms or infect others.

Quarantine means the separation of persons entering Canada from others in such a manner as to prevent the possible spread of infection or contamination.

Asymptomatic persons arriving in Canada must

- go directly to their place of quarantine, without delay, and stay there for 14 days;
- not quarantine in a place where they will have contact with vulnerable persons such as adults aged 65 and over and those of all ages with compromised immune systems or underlying medical conditions;
- ensure they have a suitable place to quarantine where they will have access to the necessities of life;
- monitor for signs and symptoms of COVID-19 until the expiry of the 14-day period;
- not leave their place of quarantine unless it is to seek medical attention;
- arrange for the delivery of essentials like groceries or medication;
- not use public transit;
- not have visitors;
- not go to school, work or any other public place; and
- practise physical distancing at all times (i.e. keep a distance of at least 2 metres from others).

We encourage asymptomatic people to use private transportation, such as a personal vehicle, to travel to their quarantine location. If they use public transportation, they must wear an appropriate non-medical mask or face covering while travelling. They must not make any stops along the way and practise physical distancing at all times.

Asymptomatic people may have to stay in a quarantine facility chosen by the Chief Public Health Officer of Canada if they plan to quarantine in a place

- where they would be in contact with vulnerable persons;
- where they would not have access to the necessities of life (e.g. food, heat, medication); or
- that is not considered suitable (e.g. it is a shelter or other place where many people would be newly exposed because of their staying there).

It is important to underscore that travellers returning to Canada may be asymptomatic upon their arrival, but could subsequently become sick. There are unfortunate cases where an asymptomatic individual can develop symptoms and deteriorate quite quickly.

If a person develops symptoms within 14 days, they must

- isolate themselves from others;
- immediately call a healthcare professional or their provincial or territorial public health authority and
  - describe their symptoms and travel history; and
  - carefully follow the instructions provided.

The 14-day quarantine period is reset (begins again) if the person develops any signs or symptoms of COVID-19 or if they are exposed to someone who is subject to the Order and exhibits signs and symptoms after entering Canada.

If a person develops signs or symptoms of COVID-19, they must act in accordance with the instructions for symptomatic individuals.

Symptomatic

Persons entering Canada who have signs and symptoms of COVID-19 or reasonable grounds to suspect they have signs and symptoms of COVID-19 are subject to the Order and required to remain in **isolation** until the expiry of the 14-day period that begins on the day on which they entered Canada because they are at risk of infecting others.

Isolation means the separation of persons who are infected with COVID-19 or who have signs and symptoms of COVID-19 from others in such a manner as to prevent the spread of infection or contamination.

Symptomatic persons entering Canada must

- use private transportation (i.e. personal vehicle) to travel to their place of isolation;
- wear a non-medical mask or face covering while travelling to the place of isolation
- go directly to the place where they will isolate, without delay, and stay there for 14 days;
- not isolate in a place where they will have contact with vulnerable persons such as adults aged 65 and over and those of all ages with compromised immune systems or underlying medical conditions;
- ensure they have a suitable place to isolate where they will have access to the necessities of life;
- undergo any health assessments required;
- monitor their signs and symptoms and report to the public health authority if they require additional medical care;
- stay inside their place of isolation;
- not leave their place of isolation unless it is to seek medical attention;
- arrange for the delivery of essentials like groceries or medication;
- not use public transit;
- not have visitors;
- not go to school, work or any other public place;
- practise physical distancing at all times (i.e. keep a distance of at least 2 metres from others).

Symptomatic persons entering Canada may be required to remain in a quarantine facility chosen by the Chief Public Health Officer of Canada if they

- have to use a public means of transportation to get to their place of isolation; or
- plan to isolate themselves for a period of 14 days in a place
    - where they would be in contact with vulnerable persons;
    - where they would not have access to the necessities of life (e.g. food, heat, medication); or
    - that is not considered suitable (e.g. it is a shelter or other place where many people would be newly exposed because of their staying there).

Q74. Who is considered a vulnerable person?

Persons aged 65 and over and those of all ages with compromised immune systems or underlying medical conditions, which makes them susceptible to complications relating to COVID-19. All of these groups are at an increased risk of more severe illness.

Q75. What is the difference between isolation and quarantine?

Isolation means the separation of persons who are infected with COVID-19 or who have signs and symptoms of COVID-19 from others in such a manner as to prevent the spread of infection or contamination.

Quarantine means the separation of persons entering Canada from others in such a manner as to prevent the possible spread of infection or contamination.

Q76. How is it determined whether travellers meet the conditions to be able to isolate or quarantine at home or in a place of their choice?

Upon entering Canada, travellers are asked questions about their health and to assess their ability to meet the conditions outlined in the Order to isolate or quarantine in an appropriate location.

Considerations include whether the person is able to isolate or quarantine at a place that is suitable (e.g. it is not a shelter or other place where many people could be newly exposed because of the individual's staying there), where they can get the necessities of life and are not in contact with vulnerable persons. If the traveller is unable to meet one or more of these conditions they will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada.

People entering Canada should also consult the local health authority of their province or territory to find out about other mandatory isolation or quarantine measures and restrictions.

Q77. How do I monitor for signs and symptoms of COVID-19?

Symptoms of COVID-19 include cough, difficulty breathing or fever equal to or greater than 38°C (signs of fever could include shivering, flushed skin and excessive sweating). Information about COVID-19 is also available at www.canada.ca/coronavirus or by calling 1-833-784-4397.

Visit the provincial or territorial public health authority website where you are located for more information, including when to contact the public health authority.

Q78. When does the 14-day period start? Is it from the day of entry into Canada or the day the traveller arrives at the place where they will quarantine themselves or isolate?

The 14-day period begins on the day the person enters Canada.

Individuals should consult their provincial or territorial public health authority for any additional measures and/or restrictions, such as a provincial emergency order that requires individuals to isolate themselves for 14 days upon entering their province from another part of Canada.

Q79. What is considered to be an appropriate non-medical mask or face covering?

Wearing an appropriate non-medical mask or face covering is an additional measure you can take to protect others around you, even if you have no symptoms. It can be useful for short periods of time to prevent respiratory droplets from contaminating others or landing on surfaces.

Examples of appropriate non-medical masks and face coverings include a homemade cloth mask, a dust mask or a bandana.

An appropriate non-medical mask or face covering is made of protective layers of absorbent fabric (such as cotton) that fit snuggly over the nose and mouth and are secured to the face with ties or loops. Masks or coverings should allow for easy breathing, stay the same shape after machine washing and drying and be changed as soon as possible if damp or dirty.

Q80. Who determines whether the traveller is wearing an appropriate non-medical mask or face covering upon entry into Canada?

Quarantine officers or screening officers will determine the appropriateness of non-medical masks or face coverings worn by travellers entering Canada.

If it is determined that the traveller is wearing an inappropriate non-medical mask or face covering they will be asked to remove it as per the guidelines provided by PHAC. The traveller will then be required to put on an appropriate non-medical mask or face covering.

Q81. Are co-travellers able to quarantine or isolate together if one of them is a vulnerable person?

Under the terms of the new Order, individuals who travelled together are able to quarantine or isolate together if one of them is a vulnerable person as long as the person is a consenting adult or is the parent or minor in a parent-minor relationship.

Q82. Am I required to comply with the Order if my province or territory has its own legal requirements for quarantine or isolation?

Yes, everyone entering Canada must comply with the Order with few exceptions.

Provinces and territories may implement their own legal requirements regarding quarantine and isolation. Persons entering Canada will be expected to comply with the federal government's Order and any measures and/or restrictions enforced by the province or territory as long as they do not contradict or replace those of the federal Order (i.e., they must be stricter than the requirements of the Order).

Individuals should consult their provincial or territorial public health authority for any additional measures and/or restrictions.

Q83. What type of masks or face coverings will be provided at border entries? If all travellers entering Canada will be required to wear masks, how will this impact the supplies available for healthcare workers?

Travellers require non-medical masks or face coverings upon arrival. Travellers can also wear homemade cloth face coverings. Masks or face coverings may be provided upon arrival as appropriate.

Medical masks, including surgical, medical procedure face masks and respirators (like N95 masks), must be kept for healthcare workers and others providing direct care to COVID-19 patients.

Even while wearing a non-medical mask or face covering, strict hygiene and public health measures, including frequent hand-washing and physical distancing, must be maintained to reduce your chance of passing on the virus to someone else. It is also important to be aware that wearing a non-medical mask or face covering in the community has not been proven to protect the person wearing it. Wearing a non-medical mask or face covering is an additional measure for people—including those who do not have symptoms—to take to protect others.

Q84. **Will the new requirements (e.g. travellers having to confirm their planned place to isolate or quarantine; being given a non-medical masks or face covering) create back-ups at airports?**

With the introduction of the updated Emergency Order, we are building on measures previously implemented on March 25, 2020, to reduce the introduction and further spread of COVID-19 in Canada. While it can be expected that processing travellers at the border may initially increase wait times, the additional measures being implemented will further contribute to the reduction in spread of COVID-19. Efforts will be made to expedite processing travellers at the borders, while respecting public health measures and guidance, such as physical distancing by maintaining a 2-metre distance between travellers. All travellers are expected to contribute to help keep Canadians safe.

Travellers with no symptoms (asymptomatic)

Q85. **Why do travellers with no signs and symptoms of COVID-19 have to quarantine themselves? Is it mandatory?**

Yes, the Order to quarantine is mandatory for travellers without signs or symptoms. They must quarantine themselves without delay and monitor for signs and symptoms of COVID-19 until the expiry of the 14-day period that begins when they enter Canada.

Given the rapid spread of COVID-19 around the world, with widespread transmission in an increasing number of countries, people who travelled outside of Canada are considered to be at risk of exposure to COVID-19. In addition, there are numerous examples of asymptomatic individuals arriving in Canada and falling ill, and emerging public health science indicates that asymptomatic and pre-symptomatic individuals may potentially spread COVID-19. Therefore, it is extremely important for their own health and that of others for persons entering Canada to quarantine and monitor for symptoms.

Thus, additional stringent measures are required to reduce the possibility of spread by persons who do not have symptoms. The Government of Canada has implemented an Order requiring anyone who is asymptomatic upon entering Canada, whether by air, land or sea (and is not exempt) to quarantine for 14 days in order to limit the introduction and spread of COVID-19.

Q86. **Why can some people without symptoms quarantine at home or a place of their choice and others must go to a quarantine facility?**

Asymptomatic travellers entering Canada will be instructed to go directly to their place of quarantine, without delay, and to remain there for 14 days. If they are unable to quarantine themselves in accordance with the conditions of the Order they will be sent to a quarantine facility at the discretion of the quarantine officer.

Considerations include whether the person is able to quarantine at a place that is suitable (e.g. it is not a shelter or other place where many people could be newly exposed because of the individual staying there), where they can get the necessities of life and are not in contact with vulnerable persons. Should the traveller be unable to meet one or more of these conditions, they will have to quarantine for 14 days in a quarantine facility chosen by the Chief Public Health Officer of Canada.

Q87. **If I don't have symptoms can I quarantine at home if there are vulnerable people living with me?**

No. Asymptomatic travellers are unable to quarantine at home if they live with one or more vulnerable persons who are at an increased risk of more severe illness as emerging science indicates that asymptomatic and pre-symptomatic individuals may potentially spread COVID-19.

Q88. **Why does my quarantine period reset if I am exposed to COVID-19 from another person subject to the Order?**

Under the new Order, the 14-day quarantine period is reset if the person develops any signs or symptoms of COVID-19, or if they are exposed to someone who is subject to the Order and exhibits signs and symptoms after entering Canada.

Persons who entered Canada may develop symptoms of COVID-19 while in quarantine and expose others who are in quarantine with them and also subject to the Order. As symptoms may take up to 14 days after exposure to appear, more stringent measures are required to reduce the possibility of spread.

Q89. **Can travellers with no symptoms take public transportation (including taxi) or rent a vehicle (from the airport) to get home or to the place where they will quarantine?**

Yes. Persons not exhibiting symptoms may take public transportation and/or rent a vehicle to get to their place of quarantine. However, they must wear an appropriate non-medical mask or face covering while in transit and go directly to the place where they will quarantine themselves without delay.

While in transit, travellers must follow the instructions of quarantine officers and screening officers to avoid spreading infection to others. For example, they must practise physical distancing — maintain a 2-metre distance — and practise good hand hygiene and cough etiquette.

Under the terms of the Order, public transportation includes an aircraft, bus, train, taxi, subway or ride-sharing service.

Persons returning to their home for mandatory quarantine should also consult their provincial or territorial public health authority for any additional measures and/or restrictions to travel within their jurisdiction.

Q90. Can travellers without symptoms who will transit home by private vehicle have someone pick them up and drive them or must they be the sole occupant of the vehicle? If someone drives them, does that person then need to quarantine for 14 days?

For asymptomatic travellers, it is recommended that they do not ask someone to pick them up.

However, if required to do so, they must wear an appropriate non-medical mask or face covering at all times, should not make any stops on the way home and must practise physical (social) distancing at all times. This is also the case if travellers need to take a taxi or public transit to their home to quarantine.

In either case, if they need to get gas, they should pay at the pump. If they need a meal, they should use a drive-thru. If they need to stop to rest, they should use rest areas or other places where they can park and rest in their vehicle, avoiding contact with other people.

If private transportation is unavailable, the Public Health Agency of Canada may arrange medical transportation, depending on the distance to the traveller's home or place of quarantine.

Anyone who has been in direct contact with someone who has or is suspected to have COVID-19 must quarantine for 14 days.

Q91. Why do travellers have to wear a non-medical mask or face covering when taking public transportation to get to their place of quarantine if they do not have symptoms of COVID-19?

Emerging science indicates that asymptomatic and pre-symptomatic individuals may potentially spread COVID-19, which may account for the occurrence of a number of secondary cases. Therefore, more stringent measures are required to reduce the possibility of spread by persons who do not have symptoms.

Wearing a non-medical mask or face covering is an additional measure travellers can take to protect others around them, even if they have no symptoms. It covers their mouth and nose and can reduce the chance that others are coming into contact with their respiratory droplets. It can be useful for short periods of time, when physical distancing is not possible in public settings such as when using public transit.

Q92. Are travellers with no symptoms allowed to take connecting flights?

Yes, persons not exhibiting symptoms may take connecting flights to their final destination to quarantine as long as they wear an appropriate non-medical mask or face covering while in transit.

Travellers will be instructed by quarantine officers or screening officers to follow additional precautions while travelling to their place of quarantine to avoid spreading infection to others.

For example, travellers must practise physical distancing when possible — maintain a 2-metre distance — and practise good hand hygiene and cough etiquette.

Persons returning to their home for mandatory quarantine should also consult their provincial or territorial public health authority for any additional measures and/or restrictions to travel within their jurisdiction.

Q93. What happens if a Canadian traveller not exhibiting symptoms misses their connecting flight and has to stay overnight in a city before getting on their connecting flight the next day? Can they stay at a hotel or with friends or family?

Travellers entering Canada and not exhibiting symptoms may be permitted, if so instructed by a quarantine officer or screening officer, to stay at a hotel overnight before continuing their trip to their final destination. They must wear an appropriate non-medical mask or face covering while in public settings and go directly to their hotel without any unnecessary stops along the way.

While staying at a hotel, travellers returning to Canada must stay in their rooms to avoid contact with others, practise physical distancing (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette at all times. To get a meal, travellers must use a drive-thru or order room service as long as their meal is delivered and left outside their hotel room door.

It is not recommended to stay with friends or family where it could be harder to avoid contact with people compared to a hotel room.

Q94. If people arrive in Canada on a charter flight, not at one of the designated four international airports, can they use a private vehicle to get to their final destination in another province to isolate there?

Yes, people may continue onward travel, including driving a private vehicle to another province to isolate.

If travellers must stop, they should follow precautions to avoid spreading infection to others. Travellers must wear an appropriate non-medical mask or face covering, avoid contact with others (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette.

If travellers need to get gas, they should pay at the pump. If they need a meal, they should use a drive-thru. If they need to stop to rest, they should use rest areas or other places where they can park and rest in their vehicle avoiding contact with other people.

Once home, travellers should use food delivery services or online shopping to purchase essential items and ask family, a neighbour or friend to help with essential errands.

Q95. What about people entering Canada by land? Can they stay overnight in a hotel during their drive home?

Asymptomatic individuals may be permitted by the instructions of a quarantine or screening officer to stay in a hotel overnight if necessary, but should go directly to their hotel without any

unnecessary stops along the way. An appropriate non-medical mask or face covering must be worn at all times when in public settings.

While staying at a hotel, travellers returning to Canada must stay in their rooms to avoid contact with others, practise physical distancing (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette at all times. To get a meal, travellers must use room service as long as the meal is delivered and left outside the hotel room door.

It is important that returning travellers avoid any unnecessary stops and any contact with others on their way home.

Q96. There are reports of RVs being spotted in store parking lots near the border. Are they allowed to stop there to shop on their return home?

Asymptomatic people travelling in an RV will generally receive instructions that it is permissible for them to stay in their RV overnight. Their RV is, essentially, their first place of quarantine.

If they must stop overnight they are to follow precautions to avoid spreading infection to others. They must stay in their RV and avoid contact with others (maintain a 2-metre distance) and practise good hand hygiene and cough etiquette. They must avoid going into stores to make purchases.

Q97. Can people stop to get gas, use a washroom or acquire essential items on their way home to isolate?

It is important for asymptomatic travellers entering Canada to avoid contact with others. As per the instructions provided upon entry into Canada, travellers must go directly to the place where they will isolate, without delay, and wear an appropriate non-medical mask or face covering while in transit.

If they must make a stop, they must take precautions to avoid infecting others. They must avoid contact with others (maintain a 2-metre distance), and practice good hand hygiene and cough etiquette at all times.

If travellers need to get gas, they should pay at the pump. If they need a meal, they should use a drive-thru. If they need to stop to rest, they should use rest areas or other places where they can park and rest in their vehicle avoiding contact with other people.

Once home, travellers should use food delivery services or online shopping to purchase essential items and ask family, a neighbour or friend to help with essential errands, if possible.

Q98. What happens if a traveller without symptoms is unable to get to a place to quarantine themselves for 14 days?

Quarantine facilities, for example, hotels designated by the Government of Canada, will be used to lodge asymptomatic persons unable to quarantine themselves in a place

- that is considered suitable (e.g. it is not a shelter or other place where many people would be newly exposed because of the person's staying there);
- where they will not be in contact with vulnerable persons; or
- where they will have access to the necessities of life (e.g. food, heat, medication).

Transportation from the port of entry to the quarantine facility will be provided by the Government of Canada.

Travellers with symptoms

Q99. Why can some people with symptoms isolate at home while others must go to a quarantine facility or hospital?

People entering Canada who report having COVID-19 or signs and symptoms of COVID-19 or have reasonable grounds to suspect they have signs and symptoms of COVID-19 will be instructed to go directly to their place of isolation, without delay, and remain there for 14 days. If they are unable to fulfil the conditions of the Order and isolate themselves, they will be sent to a quarantine facility, or transported to a hospital, at the discretion of the quarantine officer.

Considerations include the severity of symptoms or illness and whether they have a suitable place to isolate where they will have access to the necessities of life and will not be in contact with vulnerable persons. In addition, symptomatic travellers must have private transportation to get to their home or place of isolation.

For example, if they have onward connections or the distance to get home is too great for PHAC-arranged medical transportation or if they live with one or more vulnerable persons, travellers will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada.

Q100. How is symptomatic being defined?

Anyone who has COVID-19 or has signs and symptoms of COVID19 or has reasonable grounds to believe they have signs and symptoms of COVID-19 is considered to be symptomatic. Signs and symptoms of COVID-19 include a fever and a cough or a fever and difficulty breathing.

Q101. Can symptomatic travellers who are going home to isolate by private transportation be picked up and driven by someone or must they be the sole occupant of the vehicle?

Symptomatic individuals must have private transportation to get to their place of isolation. They cannot have someone pick them up.

If private transportation is unavailable, the Public Health Agency of Canada may arrange medical transportation depending on the distance to the traveller's home or place of isolation.

If the distance to get home is too great for the PHAC-arranged medical transportation, travellers will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada..

Q102. **If I am symptomatic, can I stop at a hotel while I am driving home?**

No. It is important that you avoid contact with others. Go to the place where you will mandatorily isolate for 14 days. This means that you must:

- wear a non-medical mask or an appropriate face cover during your travels to the place of isolation;
- go directly to your place of isolation using private transportation (i.e., your personal vehicle) and stay there for 14 days.

If you have to make a stop, take precautions to avoid spreading the infection to others. Wear a non-medical mask or an appropriate face cover, avoid contact with others (maintain a two-metre distance from others), make sure you have good hand hygiene and practise cough etiquette.

Q103. **Can I stop at a store to acquire essential items on my way to self-isolation?**

No. It is important that you follow the instructions of a quarantine officer or a screening officer and that you avoid all contact with others.

Once home, use food delivery services or shop online to purchase essential items, and ask a family member, a neighbour or a friend to help with errands, if possible.

Q104. **What happens if a traveller with symptoms is unable to get to a place to self-isolate?**

If private transportation is unavailable, PHAC will arrange for transportation for medical reasons right up to the traveller's home or place of isolation over a distance requiring no more than 12 hours on the road. If the traveller has onward connections or the distance to get to their place of isolation is too far for PHAC-arranged medical transportation, travellers will be required to complete their 14-day isolation in a quarantine facility chosen by the Chief Public Health Officer of Canada.

Quarantine facilities, for example, hotels designated by the Government of Canada, will also be used to lodge symptomatic persons unable to isolate themselves in a place:

- that is deemed suitable (e.g., it must not be a shelter or another location where several persons could be newly exposed because of the person's stay);
- where these individuals with not come into contact with vulnerable persons;
- where these individuals will have access to basic necessities (e.g., food, heating, medication).

Transportation between the point of entry into Canada and the quarantine facility will be provided by the Government of Canada.

Compliance and enforcement of the law

Q105. **Who will verify compliance with the Order (that is, spot checks)?**

When entering Canada, travellers are required to provide their contact information to the Government of Canada for compliance monitoring and verification purposes.

If there are concerns that a traveller is not complying with the requirements of the Emergency Order, the assistance of peace officers may be requested to establish contact with the traveller and confirm compliance. This could include a visit to the traveller's place of isolation. PHAC is working with the Royal Canadian Mounted Police (RCMP) and provincial law enforcement agencies to verify the compliance of returning travellers with the Emergency Order.

Q106. **What happens if someone does not comply with the Order?**

Failure to comply with the Order is an offence under the *Quarantine Act*. Individuals who contravene the mandatory isolation or the mandatory quarantine requirements may be subject to a range of enforcement measures under the *Quarantine Act*, including verbal and written warnings, arrest, detention or escort to a designated quarantine site.

The Government of Canada will carry out spot checks to verify compliance with the Order.

Maximum penalties include a fine of up to $750,000 or imprisonment for up to six months. Peace officers will use their discretion in determining the most appropriate action in each circumstance. Further, a person who causes a risk of imminent death or serious bodily harm to another person while willfully or recklessly contravening this Act or the regulations could be fined up to $1,000,000 or be given a prison sentence of up to three years, or be subject to both measures.

Amendments under the *Contraventions Act* now allow for increased flexibility in enforcement for offences under the *Quarantine Act*. Law enforcement agencies, including the Royal Canadian Mounted Police (RCMP), local and provincial police forces, can issue tickets to individuals with fines ranging from $275 to $1,000, based on the seriousness of the non-compliance with the *Quarantine Act* and the Order.

The Public Health Agency of Canada (PHAC) will work with federal and provincial partners to promote, monitor and verify compliance with the Order.

Q107. **How does the Public Health Agency of Canada collaborate with its federal and provincial partners to verify compliance with the Order?**

PHAC is working with the Royal Canadian Mounted Police and provincial law enforcement agencies to verify the compliance of returning travellers with the mandatory isolation order using a risk-based approach, based on the information given by travellers at the border.

The information required to follow up on travellers is collected at the border and sent to law enforcement provincial agencies.

Subsequent to regulatory amendments made under the *Contraventions Act*, police authorities, including the Royal Canadian Mounted Police and local and provincial police services, can now issue tickets to individuals who do not comply with Orders under the *Quarantine Act*, such as Orders requiring that individuals self-isolate after an international trip.

Q108. **How many Canadians were sanctioned under the *Quarantine Act*? Of this number, how many were given a fine? How many were given a prison sentence?**

PHAC recommends a risk-based gradual compliance approach, recognizing that authorities will exercise their discretionary power in responding to offences. The amendments made to the *Contraventions Act* now allow for greater flexibility in enforcement for offences under the *Quarantine Act*. Agencies responsible for law enforcement, including the Royal Canadian Mounted Policy (RCMP) and local and provincial police forces, can issue tickets to individuals with fines ranging from $275 to $1,000, depending on the seriousness of the non-compliance with the *Quarantine Act* or the Order.

On the basis of the information we have received from the police so far:

- no sanction has been given under the *Quarantine Act* or pursuant to the amendments to the *Contraventions Act* since the implementation of the two Orders since self-isolation became mandatory (issued on March 25 and April 14, 2020). Three Canadians have received verbal or written warnings from peace officers;
- a $1,000 fine was issued pursuant to the amendments to the *Contraventions Act*;
- no subpoenas, summons, recommendations to prosecute or prison sentences have been issued under the *Quarantine Act*.

Essential Services Workers

Q109. **Are essential service workers exempt from enforcement of the Order?**

Persons who cross the border regularly to ensure the continued flow of goods and essential services, or individuals who receive or provide other essential services to Canadians, are exempt from the requirements to quarantine themselves, as long as they do not have symptoms of COVID-19 upon entry in Canada.

Officers with the Canada Border Service Agency will assess whether persons crossing the border are exempt from the Order.

Persons exempt from mandatory quarantine are still required to respect the intent of the Order to minimize the spread of COVID-19 in Canada, including wearing a non-medical mask or appropriate face covering upon entry into Canada, and while in transit or in public settings. They will receive a handout at the border advising them to monitor their health for symptoms of COVID-19 and to be aware of and respect the public health guidance and instructions of the area where they are travelling or located, as well as the link to the Canada.ca/coronavirus website where they can obtain further information.

Q110. Why are some essential service workers not allowed to work with persons 65 years of age or older until they complete their 14-day quarantine?

Adults 65 years of age and older are one of the populations at the greatest risk of severe COVID-19 disease. Recent circumstances have highlighted the fact that residents of long-term care homes are vulnerable to infections due to their communal living spaces, shared healthcare providers, external visitors and transfers from other healthcare facilities.

Persons entering Canada whose work requires them to provide direct care to persons 65 years or older must complete the mandatory 14-day quarantine to reduce the possibility of spreading COVID-19.

Q111. How will employers of temporary foreign workers support compliance with the Order?

Employers have an important role to play in helping to prevent the introduction and spread of COVID-19. Importantly, employers must not, in any way, prevent or inhibit workers from meeting their obligations under the *Quarantine Act*. The employer is responsible for regularly monitoring the health of workers who are in quarantine, as well as any employee who becomes sick after the quarantine period. If a worker becomes symptomatic at any time, the employer must immediately arrange for the worker to be completely isolated from others, and contact local public health officials. It is also suggested that the employer contact the appropriate consulate.

Like all Canadians, the employer is asked to report a violation of the *Quarantine Act* on the part of a worker placed under quarantine or in isolation to local law enforcement. This includes workers who do not respect the mandatory quarantine or isolation period.

Q112. I am a temporary foreign worker and do not have a place to quarantine myself for 14 days in Canada. What must I do?

The employer must lodge quarantined asymptomatic workers in accommodations that are separate from those not subject to quarantine. Finding alternate accommodations (e.g., hotel) may be necessary if this requirement cannot be met. Appropriate quarantine accommodations must allow for an environment that ensures access to the essential necessities of life (e.g., food, water, heating, etc.) while at the same time preventing exposure to vulnerable populations.

Quarantine facilities (for example, hotels designated by the Government of Canada) may be used to lodge symptomatic or asymptomatic persons unable to isolate or quarantine because they do not have appropriate accommodations.

Order 11 – Order Minimizing the Risk of Exposure to COVID-19 (Prohibition of entry into Canada from the United States)

Q113. Why is Canada accepting asylum seekers during the pandemic?

Canada is committed to protecting the health, safety and security of Canadians while continuing to uphold our domestic and international obligations with respect to asylum seekers. The Order will continue to prohibit foreign nationals from entering Canada from the U.S. temporarily for the purpose of making a claim for refugee protection, subject to some exceptions. However, the asylum claims of those who meet an exception will be processed.

Q114. **The Government of Canada has implemented extraordinary restrictions at the border and within Canada on foreign nationals, permanent residents and Canadians to respond to the pandemic. What measures are being put in place to help mitigate any risks to public health that may be increased by re-opening the border to asylum claimants?**

Foreign nationals who enter Canada at a place other than an official land port of entry will continue to be prohibited from entering Canada for the purpose of making a claim for refugee protection, unless they meet an exception or exemption to the prohibition.

Individuals ineligible to make a claim under the STCA would be removed to the U.S., a designated Safe Third Country, while those who are prohibited from entering Canada to make a claim for refugee protection will be directed back to the U.S. While the global flow of persons has slowed due to the pandemic, this policy change on asylum may result in increased numbers of people entering Canada. All foreign nationals who enter Canada including asylum seekers are still subject to the mandatory isolation period of 14 days upon entry into Canada.

Where they are not able to appropriately isolate or quarantine, the Federal Government will work with claimants to find suitable accommodations for the quarantine period upon entry into Canada. Discussions between PHAC, IRCC, and CBSA are underway to establish an efficient process at the border.

Q115. **What are the exceptions under STCA?**

Exceptions to the Safe Third Country Agreement are based on principles that take into account the importance of family unity, the best interests of children and public interest.

There are four types of exceptions:

- Family members exception
- Unaccompanied minors exception
- Document holders exception
- Public interest exceptions

Despite qualifying for one of the exceptions outlined above, refugee claimants must still meet all other eligibility criteria of Canada's immigration legislation. For example, a person seeking refugee protection will not be eligible to make a refugee claim in Canada if he or she has been determined to be inadmissible to Canada on grounds of security, violating human or international rights, or criminality.

