COVID-19
EVERGREEN QUESTIONS AND ANSWERS

Questions and answers:

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SITUATION IN CANADA

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

Our top priority is the health and safety of Canadians. The Public Health Agency of Canada is actively monitoring the situation with respect to the new coronavirus (COVID-19) and is continually assessing the risks in order to adapt the Canadian response accordingly.

The Government of Canada has created the necessary infrastructure to address 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 documents 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, 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** - Public health measures should be tailored to the situation and evolve as new information becomes available.
- **A precautionary approach** - A timely and reasonable preventive action should be proportional to the threat and supported 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. Some 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 provincial and territorial Chief Medical Officers of Health.
- The development of the 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 at 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 focused 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 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. Is Canada considering basing its plan on the WHO guidelines for reopening the economy and borders?

Canada has a strong history of pandemic planning and is an international leader. The 2006 pandemic plan was released after the SARS crisis and was used as a driver for our response to the subsequent H1N1 pandemic. Since H1N1, we have continually updated our plan. One of the key lessons we learned from H1N1 is that we need a flexible, scalable planning approach.

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

We continually assess the impact of our public health measures on the number of reported cases and adjust 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 is continuing to grow.

INFORMING CANADIANS

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

For the latest information, visit Canada.ca/coronavirus. You can also follow Canada's Chief Public Health Officer, Dr. Teresa Tam, on Twitter (@CPHO_Canada).

A new toll-free telephone number (1-833-784-4397) has been established to answer Canadians' questions about the 2019 novel coronavirus. The service is available from 7 a.m. to midnight.

Canadians travelling abroad are encouraged to consult the travel health advice at travel.gc.ca/.

Q4. Why is the Government of Canada running an advertising campaign about COVID-19?

The Government of Canada is implementing a comprehensive national public education campaign about COVID-19 to provide Canadians with credible information on behaviours that protect individuals and overall public health. The campaign will include advertising, social media

marketing, development of information resources, partnership building and awareness activities targeting at-risk populations. This work will complement the Public Health Agency of Canada's existing awareness and communication activities, including the COVID-19 information website, with a virtual assistant to help Canadians effectively find the information they need, a toll-free telephone line, a self-assessment tool, digital advertising, social media posts and regular media updates.

Educating the public plays a key role in our response to COVID-19, as that contributes to:

- improving awareness and understanding of symptoms and treatments;
- providing information on preventive measures such as self-isolation;
- countering misinformation and addressing public concerns.

Advertisements are expected to be broadcast on a number of ethnic radio stations and newspapers by the end of April 2020. However, given the current situation, with some print media closed and our 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 in funding to develop and launch virtual health tools to support Canadians.

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

This funding will support the development and reach of the following:

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

- The **Wellness Together Canada** portal, helping Canadians access self-help tools and find credible information on mental health and substance abuse issues. It also connects Canadians with trained peer-support workers, social workers, psychologists and other professionals for confidential chat sessions, phone calls and online counselling.

- **Our artificial intelligence capability**, helping us gain new insights and knowledge about the emergence, spread and health risks of COVID-19. Health Canada and the Public Health Agency of Canada have contracted with BlueDot to enhance and expand our current expertise in this area.

In addition, the Government of Canada is working with the provinces and territories and with Canada Health Infoway to support the use and adoption of virtual health care services. As a result, Canadians will be able to continue to have their regular health needs met in a safe and secure manner by telephone, text messaging or videoconferencing, aside from in-person visits.

Q6. **Can you provide a breakdown showing how the money will be spent?**

Our Government is committed to working with the provinces and territories to identify priorities for this investment. Health Canada is already working with the provinces and territories, along

with Canada Health Infoway, to identify where additional support is needed for virtual care technology and infrastructure.

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

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

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

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

Our government knows that many contact-tracing tools are being developed to help digitize the process, including mobile apps, and we are monitoring these developments closely. It is important that these apps safeguard users' privacy