Q116. **What are the exceptions to the prohibition on entry of foreign nationals arriving in Canada between ports of entry by land or at airports?**

Foreign nationals who enter other than at an official land port of entry (including those who enter at airports or in between official land ports of entry) to make an asylum claim entry will continue to be directed back to the U.S., a designated Safe Third Country, with exceptions for:

- unaccompanied minors;
- American citizens and habitual stateless habitual residents of the United States.

NOTE: Parents and legal guardians of U.S. citizens under the age of 18 fell under the exceptions under Order 9. However, this does not align with the STCA and is removed by Order 11.

Q117. **Can refugee claims be made at airports?**

Refugee claims will continue to be prohibited at airports and other non-land ports of entry, unless the claimant is an unaccompanied minor, a US citizen or a stateless habitual resident of the US.

Quarantine Facilities

Q118. **How will the Public Health Agency of Canada lodge and feed people who enter Canada who are not allowed to return to their homes for 14 days?**

The Government of Canada has designated quarantine facilities, e.g., hotels, to prevent a possible propagation of COVID-19. Quarantine facilities will be used to lodge travellers arriving in Canada who cannot self-isolate or quarantine because they cannot comply with the conditions of the Federal Emergency Order (e.g., if they are living with a vulnerable person, have no private transportation if they are symptomatic). Transportation between the point of entry and the quarantine facility will be provided by the Government of Canada.

These measures will help protect seniors and medically vulnerable people, who are at the greatest risk of severe COVID-19 disease.

The PHAC is working with its partners to provide travellers who will be isolated in a designated quarantine facility with the basic necessities, including food and all medical supplies and care.

Q119. **If a traveller returning to Canada is required to stay in a quarantine facility, do they have to pay for the costs associated with their stay?**

Costs associated with staying in a quarantine facility are not billed back to travellers who are required by a quarantine officer to quarantine or isolate in a designated quarantine facility. Transportation to the facility is also provided at no cost to the traveller.

When travellers are in a quarantine facility, they are provided with three meals daily and other essentials through our contract with the Canadian Red Cross. All these items are delivered to their rooms. They also have access to a toll-free phone number for the Canadian Red Cross where they can identify essential items that they require.

Q120. **How will my medical needs be tended to if I am required to stay in a quarantine facility?**

Persons requiring care for other health problems will have access to medical care and emergency medical services at the quarantine facility.

Q121. **How many people are in quarantine in federal facilities?**

As of 8:00 pm EDT on May 3, 2020, the total number of travellers who were lodged in 2020 was 387. This number does not include travellers placed in quarantine at the Canadian Forces Base in Trenton or at the Cornwall NAV Centre.

Q122. **Where are the federally designated quarantine sites? Are hotels used as quarantine sites for travellers who self-isolate for 14 days upon their return from abroad?**

The Government of Canada has established designated quarantine sites that offer lodgings to travellers entering Canada who either present known COVID-19 symptoms or who are asymptomatic and do not have appropriate lodgings to self-isolate. In order to protect the privacy and security of travellers, the locations of these designated quarantine sites are not made public.

MODELLING AND SURVEILLANCE

Q123. **What is predictive modelling?**

Predictive modelling is based on mathematical equations to assess the possible number of cases that may occur in the coming weeks or months. There are many variables included in the calculations that are based on what we know about the affected population, the disease, the virus and how it spreads. We can then modify the calculations in ways that reflect how public health measures would decrease transmission and assess how well these measures may control the epidemic.

Q124. **What are the objectives of modelling?**

The objectives are to:

- predict the possible number of cases of COVID-19 that may occur in the coming weeks or months; and
- assess the best methods to control the epidemic in Canada.

The projections help us to decide what public health measures we need to use, and how to prepare the health care system for the anticipated number of patients who may be affected by COVID-19.

Q125. **What factors are the modelling data based on? What information is used to make predictions?**

There are two major types of models:

- Forecasting models: Forecasting models use our knowledge of how the epidemic has evolved in Canada and in other parts of the world in recent days and weeks, in order to forecast how many new cases we may expect to see in the coming week or so. These

models are based on the hypothesis that the number of infections will continue to increase at the same pace as they have in previous days or weeks.

- Dynamic or mathematical models: Dynamic or mathematical models use our knowledge of the virus causing COVID-19 (the SARS-CoV-2 virus) and how it spreads based on studies from around the world. This knowledge is used to produce a mathematical representation (i.e., a model) of how COVID-19 may spread in the Canadian population under different public health measures to control the disease. These models are invaluable planning tools, and they are adjusted as we get a better data on the actual epidemic situation. The resulting predictions will change over time.

Q126. What are the different public health measures being used by communities and modelled to anticipate their potential impacts on the epidemic?

The main public health measures whose impact we are trying to measure through modelling are:

- Social or physical distancing: Adopting measures such as closing schools, universities, assembly or meeting places, and teleworking, in order to reduce the possibility that an infected person will transmit the virus to another person.
- Case detection and isolation: Identifying infected people through public health testing and surveillance and isolating them (at home or in hospital) so that they cannot transmit the infection to someone else.
- Contact tracing and quarantine: Finding out who has had contact with a COVID-19 case, and making sure they remain in quarantine for 14 days (or longer if they themselves start to show symptoms) so that they cannot transmit virus to others.

All these public health measures are intended to break the chains of transmission in the community.

Q127. What is the reliability of these data?

Our knowledge of COVID-19 continues to evolve internationally. The epidemic in Canada also continues to evolve, and new data on cases are disseminated every day. The predictions resulting from modelling will be updated daily and adjusted as the science evolves and new data on cases occurring in Canada become available. The models will also be updated to reflect any changes in public health measures used to control the epidemic.

This iterative approach to our modelling will help us to assess the possible impact of changes in public health measures over time. It will also help us to prepare the health care system for the anticipated number of COVID-19 cases requiring hospital care.

The actions Canadians take every day will continue to influence the predictions and the actual data.

Q128. Why propose two different models? Isn’t one enough? What is the difference between the two models and what are their limitations?

The **forecasting models** are based on data from the epidemic as it is actually evolving in Canada and allow us to understand what is happening in the short term based on our experience so far in Canada and the experience of other affected countries.

The **dynamic models** provide a long-term view of possible ways the epidemic may evolve and help us to evaluate which public health measures will minimize the impact on Canadians.

Q129. **Do we have different projections from provinces and territories that have released modelling data? If so, why?**

We are using similar methods for forecasting cases in the coming weeks, and modelling impacts of different public health measures. However, we are forecasting and modelling what is happening in Canada as a whole, while individual provinces have a local focus. Given that the provincial models are based on data from their provincial cases, their predictions will be different and specific to their evolving situation.

Q130. **What external experts are advising on this work?**

The Public Health Agency of Canada established an external advisory group to support our efforts to model and make predictions on the COVID-19 epidemic. This advisory group comprises 37 experts on infectious disease modelling and epidemiology from provincial and territorial public health organizations and from universities across Canada. The group meets twice a week.

The PHAC participates in the World Health Organization modelling group to learn from studies conducted around the world and to benchmark our studies against them.

Q131. **When will be the modelling studies conducted outside the PHAC be published?**

The modelling studies conducted outside the PHAC have been published and broadly disseminated. The PHAC is committed to scientific excellence and will provide details on the findings of these studies in reputable scientific publications. The process involved in these publications is already under way and the PHAC will make them widely available as soon as possible after their release.

Additional resources

COVID-19 in Canada: Data and modelling that inform public health measures

Statement from the Chief Public Health Officer of Canada on the release of national modelling data on the COVID-19 epidemic in Canada

Q132. **Will these models show us whether we are achieving our objectives?**

Models suggest what will happen with the different types of public health measures we adopt, and the effectiveness of these measure will be reflected in the surveillance data. We are continually evaluating the impacts of our public health measures on the number of cases reported in surveillance, and we are adjusting them as needed in collaboration with our

provincial and territorial partners. However, it is important to remember that it takes about two weeks or so before we can see the impact of public health measures in our surveillance data. This is because of the time lapse between the moment when a person is infected and when their case is reported to the Public Health Agency of Canada as a confirmed case.

Q133. **Why is there a delay in the measurement of the mortality rate and are there any plans to accelerate the release of data on this matter to reflect the current pandemic?**

The Public Health Agency of Canada (PHAC) and the provincial and territorial health authorities are working together to provide Canadians with the best and most accurate existing information, including the number of COVID-19-related cases and deaths. All efforts are made so that the data are communicated in a timely manner, but as is the case for all disease surveillance and given the heavy workload that COVID-19 is currently creating for provincial and territorial staff, there are a few delays in the communication of data to the PHAC, particularly regarding the number of deaths. The Program Sector of the Centre for Immunization and Respiratory Infectious Diseases (CIRID) is working on a data strategy that includes a number of complementary indicators, namely more up-to-date data on deaths, in order to complete what can be found in current COVID-19 case report forms and beyond.

Q134. **What is the median age for deaths in Canada?**

As of April 22, 2020 (12:00 P.M. EDT), the median age for COVID-19-related deaths is 84 years old. The median age is based on the analysis of 764 COVID-19 case report forms, which report deaths as well as age.

Q135. **In the daily epidemiology summary, only about one third of COVID-19 cases include data on hospitalizations. Why is this? Have certain provinces avoided providing data on hospitalizations? If yes, which provinces and why?**

While all efforts are being made to have timely information, there are inherent delays in collecting information in a surveillance system flowing from the local to the national level. The Public Health Agency of Canada (PHAC) will continue to work closely with provincial and territorial public health authorities to provide the most accurate information to Canadians. As noted above, detailed data for approximately 65% of reported cases was received at the national level from the provinces and territories. The data on these cases is preliminary and may be missing values for characteristic of interest, where it may be coded as [translation] “unknown.” In most cases, when information regarding hospitalizations is not available on the case report form, this is because the hospitalization status was [translation] “unknown.”

Q136. **Is the total number of COVID-19-related deaths in Canada higher than the number reported and will modelling based on global death statistics be necessary once the pandemic is over in order to understand the true extent of the number of deaths?**

As of the morning of April 15, 2020, there were 27,063 cases and 903 COVID-19-related deaths reported in Canada, leading to a case fatality rate (CFR) of 3.3%. The CFR is a commonly used method proposed by the World Health Organization. It represents the number of deaths divided by the total number of cases.

As seen in all countries, this measure varies over time during an epidemic. The projections obtained at the beginning of the epidemic are often lower because deaths usually occur later in the course of the illness. Other emerging factors, such as recent outbreaks among vulnerable populations in long-term care facilities and additional factors affecting data reporting may influence the projections at any time. We expect that the CFR's accuracy will increase as the epidemic develops.

Our knowledge on COVID-19 continues to evolve every day. Projections based on these models will be updated and adjusted as science evolves and as new data on cases in Canada becomes available.

Data Modelling—April 28, 2020

Q137. **What are the current modelling numbers? How do these numbers compared to those that were initially published?**

According to current modelling, it is estimated that the cumulative number of cases in Canada will be between 51,196 and 66,835, with approximately 3,277 to 3,883 deaths from now until May 5.

In the model presented on April 9, it was estimated that there would be between 22,580 and 31,850 cumulative cases on April 16. The actual cumulative number of deaths reported on April 16 was 29,826.

According to the projections, the number of COVID-19-realted deaths was expected to be from 500 to 700 on April 16. The actual cumulative number of deaths that were reported on April 16 was 1,048. The modelling has now been adjusted to correct the underestimated number of deaths in the previously published model.

Q138. **With such a wide range between best-and-worst-case scenarios, what's the value of the modelling exercise?**

The objectives of modelling are to help predict the potential number of COVID-19 cases that may occur in the coming weeks or months, and to assess the best methods to control the epidemic in Canada. As a result, modelling provides information on what could happen under various scenarios, allowing us to prepare for the worst-case scenario and to guide public health action to ensure the best possible outcomes. These various projections help us to decide what public health measures we need to use and how to prepare the health care system for the anticipated number of patients affected by COVID-19.

Q139. **The number of predicted deaths was evaluated incorrectly two weeks ago. Why should we believe that these numbers are correct now?**

PHAC predicts the number of deaths according to a statistical range based on a case fatality rate of 2.2%, which is the ratio between the number of deaths and the number of cases. The World Health Organization uses this ratio as well.

We must accept that the models have inherent limits. The case fatality rate established at the beginning of an epidemic is usually low because the increasing number of cases (the denominator) is much faster than the increasing number of deaths (the numerator) during this period.

Emerging factors, such as recent outbreaks in vulnerable populations at long-term care facilities, were not included in our early calculations. Modelling projections are also highly sensitive to changes in our actions (e.g. the degree to which people follow physical distancing directions).

Q140. **Was the method refined in order to make the predictions more specific?**

The models are unable to predict what will happen, but they are able to help us understand what *could* happen. Within the frame work of the dynamic modelling approach, the models are continuously being updated as information regarding the transmission of the virus at the basis of COVID-19 becomes available. For weekly projections, the method will depend on what is most consistent with the course of the pandemic—according to the number of cases and deaths reported in the previous weeks.

The short-term projections on the cumulative number of cases have proven to be effective. The short-term projections of the number of deaths rely on a different method. In the initial report, the death projections were based on a fixed value of the calculated case fatality rate, which did not account for the fluctuation of this rate over time. The case fatality rate was particularly influenced by the significant number of deaths in long-term care facilities. We estimate that the new method will be more accurate.

Q141. **What new data or variables, if any, have been added? What are the exact variables being used (age, gender, underlying health problems)?**

Predictive modelling uses mathematical equations to predict how many cases of a disease may occur in the coming weeks or months. The calculation involves a number of variables that rely on our knowledge of the affected population, the disease, the virus and how it spreads. We can then modify the calculations in ways that reflect how public health measures would reduce transmission and assess how well these measures may allow us to control the epidemic.

The method employed to make these predictions uses the course of the epidemic, in this instance, the cases and the deaths that have been reported over previous weeks. This dynamic modelling approach helps us try to predict potential total numbers of cases over the whole epidemic according to different scenarios for levels of control.

These total numbers are then used to assess how many Canadians may be mildly or severely affected, and how many may die, according to global estimates of differences in severity among different age groups, while accounting for the age profile of the Canadian population. Models are being developed by partners in universities to assess province-specific numbers of cases and health care needs that account for local data on underlying health conditions, age, and gender.

Q142. **Which dates are the modelling projections based on?**

PHAC updates its modelling work periodically, including the national projections of the total number of cases. The projections presented on April 9 were produced on April 6, for a 10-day period, namely until April 16. Similarly, the projections presented on April 28 were produced on April 24, for a 10-day period, namely until May 5.

The modelling of the projections based on the data that was received on April 18 provided a projected range of 39,950 to 47,235 cumulative cases reported in a 10-day period, as well as 2,330 to 4,017 cumulative deaths on April 28.

Q143. **Dre Tam reiterated that the course of this pandemic is not the same in all areas of the country and is also not the same in all demographic groups. Are you developing demographic models or providing models that cover specific vulnerable populations, such as those in long-term care facilities or those who are homeless?**

PHAC uses a variety of modelling methods to evaluate and understand how COVID-19 could spread over the course of the following weeks and months. Based on the data of reported cases, provided by the provinces and territories, the patterns of spread and the populations affected are different in every administration.

We do not have a specific model for transmissions in long-term care facilities. However, while we undertake model-based projections for the country as a whole, we are also developing models that consider the wide range of differences among provinces, territories, municipalities, and vulnerable populations.

Such models, which can account for local demographic variations and reflect the complexity of epidemics within each province, are more useful for planning at provincial and local levels.

PHAC is committed to scientific excellence and will provide the details of its modelling results through reputable scientific publications. The process for these publications is already underway. PHAC will make these results widely available as soon as possible after their publication.

Q144. **Are you collecting data based on race and ethnicity, including Indigenous populations? Would that not make your modelling more accurate?**

There are no indications that race or ethnicity are risk factors for COVID-19. It is the circumstances or the settings that make it difficult to apply public health measures, such as physical distancing, which affects the risk of spread.

The national COVID-19 case report form collects data on Indigenous status (i.e. First Nations, Métis and Inuit). However, data on Indigenous status of COVID-19 cases reported by provinces and territories are not complete.

Q145. **The modelling data for British Columbia and Ontario show that they have already reached their peak in cases spreading within communities and that the numbers appear to be going down. Is this the case for all of Canada? As provinces see the number of cases decline and begin to ease the restrictions, how will this affect the modelling data?**

Surveillance data suggest that, overall, the public health measures put in place across Canada are having a large impact and slowing the epidemic. The degree of control over the epidemic varies strongly from one jurisdiction to the other. We are watching this situation closely.

The epidemic in Canada continues to evolve and model-based projections continue to be updated and adjusted as new data becomes available. The models are also updated to reflect all changes in public health measures that are being implemented to control the epidemic.

Modelling allows us to assess the potential impact of public health measures over time, adapt calculations to reflect how public health measures decrease transmission, and assess how well these measures may control the epidemic. The modelling data presented accounts for changes to the public health measures (e.g. timing, type, location). Modelling data also helps to inform us about when we can reopen schools, workplaces and other venues and when restrictions need to be increased again, if necessary.

It is important to remember that we must not let our guard down, and we must be realistic and recognize that this epidemic will continue for some time. If the public health measures are eased too quickly, it is likely that the epidemic would accelerate very quickly.

Q146. **Have you considered reopening certain provinces and territories, as a number of them have begun to announce their plans? Could this impact regions that are more affected?**

Surveillance data suggest that, overall, the public health measures put in place across Canada have a significant impact and are slowing the epidemic. The degree of control over the epidemic varies strongly from one jurisdiction to the other. We are watching this situation closely.

The epidemic in Canada continues to evolve and model-based projections continue to be updated and adjusted as new data becomes available. The models are also updated to reflect all changes in public health measure that are being implemented to control the epidemic. PHAC is working with university partners to explore to possible effects of removing the public health measures.

Modelling allows us to assess the possible impact of public health measures over time, adapt calculations to reflect how public health measures decrease transmission, and assess how well these measures may control the epidemic. The modelling data presented take into account changes to the public health measures (e.g. timing, type, location). Modelling data also helps to inform us about when we can reopen schools, workplaces and other venues and when restrictions need to be increased again, if necessary.

It is important to remember that we must not let our guard down, and we must be realistic and recognize that this epidemic will continue for some time. If the public health measures are eased too quickly, it is likely that the epidemic would accelerate very quickly.

Q147. **How can the government talk about reopening an economy when the numbers report 3,277 to 3,883 deaths from now until May 5, if the current measures are not maintained?**

While PHAC has undertaken model-based projections for the country as a whole, it has been noted that the nature of the epidemic is different in various parts of Canada. Each region will have a different schedule for easing the current public health measures.

PHAC is working together with federal, provincial and territorial governments, as well as universities to explore the potential spread of COVID-19 in Canada and to project the range of the potential numbers of cases, hospitalizations, and deaths that may occur in the coming weeks and months, given different scenarios for public health interventions.

We are continuing to monitor the impact of our public health measures by reviewing and analyzing surveillance data on cases and outbreaks. Additionally, we are adjusting our surveillance systems as needed, together with our provincial and territorial partners.

Q148. **A lack of recent up-to-date quality data was presented as an issue while developing this modelling. Have you encountered problems during the last cycle? Are any vulnerabilities in the information you are presenting a result of a lack of data?**

While all efforts are being made to have timely information, there are inherent delays in collecting information in a surveillance system flowing from the local to the national level. The epidemic in Canada continues to evolve, and new data for cases becomes available every day. Model-based projections continue to be updated and adjusted as science evolves and as new data on the cases occurring in Canada becomes available. PHAC will continue to work closely with provincial and territorial public health authorities to provide the most accurate information to Canadians.

Q149. **What improvements have been made to ensure that you obtain quality up-to-date data for this modelling? Will there be better data during the next update and when will that happen?**

Within the frame work of the dynamic modelling approach, the models are constantly being updated as new information regarding the transmission of the virus at the basis of COVID-19 becomes available. The projected number of cases and deaths is constantly being updated with the help of forecasting methods, which include analyzing case patterns and the deaths reported in previous weeks.

The short-term projections of the cumulative number of cases have proven to be effective. The short-term projections of the number of deaths rely on a different method. In the initial report, the death projections were based on a fixed value of the calculated case fatality rate, which did not account for the fluctuation of this rate over time. The case fatality rate was particularly influenced by the large number of deaths in long-term care facilities. We estimate that the new method will be more accurate.

Q150. **There have been reports of a significant decline in visits to emergency rooms across the country for illnesses not related to COVID-19. Do you have numbers on how many Canadians could die because they're afraid to go to the hospital and catch the virus?**

It is not currently possible to predict or model the reasons behind changes in emergency room (ER) usage; therefore, this information is not part of our modelling data. The provinces and territories may have more detailed information about the situation within their individual jurisdictions.

We recognize that many Canadians may feel concerned about visiting a doctor's office or a hospital given the current epidemic; however, it must be noted that it is very important for Canadians to continue to receive care and consult health professionals if they feel unwell.

Q151. **Do you present numbers that are higher than predicted just to scare people and encourage them to respect the restrictions in their daily lives?**

The models cannot predict what will happen; however, they can help us to understand what *could* happen. The goal of distributing the modelling is not to provide Canadians with deformed or inaccurate images to scare them and encourage them to respect public health orders. The modelling aims to help us understand and to see the possible number of COVID-19 cases that may appear in the weeks or months to come. It also allows us to evaluate the effects that the public health measures have had on reducing the impact of the pandemic. The work presented by the Agency shows that public health measures are effective and, if maintained, will continue to help slow the spread of COVID-19.

PHAC continues to assess the impact of public health measures put in place to interrupt chains of transmission in the community. We must remind ourselves not to let our guard down and that we must be realistic and recognize that the battle with this pandemic is still ongoing. If the public health measures are eased too quickly, it is likely that the epidemic would accelerate very quickly.

Q152. **Will the season (temperature) affect your predictions?**

At this point, the available data does not suggest that the temperature that we predict to have over the summer in Canada will influence the transmission of the virus. The short-term projections published today do not take the season (temperature) into consideration.

Q153. What is PHAC's response to Mr. Amir Attaran's criticism of Canada's COVID-19 modelling?

The models provide information on the potential outcomes of various scenarios, allowing us to prepare for the worst and to guide public health measures in order to have the most accurate results possible. Potential scenarios that have been presented in the Government of Canada's modelling are a synopsis of modelling studies, including those conducted by PHAC, as well as other epidemiologists and modellers in Canada and around the world. The three possible scenarios presented include: [translation] "no action" where an unrestricted outbreak occurs and infects a very large number of Canadians; "weaker control of the epidemic" where the epidemic is not controlled by public health measures, but is prolonged and the peak is reduced by public health measures; and "control of the epidemic" where the epidemic is controlled due to a combination of public health measures. These scenarios are for the purpose of planning and are not projections. Studies conducted outside of PHAC were published and are widely accessible; meanwhile, studies conducted within the Agency will be published in the coming weeks.

We continue to collaborate with federal, provincial and territorial governments and universities to forecast the potential future spread of COVID-19 in Canada and to estimate a range of possible numbers of cases, hospitalizations and deaths that may occur in the coming weeks and months given the different public health intervention scenarios. Predictive modelling for COVID-19 requires that we make assumptions based on incomplete data and evolving science. These assumptions change as we get new information about the virus and more data about the epidemic in Canada. We are continuously improving the model to provide Canadians with the most accurate information on possible scenarios.

Works cited by Mr. Attaran are consistent with our own studies and those of other groups. Without public health measures, 70% of Canadians, or more, could contract an infection. If public health measures are put in place then eased too soon, the epidemic will simply continue. If public health measures are not enough to end this epidemic, they can, however, reduce the small percentage of Canadians who will need to become infected and immunized in order to create a "collective immunity" to stop the epidemic.

Additional work from the Agency and other modellers, consistent with observations from other countries, suggests that a low percentage of infected Canadians (from 1% to 10%) could be reached as a result of stronger public health efforts. These efforts would include sustained public health measures to prevent the transmission from restarting, to detect and isolate cases in Canada, and to trace back and quarantine those who have come in contact with cases.

Q154. Mr. Attaran also accused PHAC of censoring data provided to scientists. If this is the case, why does PHAC censor the data before disclosing it?

PHAC has established an external advisory group to support our modelling and forecasting efforts for the COVID-19 epidemic. The advisory group consists of over 40 experts in modelling infectious diseases and in epidemiology from provincial and territorial public health agencies and

universities around Canada. This collaborative group meets twice per week. PHAC has also committed to ensuring that the research and scientific information produced by the Agency is made available to the public in a timely manner and in compliance with the *Directive on Open Government.* This includes a daily epidemiology summary and preliminary data tables of confirmed cases. In some cases, PHAC is unable to transfer certain data if it belongs to a third party or if there are imperious reasons to limit disclosure, such as for privacy reasons. Our knowledge on COVID-19 continues to evolve at the international level. The epidemic in Canada also continues to evolve, and new data on cases becomes available every day. Projections based on models will be updated and adjusted as science evolves and new data on cases developing in Canada becomes available.

FLUWATCHERS

Q155. **Prior to COVID-19, what was the FluWatchers program responsible for? Could you give us numbers? For example, how many Canadians volunteered to participate in the FluWatch program in 2018 and 2019?**

FluWatchers began in the fall of 2015 and is a part of FluWatch, Canada's national flu surveillance program. This is a syndromic surveillance program that monitors flu-like illnesses in Canada.

Traditional flu surveillance programs, such as surveillance in laboratories or in hospitals, only targets those who receive medical care or who test positive for the flu; therefore, a large number of potential flu cases are missed. For this reason, PHAC created the FluWatcher program, with the goal of detecting illnesses similar to the flu in those who do not receive medical care or who do not undergo flu testing. This program allows the country to receive a more precise idea of flu cases in Canada during the typical flu season. The FluWatchers program also provides additional valuable monitoring indicators, such as the number of symptomatic people who see a doctor, the number of people who are tested and their results.

The number of weekly participants went from 400 in 2015, to 2,200 in 2018, and 3,200 in 2019.

Q156. **When did the FluWatchers program begin following COVID-19 and why?**

PHAC has been monitoring FluWatchers' data since the pandemic first began in Canada to detect signs of any unusual increase in the number of Canadians who have a cough or a fever. Minimal changes were made to the questionnaire at the end of March 2020 in order to include questions specific to COVID-19. PHAC uses FluWatchers to track COVID-19 for the same reasons that it uses the program to track the flu. The vast majority of people will likely not seek treatment or undergo testing; consequently, a large portion of the population will not be considered in the traditional surveillance methods that are currently being used. The FluWatchers program also gives an idea of how many symptomatic people consult a doctor and the number of people who undergo a test, as well as their results. We hope that this program will allow Canada to have a better idea of COVID-19 cases in the country, as is the case with the flu.

Q157. **How do you differentiate between the flu and COVID-19 in the response that you are receiving?**

Syndromic surveillance programs, such as FluWatchers, are used to detect signals. If something is detected through the program, this signal is often used as a trigger to examine our other data surveillance streams to validate our observations. We are in the process of validating the results received by FluWatchers regarding data from our other flu surveillance programs. For example, at this time, according to our stream of data surveillance in laboratories, there are very low numbers of flu viruses or other seasonal respiratory viruses circulating in Canada. Other flu indicators, including hospitalizations and outbreak surveillance, have also shown low flu activity. This information can be used to differentiate the data that is received from the FluWatchers program. If the flu was circulating at a high rate, we assume that the responses from FluWatchers would likely be the flu. Given that the circulation of the flu (and other respiratory viruses) is currently very low and that flu season is coming to an end, we can assume that the responses from FluWatchers could be attributed to COVID-19.

Q158. **Can you tell us how many Canadians participated in the COVID-19 tracking through the FluWatchers program? Were there any trends in the responses?**

PHAC began to increasingly promote the FluWatchers program on social media starting on April 3, 2020, for the purpose of recruiting more participants. Since then, the number of weekly participants has gone from 3,200 to 8,700. The more participants who report, the more accurate the data.

The percentage of participants reporting a cough or a fever is low. For example, during the week on March 29, 2020, 0.5% of the 6,200 participants (namely 32 participants) reported having a cough or a fever. During the week of April 5, 0.3% of the 8,700 participants (namely 24 participants) reported having a cough or a fever. The low number of coughs and fevers could be a result of physical distancing measures and we hope that these numbers will remain low over the next few weeks.

GPHIN'S ROLE IN SURVEILLANCE

Q159. **During virus outbreaks, what data does the Global Public Health Intelligence Network (GPHIN) collect and use for alerts and in what languages is the data disclosed?**

PHAC's 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 diseases.

GPHIN users include non-governmental agencies and organizations, as well as government authorities who conduct public health surveillance. GPHIN is a significant contributor to the World Health Organization's Epidemic Intelligence from Open Sources.

Every given day, about 7,000 articles are captured in the GPHIN system. The web-based application in the GPHIN system continuously scans and acquires new sources of information worldwide in nine languages (Arabic, Farsi, English, French, Portuguese, Russian, Spanish, and simplified and traditional Chinese).

GPHIN's main data provider is Factiva, a global news database and research platform that contains nearly 33,000 sources, including newswires, newspapers, and trade publications. GPHIN also mines specific RSS feeds from relevant publications and Twitter accounts.

In addition, GPHIN analysts have programmed specific Google Alerts and monitor other news aggregators' applications, such as ProMED and HealthMap, to further increase the variety of what is included in GPHIN.

GPHIN analysts have extensive lists of websites and social media accounts from official government sources, medical expert forums, and other relevant sources that they monitor on a daily basis. Once the data is in the GPHIN system, it is processed, validated, and assessed.

Q160. **How are the threat assessments and analyses done by GPHIN compiled?**

GPHIN does not prepare threat assessments. Rather, it is an information management tool that uses machine learning and natural language processing to facilitate work for a team of multidisciplinary analysts who examine information in nine languages and proceed to do rapid risk assessments for the purpose of detecting public health threats.

Over 7,000 articles are entered into the GPHIN system daily. Once the data is in the system, it is processed, validated and reviewed, then it is included in reports, such as the daily situational report published every morning.

Q161. **What data was the first to be collected on the coronavirus outbreak and from what source?**

On December 31, 2019, at 05:16 A.M. EST, an article titled "China probes mystery pneumonia outbreak amid SARS fears" was published by the Agence France-Presse and uploaded in the GPHIN system at 05:42 A.M. EST.

Q162. **When did GPHIN first send out an alert about the coronavirus outbreak and to whom?**

The GPHIN analysts conducting their daily assessment recognized the potential importance of this issue and highlighted it in the GPHIN Daily Report, which was distributed at 07:50 A.M. EST that day to Canadian public health practitioners at the federal, provincial and territorial levels. The report included the following summary:

> International Events of Interest
>
> China—China probes mystery pneumonia outbreak amid SARS fears (Media)
>
> Authorities are investigating an outbreak of viral pneumonia in central China amid online speculation that it might be linked to SARS, the flu-like virus that killed hundreds of people a decade ago. There were 27 cases of "viral pneumonia of unknown origin" reported in Wuhan, in the central Hubei province, the city's health commission said in a statement. Seven patients were in critical condition.

Q163. **Have Chinese officials already informed Canadian officials about COVID-19? If yes, when did they provide this information and what did they say?**

Canada and China have been exchanging information about the outbreak on a regular basis since the beginning of 2020. This also began discussions between health officials and foreign affairs officials from both countries through our respective embassies in Ottawa and in Pekin. Other meetings also took place during multilateral processes such as the G20.

Minister Champagne discussed matters relating to COVID-19 with his Chinese counterpart, the State Councillor and Minister of Foreign Affairs, Wang Yi, on three separate occasions, January 30, February 14, and April 2, 2020:

- January 30—https://www.canada.ca/en/global-affairs/news/2020/01/readout-foreign-minister-holds-call-with-chinese-counterpart.html
- February 14—https://www.canada.ca/en/global-affairs/news/2020/02/readout-minister-champagne-meets-with-chinas-foreign-minister.html
- April 2—https://www.canada.ca/en/global-affairs/news/2020/04/readout-minister-of-foreign-affairs-speaks-with-chinese-counterpart.html

At the beginning of the year, as part of his regular contact with the Chinese embassy, Paul Thoppil, Assistant Deputy Minister (Asia-Pacific) for Global Affairs Canada, also had several meetings with Chinese ambassador Cong Peiwu on related matters to discuss the evolution of the outbreak. Since January, other Canadian global affairs officials in Ottawa and at the Canadian embassy in Pekin, namely ambassador Dominic Barton, took part in several conversations about COVID-19 with Chinese officials. Initial conversations consisted of sharing information on the evolution of the outbreak and evacuating Canadian citizens from Wuhan, followed by discussions on Canada's offer to provide personal protective equipment (PPE) to help China control the epidemic.

Recent high-level discussions, in Ottawa and in Pekin, have been focused on supplying Canada with medical supplies from China and on global containment measures.

Q164. **What does the GPHIN Renewal Project consist of? Why is this renewal done in steps?**

The objective of the GPHIN Renewal Project was to develop an enhanced web-based platform which meets Government of Canada information technology policies, and uses emerging technologies to provide greater automation in the collection, collation, and analysis of open source information.

Work began in January 2016 and the upgraded initial capacity was delivered in August 2016. The final version was launched in September 2018 and the technical components of the project were completed in July 2019.

This initiative was a collaboration between PHAC and the National Research Council Canada (NRC).

The GPHIN renewal project has achieved the following objectives:

- The platform is compliant with the Government of Canada information technology policies, guidelines and standards, and the government has the ability to make other improvements and innovations to the system.
- GPHIN can now leverage the variety, volume and velocity of data available—including data from social media platforms and more websites—producing visual representation of events in place and time with built-in analytics and assessment capacity while creating automated article summaries.
- The system's artificial intelligence can learn and improve the accuracy of its relevance score.

A progressive approach has allowed PHAC to develop, create, implement, and test functionality. An inspection was done after version 1 was rolled out, identifying quality and functionality issues to be fixed in version 2, leading to further improvements to the system.

Q165. **Were there any complaints about GPHINS's research system after improvements were made to the NRC's first version? What about the fact that the search results were missing at time and had to be entered manually?**

In August 2016, after the initial launch of the renewed system, analysts noted that the speed of the search function had reduced. During the summer of 2017, the NRC called on industry experts to analyze the problems and recommend changes. These changes were implemented mid-2018 and the assessment measures showed clear improvements.

Q166. **Did Shared Services Canada direct GPHIN to transfer its external servers to a private system to integrate them into the Government of Canada's system?**

An information request sent by Public Services and Procurement Canada to create interest in private sector companies to upgrade the GPHIN platform has received no response. Together with the NRC, the platform was updated within the established scope and budget.

Q167. **Have analysts been told to stop reporting on COVID-19?**

No. Since the beginning of the COVID-19 outbreak, GPHIN was and continues to be an important source of public health information for PHAC.

Q168. **Are there restrictions against sharing information with registrant?**

It is not prohibited to communicate information to registrants. GPHIN continues to regularly provide information to its users. Furthermore, GPHIN provides its users with special reports regarding COVID-19 to respond to the needs raised by organizations such as the World Health Organization.

Q169. **Can you explain how GPHIN analysts are assigned their work? How many are in charge of national health surveillance (vaping, Lyme disease) and how many are in charge of monitoring the global situation (for e.g. COVID-19, avian influenza)?**

GPHIN analysts work together on both national and global surveillance. While analysts are focused on regions and countries that correspond with their linguistic abilities, they all share responsibilities for national surveillance. This practice has been in place for several years.

Q170. **What is GPHIN's annual budget?**

GPHIN's annual budget has increased to approximately 2.8 million dollars, which includes human and operational resources.

Q171. **How does GPHIN's data selection or data analysis differ from approaches taken by ProMED, HealthMap and commercial providers such as BlueDot?**

GPHIN consists of two critical components:

- a professional multidisciplinary team of science analysts who review information in nine languages and conduct rapid risk assessments to detect public health threats; and
- an information management tool that uses machine learning and natural language processing to facilitate analysts' work.

GPHIN requires a free subscription from eligible users, which include non-governmental agencies and organizations, as well as government authorities who conduct public health surveillance.

ProMED uses information coming from volunteer [translation] "rapporteurs," as well as information from subscribers and from staff-conducted searches of the Internet, media, and various official and unofficial websites. Moderators assess these reports for plausibility, edit them as required, and often add comments or context before posting. ProMED is one of GPHIN's many data sources.

HealthMap's content is aggregated from freely available information (including ProMED) and is automatically processed by machine learning algorithms. Unlike GPHIN, there is no human information assessment published, which could influence the system's performance.

BlueDot is a private company for which you need to pay a subscription to access its data. It gathers information from official and mass media sources including the WHO and ProMED-mail.

Much of this work is complementary, and organizations rely on a broad range of inputs to help identify potential threats and provide early warning.

Q172. **Does the Government of Canada use BlueDot's AI to track people who have been in contact with COVID-19?**

PHAC and Health Canada have contracts with BlueDot. None of these contracts involve using AI to track people.

Q173. **I have confirmed with Public Health Ontario and the Institut national de santé publique du Québec that they are not collecting race/ethnicity data in**

relation to COVID-19. My understanding is that the Public Health Agency of Canada does not collect this type of data either. Could you confirm that?

It is true that the COVID-19 case report form does not include any questions on race or ethnicity, but it does include a section for identifying and classifying cases as Indigenous (First Nations, Metis, Inuit). This section is completed only when the affected person self-identifies as a member of one of the three Indigenous groups. Data from the section if often incomplete or missing.

Q174. Will other social determinants of health (such as education or income) be added as risk factors on the case report form used to collect data on COVID-19?

The case report form contains information on age and known risk factors, such as pre-existing medical conditions or residing in a longer-term care facility. These data are analyzed regularly and included in an epidemiological report.

At this time, there are no plans to add the social determinants of health (education or income) as risk factors on the case report forms used to collect data on COVID-19. If a revision of the form were considered, PHAC would call on a national advisory committee composed of provincial and territorial public health experts to discuss it, as the responsibility of collecting data rests with the provincial and territorial health authorities.

Q175. What is Health Canada's role in the Ontario Health Data Platform? Will this become the norm across provinces? Does Health Canada approve this plan, which is designated to slow the spread of COVID-19?

Understanding a patient's history is essential to safe and appropriate care. This is why sharing health information among health care providers, safeguarded by strong privacy and data security requirements, can lead to better outcomes through more informed, coordinated and integrated care. A system that is responsive to the needs of patients can also enable patients to have better access to their own health information. Health Canada is working with provincial and territorial partners, as well as key national data agencies, to support greater patient access to health data while ensuring the protection of personal health information.

Q176. Are there any Canadian COVID-19 studies and wastewater analyses?

At this time, PHAC is unaware of any Canadian studies being done on wastewater samples being done for the detection and identification of COVID-19.

It is too early to consider this type of analysis as more research needs to be done to understand its effectiveness. PHAC remains up to date on scientific knowledge on this matter.

As part of the Canadian 2019 Novel Coronavirus (COVID-19) Rapid Research Funding Opportunity, recently financed by the Canadian Institutes of Health Research, a project directed by Dr. Jeffrey Joy, from the University of British Columbia, will collect environmental samples to better understand the epidemiology and the evolution of COVID-19 (https://www.canada.ca/en/institutes-health-research/news/2020/03/government-of-canada-

funds-49-additional-covid-19-research-projects-details-of-the-funded-projects.html). However, we are still unsure of whether the wastewater samples will be used in this work.

Q177. **Why was the Emerging Infections Surveillance Program (ESP) launched and what was the scope?**

The Emerging Infections Surveillance Program (ESP) aimed to improve the process of internal management and assessment of data on emerging infectious diseases. Launched in 2016, the pilot project was limited to data on zoonic and vector-borne diseases. The pilot project provided guidance on how to improve the processes used to develop new tools and mechanisms that are currently in place.

PHAC's state of preparedness to manage the emerging infectious disease is supported by:

- a data innovation centre entirely dedicated to meeting PHAC's data needs and to the use of digital tools allowing for quick access to data and prompt analysis;
- GPHIN, a system that regularly examines and analyzes worldwide information sources for the purpose of detecting early warnings of public health threats while conducting rapid risk assessments based on this information;
- the implementation of national disease surveillance programs, together with provinces and territories, that track infectious diseases and risk factors, alerting us of any trends that could signal whether areas of growing risk are being observed;
- signal detection in laboratories that exceed the projected baselines on the rates of pathogen movement and the use of technology, such as full genome sequencing, to identify clusters of infection and support rapid public health action; and
- international collaboration under the Global Health Security Initiative (GHSI) for communication in real time assessing public health risks, detection methods, and approaches for collection techniques.

The results of this pilot project have been communicated to the GHSI under a regular and continued exchange of information.

NML'S RESPONSE TO THE OUTBREAK

Q178. **Why did scientists from the National Microbiology Lab (NML) travel to the Level 4 Wuhan Institute of Virology?**

The Institute requested samples of the viral Ebola and Henipah viruses and, in 2019, PHAC responded to their request by sending samples for scientific research. The National Microbiology Lab (NML) exchanges samples with other public health laboratories, as those laboratories do with the NML, for the purpose of contributing to the advancement of science. Transfers are subjected to rigorous protocols, namely the *Human Pathogens and Toxins Act*,

the *Transportation of Dangerous Goods Act*, the *Canadian Biosafety Standard*, and the NML's standard operating procedures.

The NML offers training to professionals from international laboratories and has trained scientists from a number of countries, including China.

If one insists…

Due to confidentiality reasons, we will not be commenting on individual employees.

Any speculation of a PHAC scientist's role in the emergence of a new coronavirus has no factual basis.

Q179. **Are the Government of Canada and PHAC supporting the investigation into a possible breach or an accident associated to the Wuhan laboratory that could, in some way, be connected to the pandemic outbreak? Will the Government of Canada provide updated information on the concerns regarding the Level 4 laboratory in Saskatchewan and the possibility of espionage or a security breach by Chinese researchers?**

Coronaviruses occur naturally and we know that they are transmitted from animals to humans. There is no evidence suggesting that another source of new coronaviruses caused COVID-19.

No speculation of a PHAC scientist's role in the emergence of the new coronavirus is based on facts. Our response to COVID-19 will continue to be based on scientific data.

TESTS AND CONFIRMING CASES

Q180. **How is Canada currently testing patients for COVID-19?**

Canadians can be confident in the methods and laboratory capabilities of Canada's NML.

The NML is internationally recognized for its scientific excellence.

Multiple provincial public health laboratories can now test for the novel coronavirus with a very high degree of accuracy.

The NML continues to provide all provinces and territories with laboratory reference services. These testing services provide a variety of support to provincial and territorial laboratories across Canada, including confirmatory testing, quality assurance, and in-depth analysis of difficult to diagnose specimens.

Q181. **What is PHAC's testing capacity?**

We continue to test on a massive scale. Canada has one of the highest screening rates in the world. We know that screening is essential for finding new cases, as well as identifying and

stopping transmission chains. We are now administering over 20,000 tests per day, close to double the amount that we administered in April, with this number continuing to rise.

We do not know the exact number of tests that must be done every day in order to ease the social distancing measures, and these numbers would vary from one administration to the next. The goal of 60,000 tests per day is based on what we can execute by maximizing the current capacity of the public health laboratories. This goal is useful for planning purposes. Provinces continue to expand their screening capacities in accordance with their needs. On some days, in certain provinces, the capacity goes beyond the number of people who wish to be tested.

Canada continues to have a positive test rate of approximately 6% to 7%, which is within the effective detection range, allowing the virus circulation to be targeted. We want to get the most accurate picture possible of what is happening in our communities. This shows that we have a relatively sensitive screening system. We continue to expand that capacity of our laboratories to ensure that this continues to be the case.

The main objective is to test those who present symptoms to detect cases and carry out contact tracing quickly. Another main objective is to intensify testing in high-risk situations, namely long-term care facilities, health care facilities, and correctional facilities, with the goal of supporting outbreak control in all situations.

Our priorities continue to be having access to reagents, assessing rapid tests outside of laboratories, and accessing authorized test kits to ensure that provinces and territories are equipped to accelerate screening according to their needs.

Q182. **Does PHAC recommend that temperatures be checked prior to entry into public places? If not, why? Will this be put in place once activities begin to gradually resume?**

In the Infection prevention and control for COVID-19: Interim guidance for long-term care homes, PHAC recommends that staff screening measures be put in place, including temperature checks twice per day. However, fever is not usually one of the first symptoms of COVID-19 and, in some cases, those who are infected do not develop a fever; therefore, it is not recommended to put measures in place that are focused solely on detecting fevers.

During the severe acute respiratory syndrome (SARS) outbreak in 2003, there were over 6.5 million travellers screened who were entering or leaving Canadian airports, with 2.3 million of those travellers screened through thermal scans. Despite intensive screening efforts, this method did not detect one single case of SARS. For this reason, it is not recommended to proceed with temperature checks upon entry at the Canadian borders.

At this time, it is essential that we all continue to practise public health measures that have proven to be effective: practice physical distancing, respiratory hygiene, hand hygiene, and staying at home as much as possible.

Members of the Special Advisory Council, which include Canadian Chief Medical Officers of Health, continue to work together closely develop a coordinated intervention to control the epidemic based on the best available scientific knowledge and evidence.

Q183. **What specific test is currently authorized in Canada to screen for COVID-19?**

Since the new diagnostic tests for the new SARS-CoV-2 virus have been put in place, Canadian public health laboratories have used the collective strengths of their network to assess these new test to ensure their accuracy, all while promoting how these testing capabilities can quickly be distributed across Canada.

After the genetic sequence of the virus was published in January, it was possible to immediately develop multiple molecular tests (polymerase chain reaction), which detect specific genetic traits of the virus. The Canadian laboratory network recommends that molecular tests target two different traits found in the virus that is used to diagnose infections, and in certain cases (such as travellers from countries that have not yet reported COVID-19 infections) additional tests incorporating genetic sequencing be done in order to provide definitive evidence that SARS-CoV-2 is present. Several testing methods have been used and tests have been conducted at a number of sites, for example a test presumed positive in a province is then confirmed by the NML, as a result, Canada was able to ensure that every confirmed case was in fact a real case.

We have a certain level of confidence in the tests; however, we must streamline their process in order for them to be performed in additional laboratories in Canada. As a result, the case definition was successively adjusted in order for cases to be confirmed using a single molecular test. This test was chosen based on the knowledge that was collected on the performance of various tests that were conducted in different Canadian laboratories. We now regularly use the most sensitive targets.

When it comes to false negative test results, it is necessary to better understand COVID-19 infections and the course that the virus takes during infections. It is likely that at the beginning or at the end of infections, the virus is not easily detected and the current molecular tests will not detect these cases. However, seeing how laboratories have responded to this epidemic, it has established that they will continue to improve their approach to testing based on evidence.

Furthermore, current molecular tests that are being used across the country, and that were created from the collective sharing of information and tools by laboratories, will soon serve as a point of reference when comparing and implementing the next phase of tests. Point-of-care rapid testing will be put in place in order to allow health care institutions to perform tests rather than requiring that specimens be sent to a laboratory for testing.

Q184. **Are the Spartan tests effective for diagnosing COVID-19? What are the false positive and false negative rates?**

Spartan Bioscience' test kit was authorized by Health Canada under an Interim Order by the Minister to allow the importation or exceptional sale of medical products as part of the response to the COVID-19 outbreak. The authorization followed a scientific assessment by Health Canada reviewers to ensure that the devices met safety and effectiveness standards, which in the case of diagnostic devices, means that they meet the requirements to accurately identify COVID-19 cases and minimize the risk of false positives and false negatives. As part of the authorization process, Spartan Bioscience is also required to submit data on an ongoing basis as additional test results become available.

Health Canada's review is consistent with international best practices and ensures that devices meet the standards set out in applicable guidance documents, including

(i) the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, issued by the U.S. FDA on March 16, 2020; and

(ii) the EUA [Emergency Use Authorization] Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 That Causes COVID-19, published by the U.S. FDA on March 12, 2020.

Q185. **Are the tests available to anyone who wants to take them?**

Rapid and accurate screening is an essential component of the public health response to this pandemic. It allows for early detection of cases, which helps control the spread of the disease. The Government of Canada is taking steps to increase testing capacity as quickly as possible to ensure that Canada's public health labs and other diagnostic labs have the resources they need to screen people with COVID-19. Several commercial reagents approved by Health Canada can be used for COVID-19 testing. However, there is a worldwide shortage of many of these reagents, which is compromising the testing capacity of labs. We need Canadian solutions to address this problem. This shortage restricts Canada's testing capacity. The National Microbiology Laboratory (NML) of the Public Health Agency of Canada (PHAC) has developed a reagent to help address this shortage. LuminUltra Technologies Ltd., a New Brunswick-based company, produces this reagent in large quantities. Even with increased capacity, screening priorities must be met in order to achieve appropriate public health goals.

Q186. **Does the lack of sampling and testing equipment prevent more tests from being performed?**

The Government of Canada has ordered over 11 million swabs from various domestic and international suppliers that are delivered in batches each week. The government purchases and produces other lab supplies to support provinces and territories in their overall lab testing efforts. In addition, we are exploring options to ensure a continuous supply of sterile swabs, including the possibility of producing swabs in Canada.

Q187. **What is the biggest obstacle to increasing screening capacity so that more of the population can be tested?**

The Government of Canada is investing $150 million to support federal public health measures such as enhanced surveillance, increased testing capacity at the NML, and continued support for preparedness in First Nations and Inuit communities. These important measures will support diagnostic testing across Canada, and the research, testing and implementation of new diagnostic tests and methods. They will also promote coordination with provincial and territorial authorities to procure and distribute lab reagents and supplies to increase screening capacity across the country.

Q188. **Which universities and manufacturers are currently involved in the development of sampling or testing equipment, or otherwise contributing to screening?**

To date, Innovation, Science and Economic Development Canada has received close to 6,000 responses to its call to action from companies across the country. Now that we have received these responses, we are contacting respondents to see how they can meet the urgent needs of Canadians and frontline health care workers. Canadian industry is playing a major role in increasing national screening capacity. It's worth noting that LuminUltra (New Brunswick) provides extraction reagent to federal and provincial labs across the country and is continually increasing diagnostic testing capacity. Spartan Bioscience is also offering a Health Canada-approved off-lab diagnostic test for screening in rural and remote areas.

Q189. **How does Health Canada's list of COVID-19 symptoms compare with the CDC's? Is the list up to date? And how important is it for Canadians who are monitoring for signs of the disease at home?**

In Canada, public health is a shared responsibility. Canadian public health guidelines for COVID-19 are evolving as the body of evidence grows and as we better understand the new virus. We continually review the latest scientific evidence and collaborate with our provincial, territorial and other public health partners across the country and around the world to learn more. The Public Health Agency of Canada is reviewing its online tool and may make changes or corrections as new information is received.

With respect to the differences between the federal government's self-assessment tool and Ontario's, the federal government provides general advice , while the provinces and territories, which manage and deliver health services, may provide more detailed advice based on their epidemiological data, risk assessment and the availability of health services. As for the differences between the Government of Canada's symptom list and that of the U.S. Centers for Disease Control (CDC), each country develops its own guidelines based on a variety of factors, including epidemiological data and risk assessments.

Q190. **How do labs report information on positive test results to public health authorities?**

The method provincial public health officials use to collect and disseminate information on positive COVID-19 tests varies from province to province. Provinces are best positioned to provide additional information on the methods they use.
However, provinces and territories do report their lab test results to the Public Health Agency of Canada (PHAC) for follow-up at the national level.

Canadian public health labs collaborate through the Canadian Public Health Laboratory Network (CPHLN), which brings together federal, provincial and territorial public health laboratory professionals to work together to strengthen Canada's public health system through coordinated laboratory services and good management. Through CPHLN, provinces and territories report daily COVID-19 lab results using a variety of tools.

One of these tools is an online platform, the System for Analyzing Laboratory Tests (SALT), which is a component of the Canadian Network for Public Health Intelligence (CNPHI). CNPHI is a scientific public health informatics and biomonitoring platform designed and run by scientists at PHAC's National Microbiology Laboratory. SALT provides a centralized and secure web-based environment for public health officials to share COVID-19 test results, with real-time visual analysis.

Remdesivir for the treatment of COVID-19

Q191. **Can remdesivir be used for any patient with COVID-19? Will it work for everyone?**

At this time, it is too early to say whether remdesivir could be used for all patients infected with the SARS-CoV-2 coronavirus. Some evidence suggests that remdesivir may have the potential to reduce the duration of symptoms in some hospitalized patients with later-stage COVID-19. Patients who received remdesivir recovered 31% faster than those who received a placebo. Specifically, the median recovery time was 11 days for patients treated with remdesivir, compared to 15 days for those treated with a placebo. It is only available as an intravenous drug.

Q192. **Are there clinical trials underway to determine whether remdesivir is effective?**

Remdesivir is still considered an experimental treatment for COVID-19. The most appropriate way to access experimental treatments that may be useful in the treatment of COVID-19 is through a clinical trial. Clinical trials provide Canadians with access to new COVID-19 treatments and provide the medical community with an opportunity to systematically collect information on the treatment's effectiveness and associated risks. To date, Health Canada has approved two clinical trials on the use of remdesivir for COVID-19 in Canada: the CATCO trial with remdesivir (part of the World Health Organization's SOLIDARITY trial), and Gilead's open-label remdesivir trial. Access to remdesivir through clinical trials is available at several sites across the country. More information on clinical trials is available on our website.

Health Canada is also aware of several international clinical trials on remdesivir for the treatment of COVID-19. Some of these studies have been completed or are nearing completion. Health Canada is closely monitoring clinical trial developments and emerging results for remdesivir.

Q193. **What is the Emergency Use Authorization (EUA) in the United States? Does this mean that the drug has been approved for the treatment of COVID-19?**

On May 1, 2020, the U.S. Food and Drug Administration (FDA) announced that it had issued an Emergency Use Authorization (EUA) for remdesivir, an investigational antiviral drug to treat COVID-19. According to information published by the FDA, "this authorization is temporary and does not take the place of the formal new drug application submission, review and approval process. The EAU authorizes the distribution and emergency use of remdesivir solely for the treatment of COVID-19; remdesivir is still an investigational drug and is not approved by the FDA". More information on the FDA's EUA for remdesivir is available on the FDA's website.

Q194. **What is an ongoing review? If it's faster, why not do it all the time?**

An ongoing review is one of the regulatory tools available to Health Canada to expedite drug submission reviews in public health emergency situations.

Under normal circumstances, all data in support of an application for market authorization must be submitted at the start of the review process. In the case of an ongoing review, the Department reviews the data as it becomes available. Several cycles of ongoing review may be

conducted during the evaluation of a product as data continues to emerge. New data that becomes available for evaluation during this ongoing review will need to be considered in the context of all other existing data and allow the benefits and risks of a drug to be determined as soon as possible.

While it is impossible to predict the specific timeline for an ongoing review, this approach will allow submissions to be filed more quickly and will allow Health Canada to initiate a review earlier without compromising its high standards of safety, effectiveness and quality.

Health Canada can evaluate drug submissions more easily with an ongoing review than with a standard drug review. They also require more review work due to multiple review cycles. For this reason, it is a rarely used regulatory flexibility reserved for public health emergency situations.

Although remdesivir is not currently authorized in Canada, it is available to patients in clinical trials and upon request to specific demographics through the Special Access Program, through which patients can access unauthorized drugs.

At-home tests

Q195. **What type of tests have been proposed for home use?**

To date, Health Canada has not authorized any diagnostic tests or sample collection kits for use by the general public to detect or self-diagnose COVID-19.

Lateral flow antibody tests, commonly referred to as “rapid tests”, have been offered illegally for home use. This type of test does not require any lab equipment and the results are presented as a coloured band on a small stick. However, Health Canada has not authorized the sale or importation of any such test, which is not recommended since the patient does not have access to a medical professional who can interpret the results.

Patients who test positive for COVID-19 should be counselled by a medical professional on how to care for themselves and how to reduce the spread of COVID-19 through self-isolation. In addition, public health authorities must have access to all test results in order to make decisions to counter the spread of COVID-19 in Canada.

Based on available information, the World Health Organization recommends the use of rapid tests only in a research context.

Q196. **What is Health Canada doing to prevent the sale of unauthorized COVID-19 tests?**

Health Canada continues to monitor the use of unlicensed medical home test kits, including those for COVID-19, taking appropriate action to stop them from being sold if necessary. When Health Canada becomes aware of possible non-compliance with the *Food and Drugs Act* or its associated regulations, it takes appropriate action and informs Canadians if necessary.

For example, on April 21, 2020, Health Canada worked with the RCMP to seize over 1,500 unlicensed kits in British Columbia.

On May 7, 2020, Health Canada issued an advisory warning Canadians not to use or rely on unlicensed COVID-19 test kits intended for sale or personal use.

Q197. **Are home test kits for COVID-19 available in other countries?**

No other international regulatory body, including the U.S. Food and Drug Administration (FDA), has approved COVID-19 test kits for home use.

It was recently reported in the media that the FDA had approved its first home test kit, but this is inaccurate. The FDA has approved the COVID-19 RT PCR test, for which only a fluid sample is collected at home. Once the sample is taken, the swabs must be sent to a lab for analysis. These are subject to strict transportation requirements.

Q198. **What types of COVID-19 tests have been authorized by Health Canada or are under consideration?**

Health Canada has authorized the sale and importation of COVID-19 diagnostic tests intended for use only by qualified health care professionals or trained operators.

Amendments to the authorization of the Spartan test kit

Q199. **What is the Spartan device and how does it work?**

Spartan's test kit consists of a portable analyzer called the Spartan Cube. The Cube performs the test with Spartan's COVID-19 test cartridges and proprietary swabs. The test kit can diagnose COVID-19 in less than an hour without having to send a sample to a lab.

Q200. **Could there be similar issues with other medical devices approved under the Interim Order?**

Each product is reviewed on a case-by-case basis, depending on the technology, and different standards for evidence requirements may be necessary. While no similar issues are anticipated at this time, Health Canada will not hesitate to take action should any issues be identified.

Q201. **Were any test kits used to diagnose patients?**

Spartan Bioscience has informed the Department that no tests were used to diagnose patients. As part of the voluntary recall requested by Health Canada, the company will have to reconfirm whether the kits were used to diagnose patients.

Q202. **Why is the Spartan test now approved only for research? How and when did problems arise?**

On March 26, 2020, Health Canada gave Spartan Bioscience Inc. conditional authorization for its Spartan Cube, intended solely for research purposes. This authorization was granted under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19, which allows Health Canada to authorize devices for fast-tracked scientific review, based on the minimum requirements.

On April 11, 2020, Health Canada completed its scientific review to ensure that the device has evidence to support that it meets the requirements for safety and effectiveness. Health

Canada's scientific review relied on analytical data from laboratory studies provided by the company, and took into consideration further clinical validation that would be carried out by public health laboratories in order to determine performance in clinical settings. Health Canada amended the conditions on the authorization, enabling the sale of the Spartan Cube, but requiring the provision of data from additional technical studies as well as sales information.

On May 1, 2020, the Public Health Agency of Canada's National Microbiology Lab (NML) provided Health Canada with a final report on clinical trials conducted in three provinces (Alberta, Ontario and Manitoba) where Spartan swabs were used to collect samples from patients under clinical conditions. These clinical trials are essential for identifying any performance issues that were not detected in the lab. The report indicates that although the Spartan Cube operated in the lab according to the manufacturer's specifications, performance issues were identified during the clinical trial. These problems appear to be related to the proprietary swab, which may not collect sufficient mucosal material for testing.

In light of the clinical results, Health Canada has placed conditions on the company's authorization, restricting the use of the product to a research context only until adequate evidence of clinical performance can be provided. Spartan's product may continue to be used for research purposes only. It is important to note that the company has informed the Department that none of the tests have been used for diagnostic purposes.

Health Canada will continue to work with Spartan to meet the regulatory requirements for the use of the test kit at points of care.

Q203. **Why didn't Health Canada wait for the results of the clinical studies before authorizing the Spartan device for sale?**

The scientific review of the Spartan test device was completed under expedited timelines as part of the Interim Order announced on March 18, 2020.

Health Canada's regulatory decision was based on in-laboratory testing of the device and not on clinical trial data of its effectiveness. The review took into consideration that further validation would be carried out by public health laboratories in order to determine performance in clinical settings. This is consistent with the approach taken by other trusted regulators.

As planned, Health Canada continued to monitor and assess the safety and effectiveness of these rapid test kits in the field to help ensure that they perform appropriately and deliver accurate results. In light of the clinical results, Health Canada has placed conditions on the company's authorization, restricting the use of the product to a research context only, until adequate evidence of clinical performance can be provided.

For information about the performance of the Spartan test, please contact the manufacturer directly.

Serology

Q204. **What is serological testing used for?**

Serology-based tests are essential to understanding the immune response to virus infection. They will play a key role in determining the extent of exposure to the virus through sero-surveillance studies.
Serological testing is not authorized to diagnose COVID-19 infections because it detects antibodies produced by the patient's immune response. Those antibodies are not likely to develop until later in the infection, thereby giving false negative results in many cases.
In the case of diagnostic tests, it's better to test directly for the presence of virus traits while infections are occurring, using molecular tests from with swabbed specimens.

Q205. **How will the results of serological testing be used?**

Using validated and effective serological tests for COVID-19 will be an important step in Canada's public health response.

On April 23, the Government of Canada assembled the COVID-19 Immunity Task Force to lead the collaborative effort to test blood samples across Canada for the presence of COVID-19. Rapid and representative national surveys will provide a snapshot of where we stand now, and what to expect in a possible second wave of infection. They can also shed light on the possible immune status of vulnerable populations and individuals, including Indigenous communities and residents of nursing homes and long-term care facilities.

Serological surveys can also help guide important public health decisions once a vaccine becomes available.

Q206. **Is the government considering the possibility of serological or immunity passports or certificates to allow people with immunity to move freely again?**

There is an active international effort to assess whether those who have recovered from illness are safe to resume daily activities.
More research is needed before making decisions in Canada.

Other respiratory viruses generally do not provide an individual with 100% immunity after recovery.

Right now, we just do not know whether individuals who have recovered from COVID-19 will have immunity, how long that immunity may last, or whether it's possible for individuals to experience less severe or potentially more serious illness if they get COVID-19 a second time.

Q207. **How is Canada currently testing patients who are suspected to have COVID-19?**

Provinces and territories conduct diagnostic testing for the virus that causes COVID-19. Canada's National Microbiology Laboratory works in collaboration with provincial public health laboratories to ensure high-quality diagnostic testing according to laboratory standards.

Q208. **How will Health Canada ensure that test kits are safe and effective?**

The Interim Order creates a tailored approval pathway for the importation and sale of medical devices that support Canada's response to COVID-19. This Interim Order, and the tailored approval pathway it creates, provides the Minister with flexibility to consider the urgent circumstances relating to the need for the medical device, authorizations granted by foreign regulatory authorities, or possible new uses for medical devices that are already approved in Canada.

As with all drugs and medical devices, Health Canada assesses and monitors the safety and effectiveness of all products authorized under this Interim Order, and will take immediate action if required to protect the health and safety of Canadians.

Manufacturers are still required to follow strict post-market safety requirements such as mandatory problem reporting, recall procedures and complaint handling.

Q209. **Why did it take so long for Health Canada to authorize a serological test?**

Providing the Canadian population and individuals with accurate information about appropriate public health measures and infection status is a pillar of the country's response to the pandemic. Canada has maintained a science-informed approach to managing the pandemic including maintaining requirements for pre-market authorization of COVID-19-specific tests.

Health Canada authorized the test after conducting a scientific review of the evidence to ensure that the test gives accurate and reliable results. More than a dozen COVID-19 testing devices are now accessible in Canada. The list of authorized testing devices is posted on Health Canada's website.

If pressed:

- Each public health laboratory across Canada will decide whether it wants to use the Diasorin LIAISON® serological test, based on its own needs and scientific review requirements.

Q210. **What is the difference between swab and serological tests? How are they used differently?**

Serological tests are used to determine whether a person has been infected with the virus that causes COVID-19. As the infection progresses, the patient's immune system produces antibodies against the virus, and it is the presence of these antibodies in blood samples that forms the basis for serological testing. Alternatively, the traits of the virus itself, rather than the human immune response, are the basis for the molecular tests that are now used to diagnose COVID-19 from swab samples.

Serological test results are valuable in determining infection rates and the prevalence of individuals with protective antibodies in certain settings or communities, such as health care workers. These results are also important to better understand the overall immune response to the virus, and to provide data for use in the development of vaccines against COVID-19.

Serological tests are not recommended for diagnosing COVID-19 infections, as antibodies are unlikely to develop until later in the infection, often resulting in false negative results. For

diagnostic testing, it's preferable to test directly for the existence of the virus while infections are occurring.

Contact tracing

Q211. **Can you tell us more about the federal government's program to recruit contact tracers?**

As part of the overall federal, provincial and territorial government response to COVID-19, the Government of Canada is supporting provinces and territories by preparing a virtual inventory to recruit and engage qualified Canadians to provide surge capacity in key areas.

To assist the provinces and territories, the Government of Canada is working with them to determine their needs. They have identified contact tracing and case registration as areas where they need assistance. As a result, they require individuals with case management, data collection and management, raising public awareness, and telephone interviewing skills. Additional calls may be made when jurisdictions identify new areas requiring assistance. As needs evolve, support will be provided in other areas requiring assistance.

The Government of Canada is reaching out in phases. The first and second phases are already underway. The first phase brought in qualified federal public servants, not currently in core functions for ongoing federal work, to work in the jurisdictions feeling the most pressure. The second phase aims to build up the inventory developed through the volunteer recruitment campaign for COVID-19 and reach out to health, public health and science faculties across the country, issuing a call for individuals interested in joining the inventory. The third phase will target retirees or individuals not currently involved in the response to COVID-19 from all health and health science professional associations.

Q212. **How many volunteers will be accepted for the National COVID-19 Volunteer Recruitment Campaign, and how many volunteers will be responsible for contact tracing? When will they begin working?**

When the process closed on April 24, over 53,769 volunteers had put their names down. The list of volunteers has been forwarded to several administrations, particularly to support long-term care projects. Each administration will decide when and how to use volunteers. For detailed plans, please contact the provincial and territorial governments.

Q213. **Does the Department plan to use digital data technology like cellphone apps to improve contact tracing? What type of digital data model is the Department considering?**

Mobile apps can help to encourage physical distancing by empowering Canadians to change their activities and reduce risky behaviours. These could complement health measures aimed at flattening the curve, such as

- avoiding crowded places and gatherings;
- washing your hands often with soap and water for at least 20 seconds; and
- avoiding touching your eyes, nose or mouth with unwashed hands.

However, any support from the federal government would be highly contingent on measures taken by developers to protect the privacy and security of users.

Q214. **A company partially based in Canada has developed a smartphone app to help with contact tracing, similar to the one used in Singapore. Will the government enlist this type of technology to make contact tracing easier?**

Contact tracing is an important public health measure used to identify individuals who have potentially been exposed to COVID-19 and to ensure that people take precautions (e.g. they self-isolate and/or monitor for symptoms) to avoid exposing others. Contact tracing is a provincial and territorial responsibility that has been ongoing since the start of the COVID-19 epidemic. While it is an essential public health tool, contact tracing requires a lot of resources. Phone apps that use location or proximity data to help alert those who have been in contact with COVID-19 patients are a useful tool to help fight the epidemic. Please address any questions on specific provincial or territorial contact tracing policies or regulations to the relevant provincial and territorial public health authorities.

DRUG, HEALTH PRODUCTS AND MEDICAL SUPPLIES

Availability of medical devices

Q215. **Does Canada have enough diagnostic tests?**

We expect there to be enough diagnostic test kits.

Health Canada is working with manufacturers to make commercial diagnostic devices available and improve Canada's COVID-19 diagnostic capacity.

As an emergency public health measure, the Minister of Health has signed an Interim Order to allow expedited access to COVID-19-related medical devices.

With this Interim Order, two new diagnostic tests are made widely available in Canada:

- the Roche Molecular Systems Inc. cobas SARS-CoV-2 diagnostic device; and
- the ThermoFisher Scientific TaqPath™ COVID-19 Combo Kit.

This will improve access to medical devices that could permit faster and more convenient testing for patients in Canada.

Point-of-care diagnostic tests are being developed and may become available through this Interim Order, which would also make patient screening easier and more convenient.

Q216. **Is Health Canada looking to the cannabis sector for additional COVID-19 testing?**

A number of options are being assessed to increase testing capacity to support provincial and territorial public health authorities. As part of this, Health Canada is working to identify lab capacity that might be available across the country in various sectors, including at licenced cannabis production sites to assist with supporting COVID-19 testing. On March 26, Health Canada sent an email to all licence holders, asking those with lab capacity that are interested in assisting to notify the Department by email. Several labs have responded indicating their

willingness to assist. The Department is currently confirming next steps, including confirming whether they have the appropriate equipment, certifications and protocols to assist.

Q217. **Is the government thinking about increasing supply of the flu shot for the next flu season in light of the demand of the COVID-19 pandemic?**

The Public Health Agency of Canada (PHAC) is preparing for the possibility of simultaneous flu and COVID-19 outbreaks in Canada this fall. To help minimize the challenges that such an eventuality could cause to the health care system, the 2020 flu campaign will focus on at-risk populations such as the elderly and people with weakened immune systems or underlying conditions.

PHAC assists in coordinating and overseeing the distribution of influenza vaccines for public programs, in collaboration with Public Services and Procurement Canada, Health Canada, manufacturers, and federal, provincial and territorial partners. PHAC does not decide how much vaccine provincial and territorial governments purchase for their populations; this decision is made by each provincial and territorial government based on past experience, the influenza season forecast, and the requirements of its immunization program.
In light of the COVID-19 pandemic, provincial and territorial governments are reviewing their vaccine orders for next year's flu season to determine whether they are sufficient or should be increased. There is still an opportunity to increase orders before final decisions are made.

Q218. **Is Health Canada aware of any medical device shortages due to COVID-19? What is being done to monitor supply?**

At this time, Health Canada has not received any word of medical device shortages from manufacturers of medical devices as a result of COVID-19.

The Department has engaged medical device industry stakeholders to look for any early signs of potential supply issues, and none have been identified to date. Health Canada continues to monitor the situation and will take appropriate action, as required, to mitigate any impact on Canadians.

Q219. **Will 3D printed medical devices be allowed to be used to alleviate supply shortages in Canada during this pandemic?**

Health Canada is aware that groups here in Canada and in other countries (e.g. the UK, the U.S., Italy, China) may be using various manufacturing techniques to address some supply issues.

Health Canada, together with other federal organizations and private sector, is facilitating the assessment of existing 3D printing capacity in Canada and will help determine possible next steps to augment capacity where needed.

It is important to note that Health Canada remains the regulatory authority for all medical devices that are intended to be sold or imported and has dedicated processes to quickly assess safety, efficacy, and quality for medical devices manufactured for the COVID-19 response, including those manufactured by 3D printing.

Health Canada has reached out to its trusted 3D printing network in the medical device industry, hospitals, universities, colleges and industrial manufacturing facilities. As of March 20, we have received responses from 34 organizations with 3D printing experience who are willing to help.

Q220. **Is there an estimate in terms of how many ICU beds Canada will require as the epidemic reaches its peak? And how many ICU beds are available now?**

According to the Canadian Institute for Health Information (CIHI), there were 3,902 ICU beds in Canada (excluding Quebec, Nunavut and Yukon), in 2017-18, which is the most recent and most complete data available. Further details can be downloaded from CIHI's website. Health care system officials in the provinces and territories are closely monitoring their jurisdiction's health system capacity, including the demand and supply for key assets such as ICU beds and ventilators as the number of COVID-19 cases rises. The situation continues to evolve as many jurisdictions are taking various actions, including cancelling elective surgeries and moving alternative level care (ALC) patients to other sites to improve their acute care capacity in hospitals.

Health Canada is currently discussing with provincial and territorial officials the availability of ICU and ventilator capacities.

Q221. **How many ventilators does Canada have now, and how many would be needed when the epidemic reaches its peak?**

The collaborative federal, provincial and territorial procurement order also includes ventilators. The federal government has contracted for more than 1,500 ventilators and is working to support the acquisition of additional ventilators in support of provinces and territories.

The global demand for these items is high, and PHAC will continue to assess needs with the provinces and territories as this event evolves.

Q222. **What is the federal government doing in terms of increasing the supply of ventilators and masks?**

The Government of Canada is investing $2 billion to purchase PPE, including for bulk purchases with provinces and territories. This includes masks and face shields, gowns, ventilators, test kits and swabs, and hand sanitizer.

Discussions are continuing within the Government of Canada (Innovation, Science and Economic Development Canada, Public Services and Procurement Canada, Health Canada and the Public Health Agency of Canada) to explore alternative PPE supply routes and to scale up domestic production with Canadian companies such as Thornhill Medical and Medicom. To ensure that these production lines meet the technical specifications appropriate for use in frontline response, Health Canada and the Public Health Agency of Canada are conducting technical evaluations. This includes the Minister of Health's most recent signing of an Interim Order to allow expedited access to COVID-19-related medical devices. The list of authorized COVID-19 devices (with authorization dates) is available here and all licenced medical devices are listed in the Medical Device Active Licence Listing.

Q223. **Is Health Canada reaching out to the three RCMP forensic labs to provide personal protective equipment to health care workers?**

The Government of Canada has not asked the Royal Canadian Mounted Police to provide personal protective equipment to health care workers. We are working directly with the provinces and territories to identify needs and buy in bulk to leverage our collective buying power. We are also accepting donations, enhancing domestic industrial capacity, and expediting the regulatory process to ensure we are able to get critically needed products to Canadian markets.

Q224. **Does the federal government have a plan in place to speed up the evaluation process for donated medical supplies to fulfil the medical equipment shortage?**

PHAC and Health Canada have been working closely with the CBSA to expedite medical supply donations.

In response to the COVID-19 pandemic, Health Canada has implemented interim measures to expedite the importation of medical equipment including hand sanitizers, disinfectants, personal protective equipment (such as masks and gowns) and swabs. Details on Health Canada's interim measures can be found here.

Q225. **Does Canada have a stockpile of syringes, needles or other necessary equipment for a pandemic vaccination campaign?**

Currently, the National Emergency Strategic Stockpile (NESS) stores goods to respond to a variety of threats and risks. These supplies include sterile needles, syringes, gauze pads, and personal protective equipment (PPE), which could be used for a pandemic vaccination campaign. These supplies could be used to supplement those of the provinces and territories. It is not NESS practice to disclose specific quantities of its inventory. PHAC is working with the provinces and territories on an ongoing basis to assess all pandemic-related needs and ensure that every effort is made to maintain an adequate supply in Canada.

Q226. **Will Health Canada ensure an adequate supply of immunization supplies to prepare for the availability of the COVID-19 vaccine?**

PHAC and Health Canada are currently working with key partners and stakeholders to predict any supply chain risks or capacity shortcomings that could impact Canada-wide mass COVID-19 vaccination campaigns.

PHAC will continue to work with its provincial and territorial partners to identify potential supply chain shortages, and will be prepared to support the rapid supply of additional commodities such as needles, syringes, PPE and medications needed for mass COVID-19 vaccination campaigns across Canada.

Q227. **How long should Canadian PPE manufacturers (not importers) currently expect to wait for authorization to sell and distribute their products to health care facilities? How many companies are currently waiting on certificates?**

The Canadian *Medical Devices Regulations* (MDR) provides a classification system for medical devices made up of four classes – Class I represents the lowest risk and Class IV represents the highest risk.

Canada issues two types of licences for medical devices:

- Medical Device Licence (MDL) – licence issued to manufacturers authorizing them to import or sell their Class II, III or IV medical devices in Canada.
- Medical Device Establishment Licence (MDEL) – licence issued to Class I manufacturers, and to importers and distributors of devices in all four classes, authorizing importation and distribution (sale) of a medical device in Canada.

The regulatory review process for medical devices has been changed in the context of the COVID-19 pandemic. On March 18, 2020, the Minister of Health approved the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19. The Interim Order enables medical devices required for diagnosing, treating, mitigating and preventing COVID-19 to undergo an expedited review without the associated fees.

Under the Interim Order, Health Canada has received a high volume of PPE and MDEL applications.

Applications received under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19

There are currently 359 requests for PPE being processed under the Interim Order. Most of these requests are on hold, as Health Canada is waiting for additional evidence that the devices meet the necessary requirements. The authorization time for a COVID-19-related request largely depends on the quality of the request and the supporting documents provided to Health Canada. It currently takes around nine days on average to process a perfect application. The list of COVID-19 testing devices authorized by Health Canada can be found on Health Canada's website: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html.

Medical Device Establishment Licence (MDEL) applications

Most PPE (e.g. masks, face shields, gowns) are Class I medical devices, and thus considered low risk compared to other classes. Companies that which to manufacture, import or distribute PPE must obtain an MDEL if they don't have an Interim Order authorization number. Health Canada's usual service standard for issuing an MDEL is 120 days. However, our objective is to process COVID-19-related MDELs as quickly as possible to make critical medical devices more easily accessible.

Given the current demand for medical devices to help fight COVID-19 and the rising number of companies trying to provide products in Canada, Health Canada is receiving an unprecedented spike in MDEL applications.

As of April 27, 2020, Health Canada had expedited the issuance of over 750 MDEL for masks, gowns and respirators. Around 450 applications are still pending.

To facilitate rapid access to COVID-19 supplies, Health Canada has implemented a temporary discretionary measure, giving MDEL applicants a provisional submission number while MDEL applications continue to be processed as quickly as possible. The submission number allows applicants to conduct licensable activities while waiting for the MDEL to be issued. As of April 27, over 380 submission numbers had been assigned to applicants while their MDEL applications were being processed. This temporary submission number is assigned to applicants who have submitted a **complete application**. Applicants who receive a submission

number or MDEL must conduct their activities in accordance with MDR requirements and must ensure that the medical devices (classes I to IV) they sell comply with the safety and effectiveness requirements set out in sections 10 to 20 of the MDR. Health Canada takes a risk-based approach with regard to regulatory compliance and enforcement, where the main objective is to mitigate the risk associated with non-compliance. The Department uses a series of regulatory compliance and enforcement tools, such as written notices (regulatory letters or warning letters), inspections, public advisories, seizures or importation seizures at the border, and recalls, as described in the Health Canada document, Guidance on Medical Device Compliance and Enforcement (GUI-0073).

All authorized MDELs can be searched in the Medical device establishment licence listing.

Additional information on the Department's initiatives to increase PPE supply can be found on the following Health Canada web page: COVID-19 personal protective equipment.

Q228. **What has been the response to the federal government's call to action to help meet our need for medical supplies (http://www.ic.gc.ca/eic/site/080.nsf/eng/00048.html)?**

As an emergency public health measure, the Minister of Health signed the Interim Order Respecting the Importation and Sale of Medical Devices for use in Relation to COVID-19 on March 18, to allow expedited access to COVID-19-related medical devices. The Interim Order will help ensure that COVID-19-related medical devices are available to treat, mitigate or prevent COVID-19 as needed.

As part of its response to the COVID-19 pandemic, the Government of Canada adopted the *COVID-19 Emergency Response Act* on March 25. Amendments to the *Food and Drugs Act* allowed Health Canada to put strong tools in place to support efforts to mitigate shortages and, if possible, prevent them. On March 30, the Minister of Health signed the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19, an interim order allowing the exceptional importation and sale of drugs, medical devices and foods for special dietary purposes needed to prevent or mitigate the effects of shortages directly or indirectly related to COVID-19.

The Interim Order allows the exceptional importation of drugs that can't fully meet Canadian regulatory requirements, such as bilingual labelling, but that are manufactured in compliance with similar standards, to ensure drug supply to Canada and to protect the health of Canadians during this time.

We are aware of the shortage of PPE and medical supplies in Canada and we are committed to doing what's necessary to protect the health of Canadians, especially frontline health care workers, from COVID-19. The Government of Canada continues to collaborate with the provincial and territorial governments to quickly assess the need for PPE items such as N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, as well as medical supplies such as disinfectant, ventilators, swabs and test kits. In order to meet these needs, we are buying large quantities of material and supplies, working with Canadian companies to increase their manufacturing capacities and investing in COVID-19 screening tests. We have also received donations from international and domestic organizations. Health Canada is also considering conservation strategies (e.g. disinfecting respirators, reusing expired masks), to ensure that these devices are always available.

The Public Health Agency of Canada, Health Canada and the National Research Council are conducting technical reviews to verify that products comply with the Government of Canada's technical specifications for COVID-19, as listed on Public Service and Procurement Canada's Buyandsell.gc.ca.

Q229. **How did Canada deal with the shortage of masks, while the United States continues to struggle?**

The Government of Canada works with the provincial and territorial governments on an ongoing basis to assess the need for personal protective equipment (PPE) like masks.
To meet demand, the Public Health Agency of Canada (PHAC) works with Public Services and Procurement Canada to process bulk supply orders and distribute PPE and medical supplies to provinces and territories as agreed upon by the federal, provincial and territorial health ministers. Through the National Emergency Strategic Stockpile (NESS), PHAC also deploys PPE and ventilators to provinces and territories who have asked for help. The purpose of the NESS is to help supplement provincial and territorial resources by providing surge support.

PPE shortages are a constant concern, as global demand remains high. This explains why, in addition to obtaining PPE and increasing national manufacturing capacity, the Government of Canada is promoting various measures such as frequent hand-washing and physical distancing to help flatten the epidemiological curve.

Distribution and quality control

Q230. **When did Canada start to procure personal protective equipment and supplies in anticipation of COVID-19?**

In January 2020, the Public Health Agency of Canada (PHAC) began to monitor the coronavirus outbreak in China and assess the National Emergency Strategic Stockpile (NESS) inventory. That same month, PHAC began working with Public Services and Procurement Canada to obtain the necessary supplies to respond to a possible outbreak in Canada, and placed bulk orders for medical supplies in addition to NESS orders.

Q231. **How much PPE was exported to China from mid-January to March 31, through all known channels (institutions, retailers, community organizations)?**

As announced on February 9, 2020, the Government of Canada donated 16 tons of personal protective equipment to China, in partnership with the Canadian Red Cross and the Red Cross Society of China. More information can be found here.

Q232. **Where will medical supplies be stored before they are distributed by Canada Post or Purolator to hospitals?**

Amazon will work directly with Canada Post to provide warehousing, and leverage its current third-party delivery channels, through Canada Post and Purolator, to deliver the products to provincial and territorial health authorities, across the country, for the frontline health care response.

Q233. **As of May 1, how many PPE shipments were shipped through Amazon Canada?**

To date, each province and territory has received five PPE shipments from Amazon.

Q234. **Do you ever have concerns about the quality/standard of medical equipment donated to Canada?**

The Government of Canada is receiving donations of medical supplies from companies both internationally and domestically, and is working to make them available for use by frontline health care workers.

Currently, donations are being managed through the Public Health Agency of Canada (PHAC), and additional partners will assist to ensure that the volume is handled as efficiently as possible and that the distribution reach is maximized.

When the federal government receives a donation, it must assess its quality. The objective is to conduct this process as rapidly as possible so that products that meet specifications can be distributed to the provinces and territories without delay.

In addition to working off a pre-existing list of product specifications, PHAC and Health Canada have formed a technical review team to assist in this regard.

An interdepartmental, multidisciplinary technical assessment committee has been established to assess donated medical supplies to verify that they meet the Government of Canada technical specifications for COVID-19 as available on the Public Services and Procurement Canada's Buy and Sell website. The process for verification varies depending on the medical device.

The interdepartmental, multidisciplinary technical assessment committee comprises representatives from the Public Health Agency of Canada (including the National Microbiology Laboratory), Health Canada and the National Research Council of Canada.

Q235. **Has the Public Health Agency of Canada rejected supply donations during their quality control? Has any equipment failed quality checks over the last two months?**

Personal protective equipment (PPE) and medical supplies received by the Government of Canada, whether given to or purchased by Public Services and Procurement Canada (PSPC), are checked by the Public Health Agency of Canada (PHAC) to ensure that they comply with the Government of Canada's COVID-19 technical specifications. If PHAC cannot account for the quality of products, they will not be allocated to the provinces and territories for frontline health care response.

To date, PHAC has received supplies that did not meet the Government of Canada's specifications for health care facilities. As these supplies did not comply with the specifications for frontline health care response, they were assessed to determine whether they had potential for use outside of health care facilities.

For example, items are sometimes damaged in transit, and PHAC ensures that these items are not distributed to the provinces and territories. During its COVID-19 response, PHAC has not delivered a small quantity of PPE, as it had been damaged in transit. PHAC continues to check PPE and donations as they are received.

<u>If pressed for more information</u>:

Because of the intense global competition for PPE and medical supplies, countries are working with a number of new suppliers and manufacturers to meet the demand of COVID-19 response efforts. As a result, PHAC does due diligence for products purchased by PSPC by doing quality control on purchased and donated supplies as soon as they are received. To date, PHAC has flagged around one million KN95 masks that did not comply with health care facilities' specifications. These masks were not distributed to provinces and territories for frontline health care. A later assessment will determine how these masks can be used in places outside of health care facilities.

Q236. **What happens to items that don't pass inspection? Are they destroyed? Are they sent back to the country that donated them?**

PPE requirements for health care workers are stricter than they are for domains outside of health care. Equipment that does not meet health care facility specifications will be subject to further review to determine its potential use in the community.

Q237. **How many of the N-95 masks received are still being tested?**

The number of N95 respirator masks and equivalents (e.g. KN95 respirators) we receive changes day-to-day, as does the number of respirator masks tested. Of the 5.342 million respirator masks received, 2.3 million are currently awaiting final testing results.

If pressed:

Of the 5.432 million respirator masks received, 2 million have been deemed non-compliant with health care facility specifications.

Q238. **Does the government require medical supplies used by local health agencies to meet certain standards? If so, what standards?**

PHAC is directing suppliers online to provide information on the items we are seeking, as well as the expedited process for suppliers to follow, including information on product specifications.

Q239. **How many swabs has Canada received to date, and how many have been distributed?**

The Government of Canada has ordered over 11 million swabs from various domestic and international suppliers, which are delivered in batches every week. In addition, we are reviewing solutions to ensure a continuous supply of sterile swabs (e.g. potentially producing swabs in Canada). The government is purchasing and producing other lab supplies to support the provinces and territories in their wider laboratory analysis efforts.

The Public Health Agency of Canada (PHAC) has shipped over 700,000 test swabs for distribution in Canada. PHAC is planning to deliver around 500,000 swabs weekly from previous orders with various companies. PHAC is working to distribute these swabs to the provinces and territories on a per capita basis without delay.

Q240. **The recent media coverage highlighted that during the week of April 6, Canada received, from China, 320,000 swabs contaminated with mould. What measures are being taken to ensure such a situation does not happen again?**

Must we receive more medical supplies from China that possibly may not be used because they do not meet Health Canada criteria?

When the provinces and territories saw problems with the swab supply in question, the product was recalled by the company, which committed to take corrective measures and replace them.

The Government of Canada is reviewing options to ensure a safe supply of sterile swabs for laboratory testing, including the possibility of producing swabs in Canada. The Government of Canada has ordered more than 11 million swabs and is supporting the provinces and territories in their laboratory analyses, particularly by ensuring that the demand for swabs is met.

PHAC is examining the personal protective equipment and the other medical supplies received by the Government of Canada, whether they were donated or purchased, to ensure they meet the technical specifications of the Government of Canada for COVID-19 before they are sent to the provinces and territories. If PHAC cannot account for the quality of the equipment or supplies, it does not distribute them for use in front-line health care. The process for verification varies depending on the medical device. For example, KN95 respirators, as an accepted alternative to N95 respirators, are visually inspected to check for defects in design and construction, and tested to confirm that they meet specifications for filtering face pieces. Gowns and surgical masks are visually inspected and tested for fluid penetration.

If pressed:

PHAC has received some supplies that do not meet Government of Canada specifications. These products do not comply with the requirements for first-line health care, but they are then assessed to determine their potential use in non-health care contexts.

Q241. Has an investigation been launched to determine why contaminated scientific equipment from ESBE Scientific was sent to Canada?

ESBE Scientific shipped 380,000 EZ Pro swabs from March 28 to April 3, 2020, which were sent to various locations in Canada. On April 11, 2020, the company published an urgent recall notice due to a swab contamination issue. The company proceeded with the recall of the product and committed to taking corrective measures and replacing the product. Provincial and territorial public health labs were immediately notified of the recall. Health Canada worked with the company to ensure the recall procedure went smoothly. The Department posts all recalls of health products in its Recall and Safety Alerts Database. Information on the recall of the EZ Pro swabs is found there.

ESBE Scientific holds an establishment licence for valid medical instruments (business number 103659). Health Canada will continue to work with the manufacturer to ensure that it is taking the necessary corrective measures and following the appropriate protocols.

It was determined that the swabs could be sterilized with ethylene oxide. All provincial public health labs were notified of this fact on April 13, 2020. The Public Health Agency of Canada (PHAC) immediately made arrangements with a company regarding the sterilization of the swabs. Health Canada authorized this sterilization process under the interim order signed on

March 18, 2020. Provinces and territories have the choice to throw out the swabs or re-sterilize them.

The Government of Canada ordered more than 11 million swabs from various suppliers and it is providing or producing other necessary elements for laboratory tests to support the provinces and territories. It is currently reviewing ways to guarantee a safe, continuous supply of sterile swabs, including options to produce and sterilize swabs in Canada.

A contract was signed with PAMA Manufacturing and Sterilization (in Mirabel, Quebec) for swab sterilization.

PHAC is continuing to work directly with the provinces and territories to identify their medical supply needs in order to make bulk orders. Public Services and Procurement Canada will continue to identify all available suppliers that have the capacity to respond to Canada's needs.

Q242. **Inasmuch as these products do not meet all of Health Canada's regulatory requirements, should Canadians be worried about their safety?**

No. While these products are typically subject to certain regulatory requirements, such as licensing and bilingual labelling, Health Canada is allowing these low-risk products to be distributed in Canada to address the current unprecedented demand in order to help slow the spread of COVID-19.

The expedited process requires companies to complete and submit a notification form that allows Health Canada to maintain a record of all hand sanitizers, hard surface disinfectants and personal protective equipment being sold in Canada under this interim approach. As with all health products, Health Canada will continue to monitor the safety of these products once they are on the market and will take the appropriate action to protect the health and safety of Canadians, if necessary.

Health Canada will continue to use all tools at its disposal to expedite the supply of safe and effective health products related to COVID-19. However, the Department is not providing blanket approval of unauthorized drugs or devices.

We will update Canadians with any new information as it arises.

Consumers and patients are encouraged to report any health product adverse events to Health Canada.

Q243. **Has Health Canada or PHAC received complaints about a batch of masks provided to health care institutions in Alberta?**

The Public Health Agency of Canada (PHAC) has no knowledge of the circumstances surrounding the purchase and is therefore not in a position to comment. We have communicated with Alberta to see if we can provide assistance.

Q244. **Are there any concerns about 3D printed medical devices produced without the usual quality checks or certification processes?**

Medical devices sold, imported or distributed in Canada must meet the safety, effectiveness and quality regulatory requirements of the *Medical Devices Regulations* or the Interim Order in cases of devices involving COVID-19. These regulated devices include medical devices manufactured via 3D printing. Health Canada is the regulatory authority for all medical devices intended to be sold or imported and has processes to quickly assess safety, efficacy and quality for medical devices manufactured for the COVID-19 response.

There are risks if devices such as personal protective equipment are not of high enough quality to properly protect patients and healthcare workers. We are working with conventional medical device manufacturers and certified 3D printing organizations regarding required device specifications and quality so Canadians can have timely access to medical devices that are safe, efficacious and of high quality.

Q245. **What measures are being taken to provide the necessary equipment and products to food production and processing companies?**

The Government of Canada is coordinating with the provincial and territorial governments to quickly assess the need for personal protective equipment (PPE) for health professionals (e.g. N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing), as well as for medical supplies (e.g. disinfectants, ventilators, swabs and analysis kits). To meet these needs, we are purchasing large quantities of equipment and supplies and we are working with Canadian companies to increase their manufacturing capacity to produce additional supplies.

The priority of the Public Health Agency of Canada (PHAC) and of Health Canada is to help the provinces and territories obtain the PPE they need for front-line health care workers. PHAC has developed a guide for employers and employees on preventing the spread of COVID-19 in the workplace. The most important measures are physical distancing, rigorous hand hygiene, respiratory etiquette, the cleaning and disinfection of surfaces and objects, the use of physical barriers and the rearrangement of the workspace to ensure physical distancing.
The Government of Canada is working to evaluate needs in the essential service sectors and to increase the domestic capacity of PPE manufacturing.

Invitation to submit an expression of interest in the delivery of logistic services

Q246. **What will the logistics provider be required to do?**

The logistics provider will be expected to handle customs documentation, secure warehousing, inventory management, reporting and transportation of the personal protective equipment to various locations in each of the provinces and territories.

The logistics provider will be expected to handle shipments by all modes of transportation, including receiving and moving products from sea ports, airports, railheads and commercial transition points.

Q247. **How long is the contract for?**

The logistics services will be required for a period of one year with a possibility of extension. Questions about the contract and tender process should be addressed to PSPC.

Q248. **How is the Government of Canada handling the importation and distribution of PPE in Canada right now?**

The Government of Canada uses existing National Emergency Strategic Stockpile (NESS) locations and resources. In addition, on April 1, 2020, a contract was awarded to Amazon to help facilitate the distribution of large quantities of PPE and medical supplies to support the COVID-19 response.

Q249. **Weeks ago the Government of Canada announced an agreement with Amazon and Canada Post to receive and distribute PPE in Canada. What is the status of that agreement and why is another one needed through this new expression of interest?**

On April 1, 2020, the Government of Canada awarded a contract to Amazon to help distribute PPE and medical supplies to support the COVID-19 response. Amazon is working directly with the Government of Canada and Canada Post to manage warehousing, and with Purolator to deliver the products to provincial and territorial health authorities across the country, for the frontline healthcare providers. This new expression of interest relates to an end-to-end logistics solution that is different than what the Amazon agreement provides for.
This new expression of interest relates to an end-to-end logistics solution that is different than what the existing Amazon agreement provides for. However, the intent is that the new solution will complement Amazon's services, and the service provider will be capable of working with the Amazon technology.

Q250. **What role does the NESS play in storing and distributing PPE to provinces and territories?**

Canada's National Emergency Strategic Stockpile (NESS) contains supplies that provinces and territories can request in emergencies when their own resources are insufficient, such as during infectious disease outbreaks, natural disasters and other public health events. The purpose of the NESS is to provide surge support to provinces and territories; it is not intended to replace supplies that provinces and territories hold or procure. Provinces and territories are responsible for preparing and maintaining their own supply capacities.

Drug shortages

Q251. **What is driving the potential for drug shortages?**

There are multiple factors that may impact the availability of a drug and increase the potential for a shortage. These include manufacturing disruptions, availability of ingredients, supply chain disruptions and increase in demand. Health Canada works with companies and partners to identify the root cause of shortages and mitigate any impact on patients as quickly as possible. Health Canada recently advised Canadians not to purchase more medication than they need, and health professionals to avoid prescribing or dispensing larger supplies of medication than necessary, to help prevent shortages caused by increased demand.

Q252. **What is the difference between an "actual drug shortage" and an "anticipated drug shortage"?**

An actual shortage means a situation in which a holder of the marketing authorization for a drug is unable to meet demand for the drug in question. An anticipated shortage means a situation in which a holder of the marketing authorization for a drug can meet short-term demand, but anticipates disruptions.

Q253. **What is the extent of the shortages of drugs linked to COVID-19 and measures taken to correct this?**

Health Canada has been actively monitoring the impact of the COVID-19 pandemic on the supply of drugs in Canada and is aware that an increased demand has resulted in supply constraints and reported shortages. The Department is proactively reviewing the Canadian supply chain to identify the sectors where supply may be vulnerable and to address these vulnerabilities before shortages occur. This increased monitoring includes regular communication with the provinces and territories, industry, health care services and patient groups; this is done daily in some cases. Health Canada is also working with international regulatory partners, specifically, the European Medicines Agency, the United States' Food and Drug Administration, the Australian Therapeutic Goods Administration and the World Health Organization to exchange information on any sign of global supply disruption. This engagement has enabled us to better identify early shortage signals, to develop potential mitigation strategies and to coordinate responses.

As part of the whole-of-government response to the COVID-19 pandemic, the *COVID-19 Emergency Response Act* was passed on March 25. The amendments to the *Food and Drugs Act* enable Health Canada to put in place more robust tools to support efforts to alleviate shortages that occur and prevent shortages from happening when possible. For example, on March 30, the Minister of Health signed an Interim Order to help prevent or mitigate shortages linked to COVID-19. This order permits the exceptional importation and sale of drugs, medical devices and foods for special dietary purposes that may not fully meet Canadian licensing or labelling requirements, but which are manufactured to comparable standards. Information for companies on how to request that a drug be added to the *List of Drugs for Exceptional Import and Sale* is available on Health Canada's website.

The drug shortages that have been designated as Tier 3 shortages can be added to the *List of Drugs for Exceptional Import and Sale*. Tier 3 shortages are those that can have the greatest impact both on Canada's drug supply and health care system and which are being actively managed by Health Canada, in collaboration with the provinces and territories, industry and health care professionals, to identify measures to mitigate the impact on patients. Currently, the Tier 3 list includes drugs that are being used to support COVID-19 patients, such as muscle relaxants, inhalers, sedatives, blood pressure stabilizers, antibiotics and pain medications, and is updated as needed. Tier 3 assignments are determined based on a recommendation from a Tier Assignment Committee, which includes federal and provincial/territorial governments, healthcare professionals and industry stakeholders.

Collaboration with companies to address the current shortages and mitigate the effects on patients is Health Canada's absolute priority. The Department is also reviewing long-term stability options. As part of these efforts, the Government of Canada has released four Requests for Information (RFI), one on April 19, 2020, and three on April 21, 2020, to ask companies to indicate whether they have access to additional stock of these essential drugs.

The RFIs will be used to identify additional supply that has not already been set aside to meet Canada's current requirements. The Government of Canada is not seeking to obtain information on products already identified to alleviate a current supply constraint or shortage, but rather additional products to strengthen overall supply. RFIs have been released for salbutamol, cisatracurium, fentanyl for injection, propofol, norepinephrine, epinephrine and azithromycin. The RFIs indicate that the Government wishes to procure a supply of up to 12 months, which could be acquired gradually, at high levels of demand. The Government will consider other RFIs for other essential drugs in short supply and drugs with promising results in clinical trials as potential treatments for COVID-19.

Health Canada will continue to work with other federal departments, provincial and territorial governments, international partners, and industry to mitigate the impact on Canadians of any shortages related to COVID-19. These efforts will help ensure that Canadians have access to the drugs they need during the COVID-19 pandemic now and as the situation continues to evolve.

Q254. **When you say that you are working with drug suppliers, what are you actually doing?**

Health Canada is working with industry, provinces and territories and other healthcare partners to mitigate the impact on Canadians of any shortages related to COVID-19. When an anticipated or actual shortage is reported to Health Canada, the Department works with companies from across the supply chain to better understand root causes, plans to resolve the shortage and measures that can be taken to mitigate the impacts on Canadians. In the event of a critical national shortage, Health Canada engages with the company reporting the shortage, as well as other companies that supply the Canadian market, in order to explore all options for meeting Canadian demand. This includes options to facilitate access to alternative supply as needed and working with companies that are able to ramp up supply for Canadians.
Health Canada is working with other federal departments, provincial and territorial governments, international partners and industry to that Canadians have access to the drugs and medical devices they need during the COVID-19 pandemic.

Q255. **What role do provinces and territories play in being alert to potential shortages in their jurisdictions?**

Addressing the complex issue of drug shortages is a multi-stakeholder responsibility requiring collaborative action from provinces and territories, manufacturers, distributers, health care professionals and the federal government. Health Canada works closely with the provinces and territories, which notify the Department of shortages of concern.

When a critical national shortage occurs, Health Canada works with stakeholders across the drug supply chain to coordinate information sharing and identify mitigation strategies. Factors such as whether the shortage is national in scope, whether alternative supplies are available, and whether the product is considered medically necessary are considered in determining the potential impact and any necessary actions by Health Canada. More information on the roles and responsibilities in addressing drug shortages can be found on our website.

Q256. **Can you confirm whether Health Canada is looking for alternative sources for Salbutamol or Ventolin?**

Health Canada is aware that an increase in demand is resulting in supply constraints for a certain number of salbutamol inhalers, such as Ventolin. Information concerning these shortages is available at https://www.drugshortagescanada.ca.

Health Canada is working closely with companies, other federal departments, the provinces and territories, and other stakeholders such as the Canadian Thoracic Society, to identify and implement mitigation measures. This includes working with companies that can ramp up supply in the Canadian market and exploring the international supply, to ensure continued supply in Canada.

Health Canada recently advised Canadians not to buy more medication than they need, and health professionals to avoid prescribing or dispensing larger supplies of medication than necessary, to guarantee that all Canadians can continue to have access to the drugs they need and to prevent shortages caused by increased demand.

Q257. **What is the current supply of the following drugs: Chloroquine and hydroxychloroquine; Ritonavir/lopinavir; and Ritonavir/lopinavir and interferon beta?**

Health Canada is closely monitoring the supply of any potential treatments for COVID-19 and is working with companies to help ensure continued supply in Canada, including working with companies that can ramp up supply for the Canadian market.

Hydroxychloroquine is marketed in Canada by four companies: Apotex Inc., JAMP Pharma Corporation, Mint Pharmaceuticals Inc. and Sanofi-Aventis Canada inc. and none of these companies have reported a drug shortage.

Chloroquine is marketed in Canada by Teva and is reported to be in shortage with an anticipated end date of December 31, 2022, due to a shortage of an active ingredient.

Ritonavir/lopinavir is marketed in Canada by AbbVie, which is not currently reporting any shortage of the drug.

Interferon-beta is marketed in Canada by EMD Serono Canada and Biogen Canada Inc and neither are reporting a shortage.

Health Canada will continue to closely monitor supplies of these drugs in Canada and will take any necessary actions in collaboration with the companies, provinces and territories and other stakeholders to help ensure continued supply in Canada. Companies are the best source for information regarding the supply of a particular drug and should be contacted for any questions about market status and the availability of a particular drug. Canadians may also wish to visit www.drugshortagescanada.ca for the latest information on any reported drug shortages in Canada.

Q258. **What is Canada doing to ensure an adequate supply of Remdesivir in Canada? Do you have some now or are you planning to obtain some? Would you consider a compulsory licence if there is a shortage here?**

Remdesivir is an investigational drug administered by intravenous infusion to certain hospitalized patients with COVID-19. Health Canada is closely watching the development of possible COVID-19 treatments, including Remdesivir. The best way to access the experimental therapies that could be used to treat COVID-19 is through a clinical trial. Clinical trials give Canadians access to new treatments aimed at preventing or treating COVID-19, and the health community will have the opportunity to collect information on the effectiveness of the treatments and associated risks.

In Canada, it is possible to gain access to Remdesivir through two mechanisms: clinical trials and the Special Access Program (SAP).

To date, two clinical trials have been approved in Canada for Remdesivir with respect to COVID-19, in several locations across the country. Additional information on the approved trials is available on our website. The information taken from these clinical trials can help support a submission to Health Canada. The Department has communicated regularly with Gilead Sciences about access to Remdesivir and possible future submissions of an application for review. Once Gilead Sciences Canada, Inc. has filed a submission with Health Canada about Remdesivir, the Department will exercise the regulatory flexibility needed to expedite the review of the application to ensure that Canadians benefit from earlier access, while ensuring the safety, effectiveness and quality of this drug. Health Canada is also working with international regulatory organizations, including the United States' *Food and Drug Administration,* to exchange scientific information on drugs and vaccines for COVID-19, such as Remdesivir, and to streamline requirements involving safety and efficacy as much as possible, in order to expedite the review and approval processes.

Before the authorization of the clinical trials, and for certain groups that were perhaps not eligible for access to Remdesivir as part of the trials, the drug can be obtained through Health Canada's Special Access Program (SAP). The SAP for drugs is another mechanism enabling Canadians to access health products on a case-by-case basis. The SAP can provide emergency access to unauthorized, non-marketed drugs to individual professionals who are treating patients with a serious illness or potentially fatal illness when conventional treatments have failed, are unsuitable or are not available. In some situations, it is possible to submit an application to obtain a non-marketed drug, such as Remdesivir, through the SAP. Each application made under the SAP is reviewed on a case-by-case basis. To date, Health Canada has authorized 12 requests for Remdesivir through the SAP.

Disinformation

Q259. **What is Health Canada doing about cases of advertising or the sale of misleading or false COVID-19 products?**

As of April 15, Health Canada has tracked nearly 200 cases of health products making false or misleading claims related to COVID-19 that were identified through proactive monitoring or complaints received.

Health Canada communicated with all parties having produced non-compliant advertising and asked them to immediately stop making illegal, false or misleading claims and to pull the advertising. If the party concerned refused to do so, Health Canada would have taken further, more concrete action, which could include stopping the sale of the product making the

allegations, site visits, public communications, recalls or the seizure of products and advertising materials.

Health Canada has not approved any product to treat or cure COVID-19. In Canada, the sale or advertising of health products that make false or misleading claims is illegal, as indicated in the *Food and Drugs Act*.

On March 27, Health Canada published an alert to warn Canadians about the risks associated with products that make false or misleading claims about COVID-19. The Department encourages anyone who has information regarding potential non-compliant advertising of any health product that has not been approved by Health Canada and to report it using the online complaint form. To keep Canadians informed, Health Canada will continue to update its online table of products whose advertising proved non-compliant and the corresponding companies or advertising media.

When Health Canada becomes aware of a possible case of non-compliance with the *Food and Drugs Act* or its regulations, it takes action to confirm or refute the non-compliance and intervenes based on the risk to the health of Canadians. The Department will continue to monitor the situation and take action as needed to ensure that health products with false or misleading claims concerning the diagnosis, prevention, treatment or cure of COVID-19 are removed from the market.

Q260. **Is there a list of the negligent parties that the public can consult?**

To fulfill its commitment to transparency, Health Canada publishes an up-to-date list every week of products for which it has taken action or is in the process of taking action in terms of non-compliant advertising, as well as the parties that engage in non-compliant advertising activity. Health Canada considers several factors to determine the appropriate measures to take in cases of non-compliance, including the compliance history of companies. The Department will continue to use the most appropriate measures to address cases of non-compliance and reduce the risks to Canadians.

Q261. **Has Health Canada been made aware of any misinformation or false claims about alcohol based hand sanitizers?**

In Canada, alcohol-based hand sanitizers are considered natural health products. Alcohol-based hand sanitizers that have been authorized for sale by Health Canada will have an eight-digit Natural Product Number (NPN) on the product label.

Health Canada has received complaints about health products that make false or misleading claims related to COVID-19. The Department is currently addressing these cases and has directed companies to remove these claims from their websites and advertising materials. Health Canada continues to monitor websites for these claims and is working with online retailers to ensure that products making these claims are removed. Selling or advertising health products making false or misleading claims is illegal. The Department takes this issue seriously and will not hesitate to use all mechanisms and tools at its disposal to stop these activities.

On March 18, 2020, in light of the unprecedented demand and urgent need for products that can help limit the spread of COVID-19, Health Canada issued an advisory announcing that the Department is facilitating access to products that may not fully meet current regulatory

requirements, as an interim measure. This includes hand sanitizers, disinfectants and personal protective equipment (e.g., masks and gowns), as well as swabs. While these products are typically subject to regulatory requirements, such as licensing and bilingual labelling, the Department is allowing certain products to be sold in Canada that may not fully meet all requirements under this interim measure. Health Canada is maintaining an updated list of products sold in Canada through this measure on its website for consumers to consult.

In addition, Health Canada is expediting approvals of products, as well as establishment and site licences related to these types of products. A list of more than 550 authorized hand sanitizer products has been published on Health Canada's website. The list is updated daily and includes information on alcohol-based hand sanitizers and non-alcohol-based hand sanitizers approved by Health Canada. If consumers see a disinfectant or hand sanitizer for sale that is making false or misleading claims, they are encouraged to report it to Health Canada using its online complaint form.

More information to help inform Canadians on buying and using drug and health products safely is available here.

Q262. **Did Health Canada send masks for analysis to ensure that they are safe and not fraudulent?**

Due to intense global competition for personal protective equipment (PPE) and other medical supplies, countries have needed to engage a diverse number of new suppliers and manufacturers. The Government of Canada is coordinating with provincial and territorial governments to quickly assess the need for PPE for health care professionals (e.g. N95 respirators, surgical masks, safety visors, nitrile gloves, gowns and other protective clothing), as well as medical supplies (e.g. disinfectants, ventilators, swabs and test kits). PHAC exercises due diligence and verifies the quality of purchased supplies upon receipt. To date, PHAC has not found any fraudulent products. However, it has evaluated some items that do not meet the technical specifications for use in health care settings in response to COVID-19. These items are not distributed to the provinces and territories for use in primary health care response and are subsequently evaluated for use in non-health care settings.

The Canada Border Services Agency (CBSA) may, at its discretion, forward imported health products to Health Canada for review. When Health Canada receives a product, it assesses it to determine if it complies with Canadian regulations. Imported health products that are found to be non-compliant are refused entry into Canada or may be seized by Health Canada.

When Health Canada targets potentially fraudulent health products, the department takes appropriate action, including working with the Competition Bureau, PHAC and CBSA to address issues of false and misleading claims related to COVID-19. Health Canada remains committed to managing risks to the public and has processes in place to prevent these imported products from entering the Canadian market.

On April 14, Health Canada issued a warning after receiving reports that fraudulent and unlicensed N95 respirators, purportedly effective in protecting consumers from COVID-19, were being sold illegally online and in some stores. Health Canada encourages Canadians to report imported health products that are potentially non-compliant or make false and misleading claims

related to COVID-19. The Department takes this issue seriously and will not hesitate to use all available means to stop these activities.

Q263. **Is Immune-Tami going to be licensed for sale in Canada?**

Health Canada has not authorised any product with the brand name 'Immune-Tami' or received any product licence application from MeOn Supplements.

Health Canada opened a case after receiving a complaint regarding this product and will take action to address any confirmed non-compliance with the *Food and Drugs Act* and/or its Regulations.

Q264. **Does MonaLisa Healing have a licence to produce/is it authorized to produce products containing CBD in Canada?**

MonaLisa Healing is not licensed to conduct cannabis-related activities in Canada. A list of federal cannabis licensees can be found here.

On March 24, 2020, Health Canada sent a warning letter to MonaLisa Healing to raise concerns about what appears to be unlicensed cannabis-related activities and improper promotion of cannabis.

In its response to Health Canada, MonaLisa Healing confirmed that it has completely suspended all activities related to hemp-derived CBD that require a licence, including unauthorized promotion, that it will not conduct any such activities without a valid licence, and that it will not engage in any unauthorized promotion to Canadians.

Health Canada can confirm that changes have been made to MonaLisa Healing's online presence, including the addition of a pop-up window informing website users that MonaLisa Healing CBD is not a cure or preventative for COVID-19, Coronavirus.

If further instances of non-compliance with the *Cannabis Act* are identified, the Department will take action, if necessary.

Q265. **Has Health Canada seen other examples of claims made about CBD in relation to COVID-19?**

Health Canada continually monitors the promotion of cannabis. No other promotion of cannabis products related to COVID-19 has been identified at this time.

Each week, Health Canada publishes an updated list of health products and e-commerce companies/platforms that do not comply with the *Food and Drugs Act* (FDA). If Health Canada becomes aware of false or misleading advertisements for products subject to the FDA, the department will take all necessary compliance and enforcement actions to ensure compliance, which may include seizure of the advertised product.

Cannabis products and their promotion are subject to the provisions of the *Cannabis Act* and Regulations. Compliance and enforcement actions, including issuing warning letters under the *Cannabis Act*, are reported in Health Canada's quarterly inspection data reports. This information is currently being updated and Health Canada expects to complete this update in the coming weeks.

Health Canada is committed to protecting the health and safety of Canadians and encourages Canadians to report any information or evidence of acts contrary to the *Cannabis Act* using this contact information.

Is Health Canada aware that MonaLisa Healing was selling CBD-infused products without a license and that a health claim was circulated in an email that the products may help prevent COVID-19? Were there any fines, penalties or consequences?

Health Canada is committed to protecting the health and safety of Canadians, including against unauthorized activities and prohibited promotion. This includes any promotion of cannabis in a manner that is false or misleading or is likely to create an incorrect impression about the attributes of the product, including its health effects or health risks. Such promotion includes claims that a product can prevent or treat COVID-19.

When reviewing regulated activities for compliance with the *Cannabis Act*, Health Canada collects information and facts and examines each situation on a case-by-case basis. Where a potential violation of the promotion prohibitions, as defined by the Act, is identified, Health Canada works with affected individuals or companies to promote compliance by ensuring that they are aware of the prohibitions and by providing them with the opportunity to comply with their legal obligations.

The *Cannabis Act* contains a number of enforcement tools that can be considered in determining appropriate measures to prevent or address non-compliance, based on a review of the situation and all relevant information, including the health or safety risk and the compliance history of the individual or corporation.

These can range from compliance promotion and education, which is intended to provide information about and prevent non-compliance, to actions to correct non-compliance or address a risk to public health or safety, such as issuing a warning letter, suspending or cancelling a federal licence, issuing a Ministerial Order, or imposing administrative monetary penalties (up to $1 million).

The Department took action when it learned that MonaLisa Healing claimed that its CBD product could help prevent COVID-19.

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Health Canada can confirm that changes have been made to MonaLisa Healing's online presence, including the addition of a pop-up window informing website users that MonaLisa Healing CBD is not a cure or preventative for COVID-19, Coronavirus.

If further instances of non-compliance with the *Cannabis Act* are identified, the Department will take action, if necessary.

Reagents

Q266. What is the scope of Canada's need for reagent chemicals used for testing COVID-19?

Canada's COVID-19 response depends on laboratory testing to detect infection early and take effective public health measures to reduce spread. Canada's public health laboratories work together through a network called the Canadian Public Health Laboratories Network to support COVID-19 diagnosis according to validated testing protocols. The global shortage of test reagents is impacting laboratory capacity. The Public Health Agency of Canada's National Microbiology Laboratory is supporting provincial requirements for testing reagents by developing in-house reagents as an interim solution and by working with the industry sector to procure supplies in bulk as they become available. Our priorities are accessing testing reagents, evaluating rapid point-of-care tests and accessing authorized test kits so that provinces and territories are equipped to ramp up testing according to their requirements.

Q267. Is the bioMérieux reagent the only one you have manufactured? Will you replicate the others?

Since the beginning of the COVID-19 outbreak, Health Canada has been working with the Public Health Agency of Canada, other federal departments and the provinces and territories to ensure a coordinated response to anticipate and meet the health product needs of Canadians. This includes working diligently with manufacturers in Canada to bring products to market and increase domestic production of therapies and diagnostic devices.

The Public Health Agency of Canada (PHAC) continues to explore all options to assist provinces in meeting the demand for testing, including reagents for which recipes have been published that can be used with existing testing devices, laboratory plastics or new designs of nasopharyngeal (e.g. nasal) swabs.

Q268. Has BioMérieux submitted its proprietary formulation to the Public Health Agency of Canada?

As part of an innovative public-private partnership, bioMérieux Canada has granted the Government of Canada the right to manufacture its products for COVID-19 testing in Canada.

The agreement with bioMérieux Canada provides for a temporary license. In addition, the facilities that the Government of Canada will use to meet a temporary increase in demand were

never designed for long-term manufacturing. In the long term, they will return to their normal operations.

Q269. **Is Canada paying for bioMérieux's temporary licence?**

The Public Health Agency of Canada has signed a temporary license agreement with bioMérieux Canada, at no cost, to receive the rights and formulation of their reagents used in COVID-19 diagnostics. Production systems for the products used to manufacture these reagents are in various stages of development and testing with the goal of alleviating some of the reagent shortages in the near future. If successful, this will improve access to COVID-19 test kits.

Masks

Q270. **Has Health Canada approved KN95 masks for use in Canada? If not why not?**

Yes, Health Canada has approved KN95 full-face respirators in the context of the pandemic as equivalent to standard N95 respirators.

Q271. **Is the KN95 respirator NIOSH certified? Does it meet an equivalent alternate standard?**

No, KN95 respirators are not NIOSH certified. They meet GB2626-2006, which is an equivalent standard to NIOSH-42CFR84. Equivalencies for masks and other equipment can be found at https://buyandsell.gc.ca/specifications-for-COVID-19-products

Q272. **Can we sell a mask that is advertised as being for non-medical use? Does it matter if there is no English text on the mask?**

If they are not used in a clinical setting and the product label clearly states that they are for non-medical use (e.g. "not for medical use," "industrial use only"), masks and respirators are not considered medical devices and are not regulated by Health Canada.

Q273. **What is the status of Health Canada's review of the "WOODBRIDGE INOAC MASK" and whether it can be used at hospitals?**

Health Canada authorized the "WOODBRIDGE INOAC MASK" on April 4. 2020. The device is intended to mitigate the wearer's exposure to hazardous particles. This device is not an N95 respirator, it is a surgical mask Level 3, which can be used in hospitals settings in accordance with the manufacturer's labelling.

Decontamination and Reuse - N95 Masks

Q274. **What are the possible decontamination methods being evaluated?**

Several proposed decontamination systems are being evaluated in Canada and around the world. Previously licensed decontamination systems (e.g. Stryker Sterizone VP4 Sterilizer, the Sterrad Sterilization System, the Steris Sterilization System, the Clean Works Clean Flow Healthcare Mini

System and the Bioquell hydrogen peroxide vapor generator) use a variety of methods, including vaporized hydrogen peroxide, ozone or ultraviolet light. New decontamination methods are being evaluated as applications are submitted under the Medical Devices Interim Order.

Health Canada is evaluating the proposed methods to ensure that they meet standards for safety, quality and effectiveness, and that requirements for key performance and safety parameters to ensure the integrity of N95 masks are maintained after reprocessing to the approved limit of reprocessing cycles.

Q275. **Is there evidence to support these methods?**

Although the virus that causes COVID-19 is a new virus, evidence from previous studies using similar viruses supports the safety and efficacy of certain reprocessing methods.

Manufacturers will be required to provide evidence demonstrating the safety and effectiveness of the chosen decontamination method.

At a minimum, this includes:

- disinfection of all harmful organisms (e.g. bacteria and viruses) that may be present in the standard medical environment;
- demonstrating maintenance of filter performance and respirator fit;
- evidence that there are no residual chemical hazards associated with reprocessing; and
- ensuring adequate labelling that describes the validated methods and reprocessing conditions applied to the respirator.

Q276. **What are the disadvantages of reprocessing versus new masks?**

Health Canada recognizes that reprocessing of single-use masks is a potential solution to provide continued access to masks for health care workers who rely on them for protection.

Each manufacturer's instructions for an authorized decontamination device must be followed.

Fitting is an extremely important aspect of N95 mask use. The disadvantage of the reprocessed N95 mask compared to the new mask is that the nose has been bent and may not allow a good fit. For this reason, PHAC recommends that the respirator be returned to the original user to increase the likelihood of a good fit. If the reprocessed respirator is returned to general circulation, it becomes very important to perform the standard leak check for the user and use only those masks that fit the user's face.

Q277. **Have other regulatory agencies approved decontamination methods? Are they being considered as well?**

Health Canada is aware that a number of devices have received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration for reprocessing N95 masks (link). Health Canada continues to evaluate guidelines from other agencies such as the United States Centers for Disease Control and Prevention (CDC) to optimize the reuse of respirators.

Chloroquine/hydroxychloroquine

Q278. **What is this medication usually used for? What are the approved indications?**

Hydroxychloroquine is an antiparasitic drug that is indicated for the treatment of malaria, as well as autoimmune diseases such as rheumatoid arthritis and lupus.

Q279. **Are there any clinical trials underway to determine if this drug is effective in children?**

Yes, Health Canada has authorized a clinical trial on the use of hydroxychloroquine to treat COVID-19 in children in Canada. The Department is also closely monitoring the progress of other clinical trials underway elsewhere in the world.

Any company or healthcare practitioner treating patients with COVID-19 who wishes to conduct a clinical trial to evaluate the effectiveness of these or other drugs is encouraged to contact Health Canada.

A list of clinical trials approved for the prevention or treatment of COVID-19 or its complications can be found at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/list-authorized-trials.html.

Q280. **Can hydroxychloroquine be used to treat any patient with COVID-19? Will it be effective in all people?**

There is some evidence that hydroxychloroquine may be effective in some patients. However, these are preliminary findings from a few small scale studies. In addition, there is very little information on the safety and efficacy of hydroxychloroquine in children.

Q281. **Has hydroxychloroquine not been shown to be ineffective against COVID-19?**

Preliminary results of clinical trials for hydroxychloroquine vary. Each trial is designed to study the drug when it is used in specific patient groups for a specific purpose. The effect of hydroxychloroquine may vary depending on its intended use (prevention or treatment of mild cases or treatment of severe cases in hospitalized patients). There is little information on its effectiveness in children who are very ill with COVID-19. The CATCO trial involves the use of hydroxychloroquine to treat children hospitalized for COVID-19. Collecting information through clinical trials remains the best way to determine whether hydroxychloroquine may have a benefit in the prevention or treatment of COVID-19 and whether this benefit outweighs the risks associated with its use.

Q282. **Has Health Canada been informed of the amount of chloroquine that has been imported into Canada? How well equipped are we to control these imports, given the danger this product poses to the health of Canadians?**

Health Canada works closely with the Canada Border Service Agency (CBSA) to make sure that imported health products meet the regulatory requirements of the *Food and Drug Act* and associated Regulations. The CBSA may, at its discretion, forward imported health products to Health Canada for review. When Health Canada receives a product, it assesses it to determine if it complies with Canadian regulations. Imported health products that are found to be non-compliant are refused entry into Canada or may be seized by Health Canada.
Chloroquine is a prescription drug in Canada for the treatment of malaria and extraintestinal amoebiasis. Under the *Food and Drug Regulations*, prescription drugs can only be imported by a practitioner, drug manufacturer, wholesaler, pharmacist or resident of a foreign country while in Canada. In special circumstances, in order not to interrupt treatment, Canadians returning from abroad may be allowed to bring with them a unit of treatment or a 90-day supply of a prescription drug based on the directions for use, whichever is less. Any other importation of prescription drugs is illegal in Canada. In recent weeks, the CBSA has forwarded more commercial imports of chloroquine to Health Canada. Those that were found to be in compliance with legislative or regulatory requirements were cleared through customs. Those that did not comply with the legislative or regulatory requirements were refused entry into Canada.

When Health Canada finds a product to be non-compliant, it always takes appropriate action — including working with the CBSA — to prevent its importation. In these unprecedented times, Health Canada remains committed to managing risks to the public and has processes in place to ensure the continued delivery of essential services to Canadians.
The Department encourages anyone who has information regarding potential non-compliant sale or advertising of any health product to report it using the online complaint form.

Q283. **Has Health Canada investigated or charged anyone selling chloroquine or hydroxychloroquine as a treatment for COVID-19? Has Health Canada seized unauthorized hydroxychloroquine or chloroquine?**

Health Canada has not approved any product to treat or cure COVID-19. Selling and advertising unauthorized health products making false or misleading claims is illegal in Canada under the *Food and Drugs Act* (FDA). It is illegal to directly or indirectly advertise either experimental therapies or the off-label use of, authorized drugs.

Health Canada has undertaken proactive monitoring of websites to detect health products that make false or misleading claims related to COVID-19. A list of products and companies/media deemed non-compliant is updated regularly. To date, the Department has not discovered any cases of illegal, false or misleading advertising for chloroquine or hydroxychloroquine through its proactive monitoring of online sites.

Health Canada works closely with the Canada Border Service Agency (CBSA) to make sure that imported health products meet the regulatory requirements of the FAD and associated Regulations. The CBSA may, at its discretion, forward imported health products to Health Canada for review. When Health Canada receives a product, it assesses it to determine if it complies with Canadian regulations. Imported health products that are found to be non-compliant are refused entry into Canada or may be seized by Health Canada.

Following a shipment of products from CBSA, Health Canada seized a shipment of chloroquine that did not comply with applicable laws.

Canadians should not take any prescription drugs that have not been prescribed by a health care professional, who can assess and counsel the patient about possible side effects — including serious side effects — and drug interactions. Health Canada recently warned Canadians about serious side effects associated with chloroquine and hydroxychloroquine, including heart rhythm problems, liver or kidney problems, hypoglycemia and nervous system problems.

Health Canada also reminds Canadians that purchasing health products online can put their health at risk and that it is risky to buy health products that claim to prevent, treat or cure COVID-19 without authorization.

The Department takes this matter seriously and will not hesitate to use all means at its disposal to put an end to these activities. 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 to public health and safety posed by false or misleading claims related to COVID-19, including on-site inspections, regulatory letters, recalls, public communications, or product seizures. In certain circumstances, where enforcement actions are not appropriate to ensure compliance, Health Canada may also refer its findings to the Public Prosecution Service of Canada for prosecution.

Health Canada will continue to monitor the situation and take appropriate action to ensure that health products that make false and misleading claims with respect to the diagnosis, prevention, treatment or cure of COVID-19 are removed from the market. Any information regarding the potentially non-compliant sale or advertising of chloroquine or hydroxychloroquine or any other health product for the treatment of COVID-19 should be reported to Health Canada using the online complaint form.

Q284. **Given the known health effects of chloroquine, if this drug is taken inappropriately or mixed with another drug that it is not supposed to be taken with, what advice does Health Canada have for Canadians who ship it here to take it as a precautionary measure to help prevent COVID-19?**

It is illegal to directly or indirectly advertise either experimental therapies or the off-label use of authorized drugs. If Health Canada becomes aware of the illegal promotion of an experimental therapy, Health Canada will contact the party involved to immediately stop the advertising and take all enforcement actions required to ensure compliance, which could include seizure of the advertised product.

Canadians should not take any prescription drugs that have not been prescribed by a health care professional, who can assess and counsel the patient about possible side effects — including serious side effects — and drug interactions. Several serious side effects are associated with chloroquine, including heart rhythm problems, very low blood pressure, and muscle and nerve damage.

Health Canada also reminds Canadians that purchasing health products online can put their health at risk and that it is risky to buy health products that claim to prevent, treat or cure COVID-19 without authorization.

Q285. **How many Canadians have become ill from taking chloroquine?**

Health Canada received 1,305 adverse reaction reports involving hydroxychloroquine as a suspected active ingredient between January 1, 2020 and April 24, 2020. Of the 1,305 reports received, only one had the active ingredient hydroxychloroquine listed for COVID-19.
The number of adverse reaction reports received can be attributed to:

- Reporting by manufacturers who have patient support programs (PSP); and
    - PSPs provide direct interaction with patients, caregivers and healthcare professionals to support patient care with a specific healthcare product. Hydroxychloroquine is often a suspect product, among others, in these adverse reaction reports.
- The large number of duplicate reports submitted to Health Canada in January and February 2020.
    - This can occur when a reporter submits an adverse reaction report to a number of manufacturers when several products are suspected to be responsible for the adverse reaction, or when a manufacturer becomes aware of a report for their product as a suspect product through another manufacturer or through the Canada Vigilance Adverse Reaction Online Database.

Warnings:

- Often it is not possible to determine if an adverse reaction reported to Health Canada is a result of using a specific health product. Other factors contributing to the adverse reaction could be a person's health conditions or other heath products they are using at the same time.
- Adverse reaction reports are suspected associations that reflect the opinion or observation of the individual reporter. The information does not reflect Health Canada's assessment of the association between the health product and the reaction(s).
- Please refer to the following link for additional cautions regarding the interpretation of information about suspected adverse reactions collected by the Canada Vigilance Program.

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

Q286. **How will Health Canada assess these health products for safety and effectiveness?**

The Interim Order allows for the importation and sale of drugs, medical devices, and special foods that support Canada's response to the COVID-19 pandemic.

As with all drugs and medical devices, Health Canada will assess and monitor the safety, quality, and efficacy of all products allowed for import and sale under this Interim Order.

Drug and medical device manufacturers will be required to follow strict post-market safety requirements.

Q287. **Is Canada guaranteed to receive adequate supply of these items?**

Supply issues related to drugs, medical devices, or foods for special dietary purposes could occur at any time. That's why Health Canada is monitoring supplies of prescription drugs, medical devices, and health products such as hand sanitizers, and enabling the continued supply of these products to Canadians.

Q288. **How does this Interim Order compare to the interim measure the Department announced last week to allow for the importation of hand sanitizers, disinfectants, personal protective equipment and swabs that do not fully meet Health Canada requirements?**

This Interim Order applies to a greater variety of products, including prescription drugs and certain special foods, and creates shortage reporting requirements for medical devices.

Q289. **And how does it compare to the shortage provisions in the Legislative Amendments?**

Both the Interim Order and the legislative amendments have provisions to allow products that are not approved for sale to be sold in Canada with certain restrictions.

The legislative amendments provide more flexibility on what may be imported, and provide additional powers such as allowing another company to make, use or sell a drug or medical device that is protected by patent in order to meet demand, when needed supplies cannot be obtained from the patent holder, subject to certain conditions as described in the interim order.

Q290. **What are the new requirements for medical device shortage reporting?**

Manufacturers and importers will be required to notify the Minister of shortages of devices considered critical during the COVID-19 pandemic. Manufacturers and importers will have to notify Health Canada within five days of becoming aware of a real or anticipated shortage. This is similar to what is already required of drug companies.

A manufacturer may allow an importer to report information on its behalf, to avoid duplication.

Having an accurate understanding of real and anticipated medical device and drug shortages will help the Minister decide which products to consider allowing for import and sale.

Q291. **How does this Interim Order affect personal importation?**

This Interim Order will not alter Health Canada's existing position, policies, and laws with respect to personal importation.
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Q292. **What qualifies as a "food for a special dietary purpose" under the Interim Order, other than infant formula?**

Foods for a special dietary purpose could include foods that are specially formulated to meet the needs of consumers with health conditions, such as low-protein foods for those with kidney disease. These could also be foods that are the primary or sole source of nutrition for a person,

such as infant formulas and specially formulated liquid diets for those unable to get proper nutrition through solid food.

Q293. **How will access to disinfectants and hand sanitizers be expedited?**

The Interim Order changes an application requirement for biocide drugs (hard surface disinfectants and certain hand sanitizers) to allow for their expedited review and authorization. In addition, the Interim Order exempts certain hand sanitizers, regulated under the *Food and Drug Regulations* (FDR), from establishment licensing

Q294. **What is the Government currently doing to address any drug and medical device shortages related to COVID-19?**

Health Canada is actively monitoring the potential impact of the COVID-19 pandemic on the supply of drugs and medical devices in Canada.

Health Canada continues to actively engage the pharmaceutical drug and medical device industry and provinces and territories to monitor for any signals of supply disruptions in Canada. Health Canada is also working in collaboration with international regulatory partners, including the European Medicines Agency, the United States Food and Drug Administration, the Australian Therapeutic Goods Administration, and the World Health Organization (WHO) to share information on any global supply disruptions.

Drug companies are required by regulation in Canada to publicly report actual and anticipated drug shortages and discontinuations within a specified timeframe on drugshortagescanada.ca. Drug and medical device shortage signals may also be reported to Health Canada by the provinces and territories, health care professionals or the public.

Health Canada has contacted all Drug Establishment Licence holders in Canada to remind them of the requirement to report anticipated and actual drug shortages, and to notify the Department of any event that may affect the quality, safety or efficacy of a drug. Medical Device Establishment Licence holders have also been requested to report any shortages to Health Canada.

Health Canada is also closely monitoring the supply of any potential treatments for COVID-19 and working with companies to help ensure continued supply in Canada, including working with companies that can ramp up supply for the Canadian market.

The Department will continue to closely monitor this situation and take any necessary action in collaboration with companies, provinces and territories and other stakeholders to help ensure continued supply of medications in Canada.

Q295. **How will these amendments enhance the Government's ability to manage drug shortages?**

These amendments will allow the Government of Canada to put in place more robust tools to support efforts to help prevent and alleviate shortages. For example, it enhances the Government's ability to put in place, through the Interim Order, a regulatory framework that allows for the importation of drugs and medical devices necessary to prevent a shortage related to COVID-19.

Q296. **Will Health Canada use these amendments to the *Patent Act* to bypass patent protection (sometimes called compulsory licensing) and allow other companies to produce patented drugs?**

The Government of Canada respects patent rights and their importance to business, and knows that industry will do everything it can to meet the needs of Canadians.

To address a pandemic such as COVID-19, the Commissioner of Patents can authorize the Minister of Health to allow another company to make, use or sell a drug or medical device that is protected by patent in order to meet demand, when needed supplies cannot be obtained from the patent holder.

The amendments to the *Patent Act* that were introduced the week of March 22, 2020, would only be used in exceptional circumstances, and include several safeguards to protect the interests of patent holders, including ensuring that a patent holder receives adequate remuneration for the use of the patent and placing limitations on the duration of the authorization.

The Minister of Health's power to seek authorization for third-party manufacturers to supply needed patented inventions is in place until September 30, 2020.

To date, the Minister of Health has not had to exercise the powers provided for in Bill C-13 regarding amendments to the *Patent Act*.

Expediting Access to Hand Sanitizers, Hard Surface Disinfectants, Personal Protective Equipment and Swabs

Q297. **Were these changes made through new regulations?**

These are interim measures implemented given the unprecedented demand and the urgent need for products that can help limit the spread of COVID-19, including hand sanitizers, disinfectants and personal protective equipment (e.g., masks and gowns). This is not a new regulation.

Q298. **What does this new rule mean?**

It is an interim measure and expedited approach. It is meant to facilitate access to imported hand sanitizers and disinfectants that do not fully meet the regulatory requirements under the *Food and Drugs Act*. Health Canada will allow certain products to be sold in Canada under this interim measure, including:

- products that are already authorized for sale in Canada but are not fully compliant with Health Canada requirements (e.g., labelling in one official language, different packaging from what was authorized); and
- products that are not authorized for sale in Canada, but are authorized or registered in other jurisdictions with similar regulatory and quality assurance frameworks.

Health Canada will allow these low-risk products to be distributed in Canada to address the current shortage in supplies. The expedited process requires an attestation form that helps Health Canada maintain a record of all hand sanitizers and disinfectants on the Canadian market. As with all health products, Health Canada will continue to monitor the safety of these products once they are on the market and will take action to protect the health and safety of Canadians, if necessary.

Q299. **Is Health Canada actively reaching out to manufacturers to get more products imported?**

Information about this expedited process was shared with all drug, natural health product and medical device establishment licence holders and product licence holders in Canada and with relevant industry associations.

Products permitted to be sold under this interim measure are being added to the list posted on Health Canada's website. At the time the advisory was posted on March 18, only hand sanitizers and disinfectants had met the criteria for sale under this interim approach. Since then, medical devices have been identified and will be added to the list in the coming days.

Q300. **How are medical devices regulated in Canada? What are Class I devices?**

Canada takes a risk-based approach to the regulation of medical devices, where the level of review before approval depends on the potential risk that the use of the device presents. This approach balances the need to provide the healthcare system with timely access to new and innovative technology, with the appropriate level of oversight and time required to assess safety and effectiveness.

In Canada, medical devices are categorized into four classes based on the risk associated with their use, with Class I devices presenting the lowest potential risk (e.g., a mask or gown) and Class IV devices presenting the greatest potential risk (e.g., a pacemaker). Class II, III and IV medical devices must have a Medical Device Licence to be sold in Canada. Companies selling Class I medical devices in Canada are required to have a Medical Device Establishment Licence. However, during this pandemic situation, Class I to IV devices can instead receive authorization under the *Interim order respecting the importation and sale of medical devices for use in relation to COVID-19*.

Health Canada is currently expediting its review of licensing applications for any medical device related to COVID-19. In addition, as with hand sanitizers and disinfectants, Class I medical devices that may not fully meet all regulatory requirements and are notified to Health Canada under this interim measure are being allowed on the market.

Q301. **How can consumers distinguish between a fraudulent product and a product imported through this interim measure?**

Health Canada will maintain an updated list of products sold in Canada through this measure on its website for consumers to consult.

Hand sanitizers and hard surface disinfectants authorized for sale by Health Canada have an eight-digit Drug Identification Number (DIN) or Natural Product Number (NPN) on the product

label. These products are listed on Health Canada's Drug Product Database or Licensed Natural Health Products Database.

Class I medical devices are not licensed by Health Canada, but companies importing or manufacturing them do require a Medical Device Establishment Licence from Health Canada. These are listed on Health Canada's website.

If consumers see a hand sanitizer or disinfectant for sale that does not have a DIN or NPN on the product label and is not on the list identified in the advisory, or if they become aware of a company importing or manufacturing a class I device without the required licence, they are encouraged to report it to Health Canada.

COVID-19-specific medical devices authorized for sale by Health Canada are listed on Health Canada's website.

Q302. **What else is Health Canada doing to improve the supply of health products during the COVID-19 pandemic?**

The Minister of Health signed an Interim Order on March 18, 2020, to speed up access to medical devices for COVID-19. The list of COVID-19 medical devices authorized under the Interim Order is available on Health Canada's website.

Q303. **Can people obtain access to medical devices and drugs that have not been authorized in Canada, but are available in other countries?**

Healthcare professionals can request access to COVID-19-related medical devices not yet licensed in Canada and drugs related to the management of patients with COVID-19 through Health Canada's Special Access Program (SAP). Applications are considered on a case-by-case basis.

For questions related to the SAP for medical devices, please contact the program via email.

Interim Order Respecting COVID-19 Related Medical Devices

Q304. **When will Health Canada be able to approve the first test kits for COVID-19 as medical devices?**

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

On March 13, 2020, Health Canada received two applications for a diagnostic device: one from Roche Diagnostics and one from ThermoFisher Scientific. These applications have received expedited review and are now approved for access by healthcare professionals through our Special Access Program (SAP).

Health Canada will immediately communicate the availability of these diagnostic devices to the concerned laboratories, the Public Health Agency of Canada and the provincial and territorial ministries of health.

Health Canada is also working with a number of other companies that are in the process of preparing and submitting information for review and will expedite those applications as well.

Q305. **How quickly are submissions sent to Health Canada regarding COVID-19 tests being reviewed?**

Health Canada is working to increase the access to diagnostic tests in Canada through an expedited review pathway. The list of authorized COVID-19 devices (with authorization dates) is available here and all licensed medical devices are listed in the Medical Device Active Licence Listing.

On March 18, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices for use by healthcare providers, including diagnostic test kits. This is an important development in the fight against COVID-19. It will help ensure quicker and more flexible approval of the importation and sale of medical devices that are necessary for Canada's response to COVID-19, including test kits.

Q306. **Is Health Canada exploring the idea of take-home antibody tests, in a similar vein as the UK? Could you comment on the efficacy of these tests?**

On March 18, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices for use by healthcare providers, including diagnostic test kits. The Interim Order will allow Health Canada to provide quicker and more flexible approval of the importation and sale of medical devices that are necessary for Canada's response to COVID-19, including test kits. The list of authorized COVID-19 devices (with authorization dates) is available here and all licensed medical devices are listed in the Medical Device Active Licence Listing.

Public health laboratories across Canada and around the world are using tests that detect the presence of the virus that causes COVID-19. These tests are being prioritized for review by Health Canada to increase the number of tests available in Canada to detect active infections of COVID-19.

Serological tests—like the take-home tests being evaluated in the United Kingdom—have limitations. These tests do not detect the virus itself. Instead, they detect the antibodies produced in response to an infection. These tests are also being accepted for review; however, the World Health Organization does not currently recommend serological tests for clinical diagnosis and Health Canada is following this advice. Research into serological testing is ongoing within Canada and worldwide. The Department is working with the National Microbiology Laboratory to validate testing and research, along with expert advice, so that we can have confidence in the test results.
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Q307. **How will these new test kits help test more patients?**

This Interim Order makes it easier and faster for certain medical devices, such as laboratory diagnostic test kits, to be imported and sold in Canada. This would help improve access to medical devices that could permit faster and more convenient testing of patients, which would avoid needing to send samples to the NML lab in Winnipeg, facilitating quicker test results.

Point-of-care diagnostic tests are in development and may become available through this Interim Order, which would permit quicker and more convenient testing of patients. Quicker test results would enable healthcare providers and patients to take appropriate actions more quickly in order to help reduce the spread of the disease.

Q308. **How often are Interim Orders used?**

Interim Orders have been needed a few times in recent years to permit access to health products quickly in exceptional circumstances to deal with a significant risk to health or safety.

The last use of an Interim Order was in August 2018 to facilitate the immediate importation and sale of AUVI-Q epinephrine auto-injectors as an emergency measure during a national critical shortage of EpiPens.

An Interim Order was also issued to allow immediate temporary access to naloxone nasal spray in July 2016 until a review for Canadian authorization was completed.

Q309. **How will Health Canada ensure that these kits are safe and effective?**

The Interim Order creates a tailored approval pathway for the importation and sale of medical devices that support Canada's response to COVID-19. This Interim Order, and the tailored approval pathway it creates, provides the Minister with flexibility to consider the urgent circumstances relating to the need for the medical device, authorizations granted by foreign regulatory authorities, or possible new indications of use for medical devices that are already approved in Canada.

As with all drugs and medical devices, Health Canada will assess and monitor the safety and effectiveness of all products authorized under this Interim Order, and will take immediate action if required to protect the health and safety of Canadians.

Manufacturers will still be required to follow strict post-market safety requirements such as mandatory problem reporting, recall procedures and complaint handling.

Q310. **Is Canada guaranteed to receive adequate supply of diagnostic test kits?**

We anticipate that there will be adequate supply of diagnostic tests. It would be at the company's discretion to allocate kits if demand exceeds supply.

Q311. **Why does the use of Altona Realstar SARS-CoV-2 PCR comply with medical device regulations when its actual use is related to COVID-19 diagnostic tests?**

The *Medical Devices Regulations* apply solely to the importation and sale of medical devices. The use of medical devices, including in laboratories, is regulated at the provincial level.

Q312. **Why are tests labelled "For Research Use Only" exempt from the *Medical Devices Regulations*?**

Tests labelled “For Research Use Only,” such as the Altona device, do not meet the definition of a medical device and are exempt from the Regulations. For further information, consult the Guidance Document: Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs).

National Emergency Strategic Stockpile (NESS)

Q313. **Who is in charge of the NESS? Where are NESS storage facilities located?**

The Public Health Agency of Canada (PHAC) maintains the **National Emergency Strategic Stockpile** (NESS). NESS facilities consist of a central depot in the National Capital Region and warehouses strategically located across Canada. For security reasons, we don't disclose specific locations.

Q314. **Is stockpiling PPE for the NESS part of the PHAC's mandate?**

In Canada, public health is a shared responsibility between local, provincial and federal levels of government. During a public health emergency, most needs will be addressed at the local level. The role of the federal National Emergency Strategic Stockpile (NESS) is based on this shared responsibility.

The NESS provides surge capacity for emergencies when local and provincial/territorial resources have been depleted. It is the sole provider of niche resources needed for rare public health events. As a result, the NESS stocks a moderate amount of personal protective equipment. However, in response to COVID-19, the Public Health Agency of Canada (PHAC) has made efforts to secure additional supply, including taking advantage of bulk purchasing mechanisms and working with domestic suppliers to support production. This included playing a key coordinating role in the Government of Canada's pandemic response efforts by arranging for the distribution of inbound shipments to provinces and territories for their immediate health care use. This work is done in collaboration with various federal departments, including Public Service Procurement Canada, Health Canada, Innovation, Science and Economic Development Canada, and Indigenous Services Canada, as well as the provinces and territories.

Q315. **How large is the stockpile and how will the supplies be allocated and distributed?**

The Public Health Agency of Canada (PHAC) does not disclose specifics related to National Emergency Strategic Stockpile (NESS) holdings.

The NESS contains supplies of personal protective equipment and ventilators. In the current environment, the inventory numbers are constantly fluctuating as stock is released, at the request of provinces and territories, to provide surge support.

Bulk orders of PPE and medical supplies have been delivered, and the Government of Canada is rapidly allocating supplies to the provinces and territories as per the allocation formula agreed upon by federal, provincial and territorial Ministers of Health. In addition to responding to requests for assistance to the National Emergency Strategic Stockpile (NESS), the Government

of Canada supported the distribution of 6.8 million surgical masks from Medicom, which were shipped directly to provinces and territories. Ontario received its allocation on April 3. As well, 1.7 million nitrile gloves are in transit to provinces and territories.

In alignment with Health Canada's guidance on optimizing the use of masks and respirators during the COVID-19 outbreak<https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/masks-respirators-covid19.html>, the NESS has also shipped almost 300,000 expired N95 masks to provinces and territories.

Q316. **Which provinces and territories have drawn on supplies from the NESS? What have they taken?**

To address immediate short-term needs, PHAC deploys supplies from the NESS based on requests for assistance. As of April 6, 23 requests for assistance from provinces and territories have been received by the NESS and completed. Items released from the NESS have included N95 masks, surgical masks, face shields, gloves, gowns and ventilators. To maintain NESS inventory, a portion of the federal, provincial and territorial collaborative procurement is retained at the NESS to provide surge support to meet the urgent needs of provinces and territories.

Q317. **Alberta's modeling data indicates that Alberta is waiting for six ventilators from the Public Health Agency of Canada. Are they coming from the NESS or from another source?**

The Public Health Agency of Canada (PHAC) continues to provide provinces and territories with personal protective equipment and ventilators from the National Emergency Strategic Stockpile (NESS) in response to requests for assistance. As part of this process, the PHAC can confirm that six ventilators have been sent to Alberta.

Q318. **How many surgical and N95 masks does Canada have now, and how many would be needed when the epidemic reaches its peak?**

The National Emergency Strategic Stockpile (NESS) contains supplies of personal protective equipment (PPE), including N95 respirators, to provide surge capacity to provinces and territories.

Based on needs identified by provinces and territories, collaborative federal, provincial and territorial procurement efforts are focused on procurement of large quantities of PPE, such as N95 respirators. PPE procurement orders are starting to arrive, and jurisdictions are discussing approaches for allocation to support an effective health system response to COVID-19.

To date, the federal government has ordered more than 200 million surgical and N95 masks.

The Public Health Agency of Canada is receiving shipments of personal protective equipment (PPE) at various locations in Canada, including the shipment of over a million masks to a warehouse in Hamilton. Once these deliveries have been appropriately validated, the PPE will be rapidly distributed to the provinces and territories for use by frontline healthcare workers.

The demand for them will continue to be assessed with the provinces and territories as this event continues to progress.

The safety of healthcare workers is a top priority. The Government of Canada continues to work with provincial and territorial partners to respond to the COVID-19 outbreak, and is taking steps to ensure that healthcare workers have the PPE they need to be safe and to protect the health of patients.

Q319. **Why were the NESS facilities in Regina closed and why were masks and gloves replaced?**

The Regina warehouse was closed following an independent evaluation of the National Emergency Strategic Stockpile (NESS) federal warehouse network. The evaluation concluded that using six warehouses instead of nine across Canada would increase distribution efficiency without sacrificing response capacity. For example, since the creation of the NESS, Canada's transportation infrastructure has improved, making it easier to maintain the same 24-hour delivery target with fewer warehouses

In addition to masks and gloves, other outdated supplies, such as bandages, sponges, intravenous administration kits and electrodes, were deemed inappropriate for distribution or donation. Many of these items were over 20 years old and were disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel. We also considered the value of the supplies in relation to shipping costs elsewhere

Q320. **How many masks and gloves were disposed of and why?**

The National Emergency Strategic Stockpile (NESS) reviews its stock of equipment regularly and as part of the review, expired material is disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel. In 2019, approximately 2 million expired masks and 440,000 expired gloves were disposed of during the closure of the NESS warehouse in Regina. The masks and gloves had been purchased in 2009 and had passed the limit of five years for their use, as recommended by the manufacturer.

While the World Health Organization allows for the donation of personal protective equipment, it requires that any equipment be supported by the manufacturer for a minimum of two years. What this means is that equipment must be donated two years before it expires.

The Public Health Agency of Canada (PHAC) follows strict guidelines when deploying materials. If the PHAC cannot account for the quality of material, it will not deploy it. Even under the current circumstances of the COVID-19 pandemic, where Health Canada guidance allows for the deployment of expired personal protective equipment, the PHAC would examine very closely any equipment that is five years old or more. This is in accordance with manufacturers' guidelines.

Q321. **How many other NESS warehouses and inventories have been eliminated or closed in recent years in Canada? How many are left?**

In the past few years, the NESS went from having nine to six warehouses in Canada. The independent evaluation revealed that with these six strategic locations, the NESS is able to fulfill its role of providing timely surge support.

Q322. **Has the decrease in the number of NESS warehouses resulted in a decrease in the number of PPE supplies, or has the same level of PPE supplies simply been consolidated in the smaller number of locations?**

The amount of personal protective equipment supplies stored by the National Emergency Strategic Stockpile is not directly correlated to the number of warehouses across the country. When a warehouse was closed, everything that was usable was moved to a new location, and anything that was damaged, expired, unusable or obsolete was disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel.

Q323. **Why doesn't Ottawa have a plan to release NESS medical supplies to other users (i.e. provincial health care systems) before they expire?**

The mandate of the NESS is to provide surge support to provinces and territories, as well as federal organizations, such as the Correctional Service of Canada. The NESS contains supplies that provinces and territories can request in emergencies when their own resources are insufficient, such as during infectious disease outbreaks, natural disasters and other public health events.

Most supplies have a specific shelf life and must be disposed of after the expiry date. As part of the normal life cycle management of the NESS inventory, expired products may be disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel. The NESS will explore ways to optimize life-cycle management of products to minimize the disposal of expired inventory, while continuing to prioritize the safety of end users.

Q324. **How is personal protective equipment distributed, and how are priorities for distribution established?**

The Government of Canada and the provinces and territories have agreed on a strategy for distributing personal protective equipment (PPE).

Based on needs identified by the provinces and territories, collaborative federal, provincial and territorial (FPT) procurement efforts are focused on acquiring large quantities of PPE and medical supplies, including N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, disinfectants, ventilators and testing supplies. The allocation of these supplies is a collective FPT decision that will support Canada's health care system in its response to COVID-19.

Additionally, to provide surge support to the province and territories, the Public Health Agency of Canada (PHAC) has released items from the National Emergency Strategic Stockpile (NESS). These items include specific types of PPE, such as surgical masks, gloves and N95 respirators, and other items, such as ventilators, disinfectants and hand sanitizers.

To receive supplies from the NESS, the provinces and territories have to submit Requests for Assistance (RFA). PHAC processes RFA as they are received and allocates supplies to provide the provinces and territories with surge capacity, while maintaining a conservative NESS inventory to ensure surge support. Given the current situation, due to high demand for PPE globally, provinces and territories are encouraged to submit RFA for shorter time frames (e.g. surge requirements for one or two weeks) with the option of submitting additional RFA as the outbreak progresses.

Q325. **Is it the Government of Canada's responsibility to restock the National Emergency Strategic Stockpile, or is it the responsibility of the provinces and territories to do so?**

The NESS mandate is to provide surge support to provinces and territories and to federal agencies, such as the Correctional Service of Canada.

PHAC has been working with Public Services and Procurement Canada to place bulk procurement orders of PPE to respond to the needs of provinces and territories, which are also working hard to ensure that they have the necessary supplies for front-line health care workers.

Canada is receiving supply orders and redistributing the majority of supplies to provinces and territories, but it maintains a conservative portion to replenish the NESS for future surge support needs.

Q326. **Has inventory been added to the NESS since the COVID-19 outbreak?**

Orders for personal protective equipment (PPE) and medical supplies were placed early on by federal, provincial and territorial governments to supplement their existing stocks. On March 9, the Prime Minister and Deputy Prime Minister wrote to all premiers to announce their intention to place a bulk procurement order for the medical supplies needed to respond to the COVID-19 pandemic.

PHAC has been working with Public Services and Procurement Canada for some time now to place bulk procurement orders of PPE to meet the needs of provinces and territories, which are also actively trying to obtain the supplies they need to be able to provide front-line health care.

Canada is receiving procurement orders, and FPT governments are working together to ensure that the health care system can effectively fight COVID-19, while replenishing the NESS to meet surge support needs.

We continue to do our best to update the population on the rapidly changing numbers of PPE; however, our priority is getting this protective equipment and delivering it to provinces so that the health care workers who need it most have access.

Q327. **Is the NESS fully integrated with other medical supply repositories in Canada?**

The NESS mandate is to provide surge support to provinces and territories and to federal populations, such as the Correctional Service of Canada. However, in support of the COVID-19

response, PHAC is also accepting and distributing medical supplies from other government departments, companies and countries.

In addition, under Canada's Plan to Mobilize Industry to fight COVID-19, the Government of Canada is providing businesses with direct support to rapidly scale up production or re-tool their assembly lines to develop products, such as personal protective equipment and other critical medical supplies, in Canada.

The Government of Canada has created the Strategic Innovation Fund to provide rapid support to Canadian companies conducting development projects and extensive, promising research aimed at providing medical countermeasures to COVID-19, including vaccines and critical medical supplies.

Q328. **Was a recent notice on the Government of Canada's Buy and Sell site a tender to identify additional suppliers for the NESS?**

The Government of Canada is exploring all avenues to secure medical supplies, including personal protective equipment (PPE), in order to prepare for and respond to the COVID-19 outbreak.

The notice posted on the Buy and Sell site to identify additional suppliers will benefit federal, provincial and territorial governments, and the National Emergency Strategic Stockpile (NESS).

More information on the Government of Canada's response can be found here.

Q329. **Does PHAC have to go to tender to replenish NESS supplies, or can it use the Emergency Rule to buy directly?**

PHAC follows appropriate laws, policies and guidelines with respect to procuring supplies or assets for the NESS. Competitive procurement practices, such as the use of established supply arrangements or requests for proposals, are routinely used to access the supply chain.

On March 14, 2020, PHAC requested and received a national security exception for the procurement of goods and services required by the Government of Canada to respond to the COVID-19 outbreak. With this authority, PHAC will not be required to go to tender to replenish NESS supplies and will work with Public Services and Procurement Canada to determine the best procurement strategy.

Q330. **A 2010 audit revealed that PHAC did not have a full, up-to-date inventory of its stockpile of emergency medical supplies for distribution to provinces during public health emergencies such as this one. Does the federal government have a full inventory of its stockpile of emergency medical supplies now? Did the federal government share this inventory with the provinces or the public? Can you provide proof of this inventory?**

Following the 2010 audit, the Public Health Agency of Canada (PHAC) put an electronic inventory system in place to track the National Emergency Strategic Stockpile (NESS) inventory. The

provinces and territories are informed of NESS assets; however, for security reasons, PHAC does not disclose the NESS inventory to the public.

Q331. **What has changed since the 2011 NESS evaluation report?**

Since the 2011 evaluation, the NESS has evolved to better align with the ever-changing risk environment and is investing in strategic assets, such as medical countermeasures and mini-clinics, to enhance the Agency's ability to support surge requests during health emergencies. In addition, there has been increased engagement with provincial and territorial partners and other stakeholders to increase awareness of NESS capabilities.

Q332. **Could you explain why the number of warehouses that store NESS supplies was reduced? Did this measure lead to a decrease in the federal government's supply of personal protective equipment (PPE)?**

Canada's National Emergency Strategic Stockpile (NESS) contains supplies that provinces and territories can request in emergencies, such as infectious disease outbreaks, natural disasters and other public health events, when their own resources are not enough. The purpose of the NESS is to provide provinces and territories with backup. It is not intended to replace supplies that provinces or territories hold or procure. Provinces and territories are responsible for coordinating and maintaining their own supply capacities.

Over the past decade, we have reduced certain supplies in the NESS. For example, blankets were previously part of the stockpile but are now available through other channels, so they are no longer needed in large supplies through the NESS. As the NESS has modernized, it has focused on stockpiling strategic medical supplies that are typically not held by provinces and territories, such as drugs and vaccines that require controlled environmental conditions.

Following an independent assessment of the federal warehouse network, the NESS moved from nine warehouse locations across Canada to six to offer the most efficient distribution system without sacrificing response capacity. For example, the NESS was created, Canada's transportation infrastructure has improved, making it easier to maintain the same 24-hour delivery target with fewer warehouses.

NESS supplies are reviewed and purchased regularly. In January, the Public Health Agency of Canada (PHAC) began monitoring the coronavirus outbreak in China, assessing its NESS inventories and procuring the supplies needed to respond to the possible outbreak in Canada.

Q333. **In the early 2000s, the NESS had 165 fully equipped mobile hospitals containing 33,000 beds (hospital beds/cots). During the events of September 11, 2001, 19,000 of those beds were deployed to Nova Scotia and Newfoundland and Labrador. What happened to those supplies?**

The National Emergency Strategic Stockpile (NESS) was created during the Cold War to provide medical and social services supplies in response to public health emergencies, particularly nuclear disasters. The mobile field hospitals remained from that time and no longer complied with the current Canadian standards of care. Since 2013, supplies from these field hospitals have been reallocated for continued use in mini-clinics, stockpiled for future

emergencies, destroyed or recycled, or donated for historical reasons in accordance with the Treasury Board's policy on disposing of surplus moveable Crown assets.

The retained items include cots and blankets, which are still used upon request to support provincial and territorial responses to health emergencies. The NESS kept one field hospital as an artefact.

Q334. **In the early 2000s, there were 10 regional warehouses. Now there are 5. Why was a decision made to reduce the number of locations?**

Until 2011, the NESS comprised 11 warehouses in 9 locations. In 2013, a decision was made to modernize and optimize stockpile warehouses. These measures were taken to reflect changes to the new NESS operating environment. These changes include improved partner capacity (federal, provincial and territorial, and non-government organizations) and better transportation infrastructure, which reduced asset delivery times across Canada. An independent assessment of the federal NESS warehouse network concluded that the use of 6 warehouses across Canada instead of 9 would ensure more efficient distribution without sacrificing response capacity.

In 2019, all NESS holdings were stored in 8 warehouses across 6 locations. In March 2020, an additional warehouse was rented in Ottawa, given the volume of supplies provided to and purchased by the NESS as part of the federal government's response to COVID-19.

Q335. **Streamlining NESS supplies put greater emphasis on pharmaceuticals than medical equipment. Can you confirm that and explain why?**

That's right. The role of the NESS is to provide surge capacity to support provincial and territorial emergency response. The NESS procures assets based on evolving treats and risks related to emergency preparedness and response. It is focused on its role as a primary supplier of medical countermeasures that provinces and territories typically do not stockpile. The NESS also has a supply of antivirals to support provincial and territorial surge capacity in case of an influenza pandemic.

Provincial and territorial governments are primarily responsible for procuring supplies and equipment for health care services. To address the unprecedented PPE shortages as a result of COVID-19, the Government of Canada took the following measures:

- ordered additional supplies as part of mass procurement efforts with provinces and territories;
- made new logistical arrangements for the delivery of supplies;
- set up national production activities for certain supplies.

VACCINE AND TREATMENT

Q336. **Is there a vaccine that protects against coronaviruses in humans? If no vaccines have been approved, are any being developed or tested?**

Currently, there is no approved vaccine that protects against coronaviruses in humans.

The World Health Organization (WHO) is working with the Coalition for Epidemic Preparedness Innovations to coordinate international collaboration to help advance the research and development of a COVID-19 vaccine.

The Public Health Agency of Canada and the Canadian Institutes of Health Research—in consultation with international partners, including the WHO and the Global Research Collaboration for Infectious Disease Preparedness — are assessing how scientists at our National Microbiology Laboratory, along with the broader Canadian research community, will participate in global research efforts.

Q337. **Canada is spending millions of dollars to fund vaccine research. If a Canadian group develops a vaccine, will the initial doses be given to Canadians first? Is that an explicit condition of all Canadian funding?**

The Government of Canada is aware that access to the right tools and technology to combat COVID-19, such as vaccines, will be essential to our response. Canada has joined other G20 countries that have committed to enhancing coordination efforts to develop, manufacture and rapidly distribute vaccines, while meeting efficacy, safety, equity, accessibility and affordability objectives.

The federal government has invested over a billion dollars in medical research to support multiple organizations working to develop vaccine candidates. Universities, small and medium enterprises, and large multinational pharmaceutical companies around the world are currently working on over 100 vaccine candidates, including 10 in Canada, that are in various stages of development. With the government's contribution to vaccine development, Canada will be better positioned to rapidly access a vaccine, when one become available.

Through the Canadian Institutes of Health Research (CIHR) and the National Sciences and Engineering Research Council (NSERC), the Government of Canada provides grants to support independent researchers working in external laboratories. CIHR and NSERC do not own the findings of the research they fund nor do they control the findings' commercialization. Rather, the researchers receiving the funding and their organizations do. Therefore, they are the initial holders of the intellectual property rights.

Giving the vaccine to Canadians first was not a condition of CIHR and NSERC funding. Conditions mainly apply to openly sharing research findings and data on the COVID-19 outbreak, for example, in peer reviewed journals and between researchers. The conditions of CIHR funding are listed on its website.

As a condition of NSERC funding, for each of the projects they proposed, applicants had to demonstrate that the research would benefit Canada. For COVID-19 grants, researchers were told that their findings would be openly accessible and proactively shared with government authorities who could make appropriate use of the findings to produce rapid results for Canada.

The Human Health Therapeutics Research Centre of the National Research Council (NRC) is also conducting vaccine research. When this work is done in collaboration with external partners, our collaborative and technology transfer agreements support benefits for Canadians.

If NRC-supported endeavours result in a vaccine candidate or new analytical tests, specific distribution plans will be developed in consultation with the Public Health Agency of Canada.

Q338. **Would Canada impose restrictions on vaccine exports to ensure that products manufactured in Canada will be available to Canadians?**

To date, Canada has not imposed new restrictions on exports in response to COVID-19. It has sought to facilitate trade by providing temporary relief from duties and taxes in order to support the importation of supplies that public health authorities, health care centres (e.g. hospitals, testing sites) and first responder organizations absolutely need to address the COVID-19 crisis.

Canada is leading the work being done by like-minded countries and within multilateral institutions to keep supply chains open so that people in Canada and around the world can have access to medication, medical supplies and other products they need, especially at such a critical time, as stated in the joint ministerial statement and the G20 trade and ministerial statement.

To ensure stable procurement of medical supplies and equipment for Canadians, Canada is

- taking measures to increase domestic supply by funding the University of Saskatchewan's Vaccine and Infectious Disease Organization-International Vaccine Centre (VIDO-InterVac);
- helping the National Research Council Canada upgrade its Human Health Therapeutics Research Centre to develop, test and scale up promising vaccine candidates so that they are ready for industrial production;
- providing support through the Strategic Innovation Fund to Medicago, a company that has found a viable, plant-based vaccine candidate that is currently in pre-clinical trials, to quickly move on to clinical trials, and then promptly increase production to respond to the pandemic;
- purchasing supplies from other countries and, only if necessary, implementing targeted, proportionate, transparent and temporary import and export measures.

Q339. **Has Canada committed to giving 10% of its supply to the WHO? What is Canada doing to ensure that vaccines will be available where they are needed most?**

In addition to national efforts, Canada is also contributing significantly to international vaccine development initiatives. Through the funding it has given to the Coalition for Epidemic Preparedness Innovations (CEPI), which is working closely with the World Health Organization to develop a COVID-19 vaccine, Canada is determined to support global efforts to develop and manufacture COVID-19 vaccines that will be available to everyone equitably.

One of the cornerstones of the CEPI is enabling equitable access to vaccines for all populations affected by pandemics. In the context of the COVID-19 pandemic, that means that relevant vaccines developed through CEPI-funded initiatives will first be made available to populations

when and where the vaccines are needed most to stop an outbreak, regardless of geography or ability to pay.

The Government of Canada has signed the Pandemic Influenza Preparedness Framework. Under the Framework, manufacturers of vaccines or antivirals must commit to at least two of the six options in return for biological materials needed to develop and test vaccines and antivirals. One of the six options is donating at least 10% of real time pandemic vaccine production to the WHO.

Q340. **Has Canada ever entered into a contract for the purchase of a pandemic vaccine with a supplier capable of producing large quantities when needed?**

Canada cannot put a procurement contract in place for the supply of a COVID-19 vaccine because currently there is no COVID-19 vaccine. By investing over a billion dollars in medical research, the federal government is supporting multiple organizations working to develop vaccine candidates. Universities, small and medium enterprises, and large multinational pharmaceutical companies around the world are currently working on over 100 vaccine candidates, including 10 in Canada, that are in various stages of development. With the government's contribution to vaccine development, Canada will be well positioned to rapidly access a vaccine, when one become available.

Canada entered into a 10-year contract with GlaxoSmithKline for the distribution of a pandemic **influenza** vaccine manufactured domestically to respond to a declared influenza pandemic, but the contract and the manufacturing facilities are intended for the production of egg-based influenza vaccines only.

Q341. **How long will it take to develop a vaccine?**

Coronaviruses are a group of viruses that can cause a wide range of illnesses from the common cold to Severe Acute Respiratory Syndrome (SARS) to Middle East Respiratory Syndrome (MERS-CoV). The challenge of developing a vaccine that protects against coronaviruses is that infection by human coronaviruses does not provide long-lasting immunity, meaning someone can be re-infected in the future following recovery from an initial infection.

Although a vaccine that provides long-term immunity remains a challenge, an outbreak vaccine aimed to provide short-term protection (similar to a pandemic influenza vaccine) to respond to a novel coronavirus outbreak could potentially be developed.

It could take years for researchers to develop a vaccine for a specific coronavirus.

For example, there are currently no licensed vaccines or specific treatments for Middle East Respiratory Syndrome coronavirus (MERS-CoV)—a particular coronavirus that was first identified in 2012. We know that work is being done elsewhere to better understand how MERS-CoV infections might be prevented and to develop a MERS-CoV vaccine. This includes vaccine development efforts being coordinated by the WHO and the Coalition for Epidemic Preparedness Innovations (CEPI).

Q342. **Is the PCV13 vaccine, used against pneumonia, useful as a therapy against COVID-19?**

There are currently no vaccines or other health products authorized specifically for the prevention or treatment of COVID-19, as it is still a relatively new virus.

For vaccines or other health products that show early promise in treating COVID-19, including secondary infections that may be associated with the illness, clinical trials are the best way to proceed, as they give the health care community a way to systematically collect information on the treatments' effectiveness and possible risks. To date, Health Canada has not received any applications for clinical trials to test pneumonia vaccines as treatments for COVID-19-related infections.

Health Canada is working closely with many potential clinical trial sponsors to support Canadians' access to COVID-19 clinical trials. To facilitate earlier access to needed therapeutic products to treat or prevent COVID-19, Health Canada will expedite its regulatory process, including the review of submissions and the approval of clinical trial applications, for any COVID-19-related health products, while ensuring the safety of trial participants. In addition to work done by professional societies, clinical trials are being coordinated across the health portfolio in Canada and globally.

Q343. **How are people being treated for this illness?**

At present, there is no drug or medication to treat people who have COVID-19. Researchers are looking at the effectiveness of existing antiviral treatments.

The World Health Organization has provided health care professionals with advice that includes recommendations for early supportive therapy, management of symptoms and prevention of complications.

The novel coronavirus causes a range of symptoms from mild to severe, depending on the individual. Therefore, if you have travelled outside of the country, it is important to monitor your health when you return to Canada. While abroad, you may have come into contact with the novel coronavirus. PHAC asks that you monitor your health for fever, cough and difficulty breathing for 14 days after you arrive in Canada. If you develop any of these symptoms, call your health care provider or your local public health authority to inform them. They will advise you as to what to do.

Q344. **Is Health Canada investigating these reports, and are there any current guidelines for the use of Vitamin C as a defence or treatment against the coronavirus?**

Since the outbreak of COVID-19, Health Canada has taken actions to support Canadians in accessing health products they need to either treat or prevent COVID-19. Currently, there are no drugs specifically authorized to treat COVID-19, since it is still a relatively new virus. Much work is being done to investigate new potential therapies, including drugs that may have been authorized for the treatment of illnesses other than COVID-19. The best way to provide Canadians with access to drugs that show an early promise in treating COVID-19 is through

clinical trials, as they give the health care community a way to systematically collect information on the treatments' effectiveness and possible risks.

Health Canada recently approved an application for a clinical trial to investigate the use of intravenous Vitamin C to improve the functioning of certain organs in patients with severe cases of COVID-19 and closely monitor the progress.

To facilitate earlier access to needed therapeutic products to treat or prevent COVID-19, Health Canada will expedite its regulatory process, including the review of submissions and the approval of clinical trial applications, for any COVID-19-related health products. In addition to work done by professional societies, clinical trials are being coordinated across the health portfolio in Canada and globally. The landscape is rapidly changing, and the health portfolio is working to adapt to shifting needs.

Q345. **Are there safety issues with the use of ibuprofen in COVID-19 cases?**

There is no scientific evidence that establishes a link between ibuprofen, or other non-steroidal anti-inflammatory drugs (NSAIDs), and the worsening of COVID-19 symptoms.

If you have COVID-19 symptoms, talk to you your health care provider about the most appropriate health products to treat fever or pain. If you are currently taking ibuprofen, especially for a chronic illness, do not stop taking it.

Q346. **Can hydroxychloroquine and azithromycin be used to treat anyone who has COVID-19? Will they be effective for everyone?**

Hydroxychloroquine is an antiparasitic drug that is indicated for the treatment of malaria and autoimmune diseases such as rheumatoid arthritis and lupus.

Azithromycin is an antibiotic used to treat pneumonia and other bacterial infections.

There is some evidence to suggest that these drugs may be effective for some patients; however, these are preliminary findings from a few very small studies. There are also some known significant safety risks associated with both drugs, such as QT prolongation, which is a serious heart rhythm condition. A health care practitioner may choose to use these drugs for off-label purposes, depending on the patient's situation, specifically the seriousness of the patient's illness, if the potential benefits outweigh the drug's known risks.

In Canada, a doctor's decision to prescribe a particular drug to a patient for a labelled or off-label use is part of the practice of medicine. While Health Canada regulates drugs, it is the responsibility of health care professionals to consider information from medical journals, reports, and peer-reviewed studies when prescribing medication.

Q347. **Does Health Canada have an official position on the use hydroxychloroquine and chloroquine to treat COVID-19?**

Health Canada recognizes that Canadians with COVID-19 need access to safe and effective drugs and treatments. Hydroxychloroquine and chloroquine are available on the Canadian market to treat other illnesses, but they have not been approved to treat COVID-19.

International reports suggested that hydroxychloroquine and chloroquine were promising drugs for treating COVID-19, but that remains to be confirmed. The best way to provide Canadians with access to drugs that show an early promise in treating COVID-19 is through clinical trials, as they give the health care community a way to systematically collect information on the treatments' effectiveness and possible risks. Therefore, Health Canada encourages manufacturers to work with researchers so that these drugs can be given to patients with COVID-19 during clinical trials.

On April 8, 2020, Health Canada approved two clinical trials for the use of hydroxychloroquine to treat COVID-19. Health Canada also approved nine clinical trials for other potential therapies. A list of clinical trials approved for the prevention or treatment of COVID-19 and its associated complications can be found in Health Canada's Clinical Trials Database. To search the database, enter "COVID" in the medical condition field.

Q348. **What is Health Canada doing about products claiming to prevent, treat or cure COVID-19?**

At this time, there is no vaccine for COVID-19 or any natural health products—including traditional Chinese medicines—that are authorized to treat or protect against COVID-19.

Selling unauthorized health products or making false or misleading claims to prevent, treat or cure COVID-19 is illegal in Canada. The Department takes this matter very seriously and will take action to stop this activity. To date, Health Canada has not approved any product to treat or cure COVID-19. 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). The Department is taking action to address complaints regarding unauthorized products on the Canadian market that make false or misleading claims for the treatment, prevention or cure of COVID-19.

The Department encourages anyone who has information regarding the potential non-compliant sale or advertising of any health product claiming to treat, prevent or cure COVID-19, to report it using the online complaint form.

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 correct non-compliance or mitigate a risk to Canadians, including site visits, public communications, recalls, and the seizure of products and advertising materials. The primary objective of the Department's compliance and enforcement approach is to manage the risks to Canadians by using the most appropriate level of intervention, in accordance with Health Canada's Compliance and Enforcement Policy for Health Products.

Q349. **What actions will Health Canada take if there is non-compliance with health products that claim to cure, treat or prevent COVID-19?**

Under the *Food and Drugs Act*, free distribution of a health product is considered advertising. If Health Canada becomes aware of companies distributing free samples of unauthorized products or free samples of authorized products making false and misleading claims, Health Canada will ask the parties involved to immediately stop the distribution and will take all necessary compliance and enforcement actions to ensure compliance, which may include seizure of the product.

As previously mentioned, Health Canada has not approved any products for the treatment or cure of COVID-19, including any traditional Chinese medicines. Selling unauthorized health products or making false or misleading claims about COVID-19, its prevention, treatment or cure is illegal in Canada.

The distribution of free samples of authorized products making false and misleading claims or any other form of advertising making such claims is illegal and considered false and misleading. The Department takes this matter seriously and will not hesitate to use all the tools at its disposal to stop such activities.

Health Canada is currently assessing this advertising issue and will take all necessary action to enforce the law if non-compliance with the legislation or regulations is found.

The Department encourages anyone who has information regarding the potential non-compliant sale or advertising of any health product claiming to treat, prevent or cure COVID-19, to report it using the online complaint form.

Q350. **Are there any natural health products, including traditional Chinese medicines, Ayurvedic medicines and homeopathic products to protect against or treat this virus?**

No authorized natural health products are approved to protect against or treat COVID-19. This includes traditional Chinese medicines, Ayurvedic medicines and homeopathic products.

Q351. **Is Avigan or favipiravir approved in Canada? Is Canada taking any steps to get them approved?**

Avigan is the brand name for favipiravir. This antiviral drug has been approved in Japan and China for the treatment of influenza. There are currently no products containing favipiravir approved in Canada.

Since the outbreak of COVID-19, Health Canada has taken measures to support Canadians in accessing health products they need to either treat or prevent COVID-19. To provide earlier access to a vaccine or therapeutic product for COVID-19, Health Canada will expedite its regulatory process for any COVID-19-related health products, including the review of submissions and authorization of clinical trial applications.

Health Canada initiated conversations with companies whose products have shown promise in fighting COVID-19, including the company that manufactures favipiravir. However, to date, Health Canada has not received a submission for a product containing favipiravir. It is ultimately up to the manufacturer to decide whether they choose to seek market authorization for their product in Canada.

For medications that show some promise in treating COVID-19, such as favipiravir, Health Canada encourages sponsors to work with researchers and offer medicine to patients in the context of clinical trials. This would ensure that there is informed consent for patients, and the

healthcare community would be able to learn whether the treatments are effective, and what the associated risks are.

Q352. **Will Health Canada or the Public Health Agency of Canada be issuing treatment guidelines if drugs like favipiravir or other antivirals, or any other drug, is found effective in another country/jurisdiction at treating COVID-19?**

At this time, there is insufficient evidence to recommend any specific anti-COVID-19 treatment for patients with confirmed COVID-19 outside of clinical trials. There are many ongoing clinical trials testing various potential antivirals registered on https://clinicaltrials.gov/ or on the Chinese Clinical Trial Registry (http://www.chictr.org.cn/abouten.aspx). Clinical guidelines are currently being developed in conjunction with the Association of Medical Microbiology and Infectious Disease Canada and the Canadian Critical Care Society.

Drugs not available in Canada can be accessed through clinical trials or the Special Access Programme. Should there be data available to support a submission to Health Canada concerning the effectiveness of a drug in treating COVID-19, if approved, directions for use would be included in the product monograph. Other organizations may provide additional guidelines for off-label use of other products shown to be effective.

Q353. **What other regulatory flexibilities is Health Canada contemplating in addition to this ongoing review model?**

Companies interested in filing a drug submission to treat or prevent COVID-19 are encouraged to contact Health Canada to discuss the details of their submission and to indicate if there are other flexibilities that Health Canada should consider for their submission in response to the COVID-19 pandemic.

Clinical trials

Q354. **Are there clinical trials underway to determine whether hydroxychloriquine and azithromycin are effective?**

Yes. Health Canada has authorized clinical trials on the use of hydroxychloroquine to treat COVID-19 in Canada and is aware of other ongoing clinical trials across the world. Health Canada is closely monitoring their developments.

Any company or healthcare professional treating patients with COVID-19 wishing to conduct a clinical trial to evaluate the effectiveness of these or other drugs is encouraged to contact Health Canada.

A list of clinical trials approved for the prevention or treatment of COVID-19 or its complications can be found in Health Canada's Clinical Trials Database by entering "COVID" in the medical condition box.

Q355. **Is hydroxychloroquine or chloroquine used in Canadian hospitals for trials or treatment?**

There are two Canadian-approved clinical trials being conducted in several locations across the country.

Since both hydroxychloroquine and chloroquine have been approved in Canada for the treatment of other diseases, medical practitioners may prescribe these drugs outside of their approved indications (off-label use). The use of off-label drugs is within the scope of medical practice and is regulated at the provincial level.

Q356. **Are "human challenge trials" sometimes authorized by Health Canada? Is this WHO document one of the reference tools used by Health Canada in the development of its regulations on "human challenge trials"? Or is there something else more up-to-date from the WHO on this matter?**

There are no ongoing vaccine trials in Canada for COVID-19, and Health Canada has not received any requests for challenge studies. The list of clinical trials authorized by Health Canada for COVID-19 is available online.

According to the *Food and Drug Regulations*, a clinical trial must be conducted in accordance with good clinical practices, with the approval of a research ethics board, with informed consent and with thorough safety monitoring to protect the participant. If carefully monitored, it may be possible to conduct a challenge study to assess the efficiency of a vaccine. Health Canada's approach would generally be consistent with international best practices, such as guidelines from the World Health Organization and other major regulatory organizations.

Q357. **Can you give us details on how plasma therapy for COVID-19 works before it is approved?**

Health Canada worked closely with clinical trial sponsors and blood suppliers, Canadian Blood Services and Héma-Québec, to provide regulatory and scientific advice in support of the development of this blood plasma testing protocol. Health Canada has recently received a clinical trial application for the use of blood plasma from patients who have recovered from COVID-19 to treat other patients. As with other COVID-19 clinical trial applications, the review of this application has been prioritized and is being expedited. Typical timelines for clinical trials to be authorized depend on the information submitted in support of the trial and can be up to 30 days. Priority review timelines vary, but it is expected that this review will be completed within one to two weeks. The objective of the Health Canada review is to protect the health of the study participants and others, to ensure that the trial is in the best interest of the study participants, and to determine whether the study objectives will be met.

Q358. **What are the criteria for plasma donations for men who have had sex with men (MSM) in the last three months? Will they be allowed to donate plasma, or is this the status quo?**

To conduct a clinical trial in Canada—including a trial using convalescent plasma from people who have recovered from COVID-19—a sponsor must submit a clinical trial application (CTA) to Health Canada for review and authorization. The purpose of the Health Canada review is to

determine whether the trial could endanger the health of the study participant or the health of others, whether the trial is in the study participant's interest, and whether the study objectives will be met. Independent of the review by Health Canada, the trial must also be approved by the research ethics boards associated with the trial sites before patients can be recruited. Therefore, it is the sponsor of the CTA who must determine the procedural protocols for the trial in their application. For trials involving plasma or blood products, this would include donor selection criteria.

To date, Health Canada has authorized a convalescent plasma clinical trial for the treatment of COVID-19. This multi-centre trial is designed to determine the safety and efficiency of COVID-19 convalescent plasma collected from donors who have recovered from a COVID-19 infection to reduce the risk of intubation or death in adults admitted to hospital for a respiratory disease due to COVID-19. Canadian Blood Services and Héma-Québec will be responsible for providing donor plasma for this clinical trial. The plasma will be collected and processed according to protocols already in place under the authority of Health Canada, including the current donor deferral for men who have had sex with another man in the past three months.

Q359. **Is Canada participating in the Solidarity II project led by WHO?**

As part of the World Health Organization (WHO) R&D Blueprint and response efforts in the fight against COVID-19, WHO has launched a multinational clinical trial to investigate potential treatments for COVID-19.

The signatories to date include Canada, Argentina, Bahrain, France, Iran, Norway, South Africa, Spain, Switzerland and Thailand. Other countries may join at a later date.

The objective is to generate reliable data by applying the same study protocol to multiple sites to obtain statistically reliable results from a sufficient number of patients.

The principal investigator in Canada is Dr. Srinivas Murthy from British Columbia. There are currently 31 Canadian hospitals in various stages of activation to implement this clinical trial.

Dr. Murthy received a $954,936 grant from the Canadian Institutes of Health Research to study treatments through observational studies and randomized controlled trials.

Initial interventions to include are the following: 1) lopinavir/ritonavir combination currently marketed for HIV versus standard of care; and 2) hydroxychloroquine, currently marketed for malaria, which will be added to the protocol at a later date.

Lianhua Qingwen capsules

Q360. **Have Lianhua Qingwen capsules been approved for sale in Canada? If so, why?**

Health Canada has licensed Lianhua Qingwen capsules with the following recommended use: "Traditional Chinese Medicine helps remove heat-toxin invasion of the lung, including symptoms such as fever, aversion to cold, muscular soreness, stuffy and runny nose, dry and sore throat, red tongue with yellow and greasy coating."

All natural health products sold in Canada must meet the requirements of the *Food and Drugs Act* and the *Natural Health Products Regulations*. Health Canada assess the safety, effectiveness and quality of natural health products based on ingredients and health claims. An eight-digit Natural Product Number (NPN) or Homeopathic Medicines Number (DIN-HM) is issued after all regulatory requirements have been met and before the product can be sold on the Canadian market.

Detailed information about Lianhua Qingwen capsules (NPN 80033781) can be found in Health Canada's Licensed Natural Health Products Database available to the public.

Q361. **Are Lianhua Qingwen capsules effective in curing COVID-19, as claimed by the manufacturer?**

At this time, no health products, including traditional Chinese medicines, have been authorized by Health Canada to treat or protect against COVID-19.

Selling unlicensed health products or making false or misleading claims about the prevention, treatment or cure of COVID-19 is illegal in Canada. The Department takes this matter very seriously and will take action to stop this activity. To date, Health Canada has not approved any product to treat, prevent or cure COVID-19. The Department is taking action to respond to complaints about unauthorized products on the Canadian market that make false or misleading claims about the treatment, prevention or cure of COVID-19.

Health Canada is currently assessing this advertising issue and will take all necessary enforcement action if there is non-compliance with the legislation or regulations.

The Department encourages anyone who has information regarding the potential misleading sale or advertising of any health product claiming to treat, prevent or cure COVID-19 to report it using the online complaint form.

Q362. **Is it true that Ephedra is one of the ingredients used in the Lianhua Qingwen capsules and is prohibited by Health Canada?**

The medicinal ingredient Ephedra (*Ephedra sinica*) is not prohibited by Health Canada. The Monograph: Ephedra provides detailed information on the requirements that must be met to ensure this ingredient is safe in natural health products. All natural health products, including products containing Ephedra, must be authorized by Health Canada and have a valid eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) to be legally sold in Canada.

Q363. **Has Health Canada received any complaints about Lianhua Qingwen capsules?**

As of April 21, 2020, Health Canada has received two complaints regarding Lianhua Qingwen. capsules. As a result of these complaints, Health Canada has opened files and is taking steps to check if there have been any cases of non-conformity. Given that these are active and ongoing files, the Department is unable to provide details regarding the compliance and enforcement actions it might consider.

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 correct non-compliance or mitigate a risk to Canadians, including site visits, public communications, recalls, and the seizure of products and advertising materials.
The Department encourages anyone who has information regarding potential non-complaint advertising of any health product claiming to treat, prevent or cure COVID-19 to report it by sending us an email at drug-device-marketing@canada.ca or using the online complaint form.

Temporary exemption under the Controlled Drugs and Substances Act *for medical treatments*

Q364. **Was this exemption requested by provinces and territories?**

Health Canada received inquiries from a few jurisdictions regarding measures that would be implemented to facilitate access to certain medical treatments during the pandemic. The Department has taken quick action to respond to their concerns and to prevent potential issues related to accessing medical treatment during the pandemic.

Q365. **How soon will pharmacists and practitioners be able to begin doing these new activities?**

In response to the COVID-19 outbreak, Health Canada has temporarily exempted certain new activities that apply to pharmacists who are registered and entitled to practice pharmacy under the laws of their province or territory and are entitled to conduct activities with controlled substances. They may practice these activities if their province or territory and licensing body adopt these measures. Health Canada recommends contacting the provincial and territorial licensing bodies for more information.

Given the seriousness of the COVID-19 outbreak, Health Canada is working quickly to help jurisdictions maintain access to medications for Canadians.

Q366. **What activities are currently authorized for pharmacists?**

Pharmacists are medication experts and play a significant role in monitoring patients and medication to ensure safe and optimal use while contributing to the delivery of outcome-focused care. According to the regulations under the *Controlled Drugs and Substances Act*, a pharmacist is authorized to sell or provide a controlled substance to a person if they have received a prescription or a written order from a practitioner.

While these regulations do not permit pharmacists to prescribe medication, other related activities that are included in the meaning of *sell* or *provide* are permitted as long as the quantity dispensed does not exceed the amount originally authorized. These activities include, but are not limited to:

- **Adjusting the formulation:** adjusting the dosage form in which the drug is prescribed
    - E.g. change from pill to liquid formulation;

- **Adjusting the dose and regimen:** a structured plan that specifies the frequency in which a dose of medication should be ingested
    - E.g. change from 20mg per day for 5 weeks to 10mg per day for 10 weeks;
- **De-prescribing:** the planned and supervised process of reducing or stopping a medication; and
- **Part-filling:** dispensing a quantity of a medication that is less than the total amount of the drug authorized by a practitioner
    - For greater clarity, this includes part-fills requested by a patient, when a pharmacy is dealing with an inventory shortage or other situations where the nature of the part-fill is a matter of discussion between the pharmacist and patient.

With the goal of supporting better medication management and protecting the health and safety of Canadians, Health Canada has shared with pharmacists an interpretive guide on activities related to prescribing controlled substances under the *Narcotic Control Regulations*, *Benzodiazepines and Other Targeted Substances* and Part G of the *Food and Drug Regulations*.

Q367. **If a patient doesn't have a prescription, can a pharmacist now prescribe new medications for patients?**

With this exemption, pharmacists can be authorized to renew or extend prescriptions in order for the patient to have access to a medication. Pharmacists are not authorized to prescribe new medical treatment with controlled substances (e.g. narcotics).

Q368. **Does this exemption apply to other healthcare professionals?**

This exemption applies to other healthcare professionals, including nurse practitioners, dentists and veterinarians, allowing them to verbally prescribe narcotics (depending on the prescriber's scope of practice and the provincial or territorial authorization).

Q369. **Has there been any consideration of permanently giving pharmacists extended authorities?**

Pharmacists are medication experts and play a significant role in monitoring patients and medication to ensure safe and optimal use in patient care.

With the goal of supporting better medication management and protecting the health and safety of Canadians, in March 2019, Health Canada launched an official consultation for input on ways to modernize the role of pharmacists in the healthcare system. The Department is currently analyzing all feedback received. There will be another opportunity to comment on any draft regulations that are developed in the *Canada Gazette*, Part I. Health Canada encourages everyone to participate in the consultation.

Q370. **Are there any special provisions being made to assist supervised consumption sites during the COVID-19 pandemic?**

Health Canada recognizes that local precautionary measures taken to combat the pandemic may impact the operations of supervised consumption sites and services. The Department continues to work directly with site operators to assess situations on a case-by-case basis and determine appropriate modifications to their protocols and practices. Operators are encouraged to contact the Office of Controlled Substances' exemption section at (hc.exemption.sc@canada.ca).

VIRUS TRANSMISSION

Q371. **How is COVID-19 transmitted?**

Based on current evidence, COVID-19 is most often transmitted from an infected person:

- Through respiratory droplets produced when an infected person coughs or sneezes;
- Through close personal contact with an infected person, such as direct contact or a handshake;
- Through contact with surfaces contaminated with the virus, followed by contact of unwashed hands with the mouth, nose or eyes.

In general, coronaviruses are a large family of viruses, some of which cause disease in humans, while others circulate in animals, including camels, cats and bats.

Q372. **Can COVID-19 be transmitted when a person is not showing symptoms?**

Now that more countries have had large numbers of cases and have analysed transmission patterns, recent studies provide evidence that infected people can transmit the virus before they develop symptoms. We refer to this as pre-symptomatic transmission.

There is also evidence that some infected people who never develop symptoms are also able to transmit the virus. This is called asymptomatic transmission. We do not know how much of a role pre-symptomatic and asymptomatic transmission plays in driving this epidemic at this time—but we know that it is occurring among those in close contact or in close physical settings.

While the primary driver of the global COVID-19 pandemic has been individuals with visible symptoms (coughing and respiratory droplets are key ways the virus is spread), evidence of asymptomatic transmission points to the importance of everyone, even those who feel fine, following the proven methods of preventing transmission.

The following are methods proven to prevent the transmission of COVID-19:

- Staying at home as much as possible;
- Practicing physical distancing;
- Washing your hands;
- Protecting those most vulnerable from infection and limiting their exposure to others;
- Coughing into a tissue or your sleeve.

Q373. **What should you do if you have been exposed to an individual who has a confirmed case of COVID-19?**

If you **do not have symptoms**, but believe you were exposed to a source of COVID-19, the Public Health Agency of Canada asks that for the next 14 days you do the following:

- Monitor your health for **fever**, **cough** and **difficulty breathing**;
- Avoid places where you cannot easily separate yourself from others if you become ill.

To further protect those around you, wash your hands often and cover your mouth and nose with your arm when coughing or sneezing.
If you **develop symptoms of COVID-19**, isolate yourself as quickly as possible. Immediately call a healthcare professional or the public health authority https://www.canada.ca/en/public-health/services/publications/diseases-conditions/2019-novel-coronavirus-information-sheet.html Describe your symptoms and travel history. They will advise you on what action to take.

Q374. **What are the statistics on asymptomatic cases in Canada?**

The Public Health Agency of Canada (PHAC) and provincial and territorial public health authorities are working together to provide Canadians with the best and most accurate information available. Every effort is made to ensure timely reporting, but as with any disease surveillance, there are delays in reporting some data.

Provinces and territories report data using the Coronavirus Disease (COVID-19) Case Report Form. According to the 22,217 disease case report forms received as of April 22 at 11:00 a.m. (EDT), PHAC is aware of 220 cases that were classified as asymptomatic, representing 2.7% of cases for which symptom status was known (n=7,879). It should be noted that the presence of symptoms was unknown in 65% of cases reported to PHAC.

This is not an accurate representation of asymptomatic cases due to incomplete data and the fact that COVID-19 screening focuses on symptomatic individuals. In addition, data on these cases on the report form are preliminary and may have missing values for characteristics of interest. Provinces and territories may not systematically update detailed data. Although a patients' condition may change as the disease progresses, PHAC does not receive regular updates on the patients' status.

Q375. **Are Canadians at risk for contracting COVID-19 if they touch a surface that could potentially be contaminated?**

In general, coronaviruses do not survive on surfaces that have been contaminated.

The best way to prevent COVID-19 and other respiratory illnesses is to do the following:

- avoid touching your eyes, nose and mouth with your hands;
- consistently practice good hand hygiene measures, which includes frequent handwashing with soap and warm water for at least 20 seconds, or using an alcohol-based hand sanitizer or a Health Canada-approved alcohol-free hand sanitizer when soap and water are not available;
- maintain good respiratory etiquette, such as covering your mouth and nose with your arm or sleeve when coughing or sneezing, disposing of any used tissues as soon as possible, and washing your hands immediately after with soap and water or an alcohol-based hand sanitizer when soap and water are not available;

- regularly clean and disinfect surfaces that people touch frequently such as toilets, bedside tables, doorknobs, telephones and television remotes with regular household cleaners or diluted bleach (one part bleach to nine parts water).

Q376. **Are Canadians at risk for contracting COVID-19 from products shipped within or from outside of Canada?**

It is not yet known how long the virus causing COVID-19 lives on objects and surfaces; however, early evidence suggests it can live on objects and surfaces from a few hours to days depending on a variety of factors, including:

- temperature;
- type of surface;
- humidity of the environment.

Products shipped within or from outside of Canada could also be contaminated. However, because parcels generally take days or weeks to be delivered, and are shipped at room temperature, the risk of spread is **low**. There is no evidence that coronaviruses could enter Canada simply by existing on parcels or packages.

To protect yourself from COVID-19, make sure to do the following when handling products shipped within or outside of Canada:

- practice good hygiene measures;
- regularly clean and disinfect surfaces;
- Do not touch your eyes, nose and mouth.

Q377. **Can COVID-19 be transmitted through food or water?**

There is currently no evidence to suggest that food is a likely source or route of transmission of the virus, and there are currently no reported cases of COVID-19 transmission through food. The virus is not likely to infect people through food.

Scientists and food safety authorities around the world are closely monitoring the spread of COVID-19.

The novel coronavirus causing COVID-19 is not considered a foodborne pathogen.

Routine cleaning and disinfection methods, as well as cooking food to a safe internal temperature, eliminate coronaviruses.

If the CFIA becomes aware of a potential food safety risk, actions will be taken to ensure the safety of Canada's food supply.

Animals

Q378. **Can I get the virus from animals in Canada?**

The spread of COVID-19 currently results from person-to-person transmission. There is no evidence that pets and other animals play a role in the transmission of the disease to humans. Scientists are still trying to understand if and how the disease affects animals.

Q379. **Can my pet or other domestic animals get the virus?**

It is possible that some types of animals may be able to get infected with the coronavirus that causes COVID-19, but it is not yet clear whether they would get sick.

As a precautionary measure, if you have symptoms of COVID-19 or if you are in self-isolation due to contact with a case of COVID-19, you should follow similar recommendations with animals as with people.

- Avoid close contact with animals while you are sick
    - Maintain good hand hygiene and avoid coughing or sneezing on your animals
    - Do not visit farms and avoid contact with livestock
- If possible, have another member of the household take care of your animals
    - If this is not possible, always wash your hands before and after touching the animals, their food and supplies, and follow good respiratory hygiene practices when coughing or sneezing
- Limit contact between your animals and the people and animals not part of your household until you are no longer sick

These measures, which are basic practices to prevent the transmission of disease between humans and animals, are recommended as a precautionary measure. If you have any concerns, consult a veterinarian or public health professional who can help you find answers to your questions.

More information about animals and COVID-19 can be found on the Canadian Food Inspection Agency (CFIA) website.

Q380. **Am I at risk of getting COVID-19 if I have had contact with an animal recently imported from an affected area (e.g. a dog imported by a rescue organization)?**

All animals entering Canada must meet the import requirements set out by the Canadian Food Inspection Agency. There are currently no specific requirements in place in Canada restricting animal importation related to the COVID-19 outbreak, as there is no evidence that pets or other domestic animals can spread the virus. However, until we know more, importers, rescue organizations and adoptive families should consider limiting or postponing importing animals from affected areas.

Any animals that are imported from an affected area should be closely monitored for signs of illness. If an animal becomes sick, contact your veterinarian and inform them of the situation. Call ahead to ensure they are aware of the circumstances.
Animals imported from other countries can carry a variety of diseases that we don’t have in Canada, and that can spread between animals and humans. Therefore, it is always a good idea

to have a recently imported animal examined by a veterinarian so that they can advise you on appropriate treatments and vaccinations to keep the animal healthy and protect your family. Take these precautions to prevent diseases from spreading from animals to humans:

- Always wash your hands after touching animals, their food or supplies, and cleaning up after them;
- Do not kiss animals, share food, or let them lick your face;
- Regularly clean and disinfect areas where animals live.

For further information on animals and COVID-19, visit the following websites:

- https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/COV-19/COVID19_21Feb.pdf
- https://www.who.int/en/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters

Q381. **Why is Canada conducting a review of the evidence on the transmission of COVID-19 in children?**

It is important to monitor how the transmission of the disease varies in different groups within the population in order to understand its transmission dynamics. It has been demonstrated that children are important vectors in the transmission of other respiratory diseases (e.g. influenza). Therefore, it's interesting to consider whether there is any evidence that SARS-CoV-2 is more or less prevalent in children than in other age groups.

Q382. **Is there a timeline for the publication of the review on transmission in children?**

The Public Health Agency of Canada (PHAC) conducts literature reviews and evidence syntheses on a variety of topics related to the fight against COVID-19, including a recent rapid review of the evidence on transmission in children. PHAC will provide detailed results of the literature review through reputable scientific publications and websites. The process for these publications is already underway.

Q383. **Is the information being revised or is the government working with partners?**

These rapid reviews are conducted by people from a variety of fields, including synthesis research, infectious diseases and epidemiology, to provide a summary of existing evidence that can be used in decision-making. PHAC is working with the National Collaborating Centres for Public Health and other external partners to gather evidence to guide Canada's response to COVID-19.

PREVENTION AND RISKS

Q384. **How can I protect myself from this virus?**

You can stay healthy and prevent the spread of infections by doing the following:

- Washing your hands often with soap and warm running water for at least 20 seconds;
- Using alcohol-based hand sanitizer or an alcohol-free hand sanitizer approved by Health Canada only if soap and water are not available;
- Avoiding touching your eyes, nose or mouth with unwashed hands;
- Avoiding contact with sick people, especially if they have a fever, a cough or difficulty breathing;
- Coughing or sneezing into your arm to reduce the spread of germs;
- Staying home if you become sick to avoid infecting others.

Q385. **Should the general population in Canada wear masks to protect themselves from this virus?**

The following are methods proven to prevent the transmission of COVID-19:

- Staying at home as much as possible;
- Practicing physical distancing;
- Washing your hands;
- Protecting those most vulnerable from infection and limiting their exposure to others;
- Covering your cough with a tissue or your sleeve.

Healthcare workers need medical masks, including surgical masks, medical procedure masks and respirators such as N95 masks. It is extremely important that we keep the supply of medical masks for healthcare workers because they urgently need them for medical procedures and to care for individuals who have COVID-19.

Wearing a non-medical mask or face covering (i.e. made to completely cover the nose and mouth without gaping, and secured to the head by ties or ear loops) in the community has not been proven to protect the person wearing it. However, wearing a non-medical mask or face covering is an additional measure that you can take to protect others around you.

Wearing a non-medical mask is another way of covering your mouth and nose to prevent your respiratory droplets from contaminating others or landing on surfaces. A cloth mask or face covering can reduce the risk that others are coming into contact with your respiratory droplets, in the same way that covering your cough with tissues or your sleeve can reduce that risk.

For short periods of time when physical distancing is not possible in public settings (e.g. grocery stores or in confined areas such as public transit), wearing a non-medical mask is one way to protect those around you.

Non-medical masks or facial coverings should not be placed on young children under age two, or anyone who has trouble breathing, is unconscious, or is unable to remove the mask without assistance.

Q386. **What was the idea behind changing the advice about wearing a mask? What motivated this advice?**

Canadian public health guidelines on COVID-19 have evolved in response to the accumulation of evidence and the understanding of the new virus. We continually review the latest scientific evidence as it develops and work with our partners across the country and around the world to learn more. From the onset of the COVID-19 outbreak, masks were recommended to symptomatic individuals who were known or thought to have COVID-19 when they were within two metres of other people or if they left their homes for an essential reason (i.e. to seek treatment). Masks were not recommended for widespread use by healthy people in the community.

The thinking on the use of masks evolved with the emergence of evidence that the virus can be transmitted by infected people before symptoms appear (pre-symptomatic transmission). It has also been proven that some infected people who never develop symptoms are also capable of transmitting the virus (asymptomatic transmission). The extent to which pre-symptomatic and asymptomatic transmission plays a role in the spread of COVID-19 is unknown at this time, but it is known to occur among people who have close contact or are in close physical environments. This evidence has led to the advice of the Council of Chief Medical Officers of Health that individuals could wear non-medical masks and face coverings as an additional layer of protection in environments where physical distancing may not be possible.

Healthcare workers on the front lines of the COVID-19 pandemic need medical masks, including surgical masks, medical procedure masks and respirators such as N95 masks, and it is extremely important that we keep the supply of these masks for them. Although it has not yet been proven that wearing a non-medical mask or face covering in the community protects the person wearing it, it is an additional measure that individuals can take to protect those around them.

Wearing a non-medical mask is another way of covering your mouth and nose to prevent your respiratory droplets from contaminating others or landing on surfaces. A cloth mask or face covering can reduce the risk that others are coming into contact with your respiratory droplets, in the same way that our recommendation of covering your mouth with a tissue or your sleeve when you cough can reduce that risk.

It is important to note that wearing a non-medical mask is not a substitute for proven methods of preventing transmission, including:

- Staying home when sick;
- Practicing physical distancing;
- Washing your hands;
- Protecting those most vulnerable from infection and limiting their exposure to others;
- Covering your cough with a non-medical mask, or coughing into tissues or your sleeve.

Q387. **Has Health Canada seen an increase in the number of calls from people reporting health issues related to cleaning products and disinfectants during the COVID-19 pandemic? Have there been more instances of misuse of cleaning products, such as improper use of bleach or improper mixing of products since the COVID-19 outbreak?**

Health Canada and five poison centres in various regions across Canada have worked together to analyze the number of calls to poison centres related to exposure to cleaning products. The data was collected by the poison centres and has been shared with Health Canada for compilation to provide a Canada-wide overview.

The analysis compared the number of reported exposures in 2019 and 2020. Data for January 2019 was not included because information from one of the poison centres was unavailable. In addition, data from April 2020 is not yet available.

Comparing reports made in February and March 2019 to data from the same months in 2020, poison centres have seen a 58% increase in the number of exposure cases related to cleaning products, bleach, disinfectants, hand sanitizers, chloramine and chlorine gas (i.e. cases caused by mixing cleaning products and bleach).

The increase in the number of reports may be due to various factors, including the following:

- people, including children, are spending more time at home;
- an increase in the amount of cleaning products available in households due to the increased purchases as a preparedness measure;
- an increased availability of products due to increased cleaning and disinfecting practices at home and elsewhere.

Health Canada is closely monitoring the situation and has taken steps to inform Canadians about the safe use and storage of cleaning and disinfecting products through regular announcements on social media and its website.

Q388. **Can vaping/smoking/doing drugs damage the lungs, making someone more vulnerable to COVID-19?**

No direct evidence has been published on vaping or drug use and its association with COVID-19 outcomes.

Studies that have looked at the association between smoking and COVID-19 disease severity indicate that smokers may be more susceptible than non-smokers.

Q389. **In the US, people under age 44 make up a large proportion of hospitalizations. What are we seeing with younger people in Canada?**

In Canada, people under the age of 40 make up 31% of cases. Compared to other age groups, people under the age of 40 have milder conditions with only 9% of hospitalizations and 4% of ICU admissions being reported from this age group. (These numbers are subject to change as new cases are identified and the situation evolves).

Q390. **What is your message to young people (especially those who smoke/vape/do drugs) who think they are immune to COVID-19?**

Everyone is susceptible to this virus—you are not immune. Vaping can increase your exposure to chemicals that could harm your health (e.g. cause lung damage). It is also important to remember that equipment used for vaping or doing drugs should never be shared with others. At this time it is particularly important to maintain a healthy lifestyle.

Q391. **Until February 22, PHAC still assessed the public health risks associated with COVID-19 as “low”. When did the risk assessment change? What are the current public health risks associated with the coronavirus in Canada?**

The public health risk assessment provided in the Health Portfolio Situation Reports was based on the risks COVID-19 posed to the Canadian population at that time. As of February 22, 2020, the risks to the Canadian population were low, as there was no evidence that COVID-19 was being transmitted within the Canadian population. On March 5, an update of the assessment indicated that the established risks were still low for the general population at that time, but moderate for the elderly and those with underlying medical conditions.

The confirmation of community transmission of COVID-19 in the Canadian population led to the establishment of a high risk. The current public health risk assessment for the coronavirus in Canada, effective March 16, shows that the risk is high for the general population.

5G TECHNOLOGY AND COVID-19

Q392. **What is the Government of Canada's role in wireless communication technology?**

The Government of Canada's approach to the safety of radiofrequency exposure is one of the most rigorous in the world. Health Canada's mandate on the issue of human exposure to radiofrequency electromagnetic energy is to conduct research on potential health effects, analyze relevant scientific literature and develop exposure guidelines commonly referred to as Safety Code 6. We continuously monitor the research and scientific literature on the health effects of radiofrequency exposure to ensure that the limits recommended in Safety Code 6 comply with the current scientific consensus to prevent potential adverse health effects.

Innovation, Science and Economic Development Canada (ISED) is responsible for the deployment of 5G wireless technology. To help protect Canadians, ISED has adopted the limits in Health Canada's Safety Code 6 for wireless devices and their associated infrastructure.

Safety Code 6 has always maintained an exposure limit below the threshold for the occurrence of all established harmful health effects. The Government of Canada continues to monitor the best available evidence and will take appropriate action if new scientific evidence becomes available.

Q393. **What is Safety Code 6?**

Safety Code 6 includes Canada's guidelines for exposure to radio frequencies. Safety Code 6 covers all frequencies (and combinations of these) within the range of 3 kHz to 300 GHz. This range includes frequencies used by existing communication devices, as well as those that can be used by devices using 5G technology (i.e. above 6 GHz).

Q394. **How does Safety Code 6 protect the health of Canadians?**

The exposure limits recommended in Safety Code 6 are designed to protect all Canadians from all scientifically established adverse health effects from exposure to radiofrequency electromagnetic fields. These effects are tissue heating (such as the skin heating) and nerve stimulation (a tingling sensation in the skin). This means that if a person, including a young

child, were exposed to radiofrequency energy from multiple sources within the limits of Safety Code 6 for 24 hours a day, 365 days a year, there would be no adverse health effects.

Q395. **Is radiofrequency exposure from cell towers and antenna installations safe?**

Yes, radiofrequency exposure from cell towers and antenna installations is safe. There is no scientific basis for the recent theory that the deployment of 5G networks and the COVID-19 outbreak are linked. The World Health Organization and the International Commission on Non-Ionizing Radiation Protection have also recently shared this message on their websites. ISED manages the use of the radiofrequency spectrum and requires all antenna systems to comply with the limits of Safety Code 6 to protect the public from overexposure. Additional information on antenna towers can be found at www.ic.gc.ca/towers.

Q396. **How does Canada compare to other countries in regulating radiofrequency emissions?**

The exposure limits in Safety Code 6 comply with the scientific standards used in other parts of the world, including the United States, the European Union, Japan, Australia and New Zealand. Internationally, while a few countries have implemented more restrictive limits for exposure to radiofrequency electromagnetic fields from cell towers, the scientific evidence does not support the need for more restrictive limits than those in Safety Code 6.

The exposure limits of Safety Code 6, and Health Canada's conclusions, are similar to those of the International Commission on Non-Ionizing Radiation Protection, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks and the World Health Organization.

SAFETY OF EMPLOYEES

Q397. **What is Health Canada doing to ensure federal employees are taking the appropriate precautions?**

Health Canada's Public Service Occupational Health Program (PSOHP) provides occupational health services and occupational hygiene consultative services to Government of Canada departments.

As per usual protocols for these types of situations, PSOHP issued a general Occupational Health Advisory to departments and agencies which provided information on novel coronavirus and recommended precautions for employees such as: frequent hand hygiene, proper cough and sneeze etiquette, and self-monitoring for symptoms.

The advice and information is based on the science and risk level as assessed by the Public Health Agency of Canada and the World Health Organization.

In addition, given the variety of federal work settings, PSOHP developed supplemental advice for specific workplaces. The first priority was advice for employees based at airports who interact with travelers, for example, what personal protective equipment should be used when searching luggage or escorting an ill traveller. Health Canada Occupational health nurses also supported our departmental partners with information sessions for personnel at airports and CFB Trenton.

The department is also working with Global Affairs Canada to ensure that departments and agencies with employees in affected countries have all of the occupational health information they require.

Health Canada's occupational health experts will continue to work closely with departments to ensure the health and safety of employees in the federal public service.

Q398. **What protocols did Health Canada follow after receiving confirmation that an employee tested positive for COVID-19?**

A Health Canada employee who works at Tunney's Pasture has tested positive for COVID-19. The employee is in self-isolation and is following the direction of local public health authorities.

The Department followed established protocols.

- The area where the employee works, including common areas, has been properly cleaned, according to Public Services and Procurement Canada standards. This was done in collaboration with Statistics Canada as the two departments share common work space.

In addition, local public health authorities have been in contact with the employee for any relevant contact tracing. This involved contacting certain colleagues who have also been advised to self-isolate by local public health authorities.

The Government of Canada has asked teleworking to be used whenever and wherever possible, subject to each department's operating requirements. Departments and agencies are actively exercising this flexibility. We are constantly re-assessing the situation and striving to balance both our duty to Canadians and the health and safety of all public servants.

The government is working on a means to centralize information on confirmed cases within the public service. Treasury Board Secretariat has been working closely with Health Canada and the Public Health Agency of Canada to provide workplace-related information and advice to departments and agencies so they can manage their workforce accordingly.

Q399. **Can you confirm that a certain number of employees who work at Canada's National Microbiology Laboratory in Winnipeg have tested positive for COVID-19?**

Two employees working at Canada's National Microbiology Laboratory in Winnipeg tested positive for COVID-19. The employees are in isolation and are following the guidelines of the local public health authority. Contact tracing is underway by the local public health authority who will implement all necessary follow-up procedures to prevent the spread of the virus.

Procedures for cleaning and disinfection of work and common areas have been followed according to established lab protocol. Our employees continue to practice effective public health measures, including physical distancing, hand washing and respiratory etiquette. It is not unexpected that we would see cases amongst our workforce as COVID-19 infection is circulating in our community. We are prepared for such circumstances through business continuity plans that ensure that critical NML operations continue under circumstances where employees are ill or absent. For federal employees whose duties allow them to work from home, this arrangement is supported as part of the Government of Canada's policy during the COVID-19 pandemic. We wish our employees a speedy recovery and our thoughts are with them and their families during this difficult period.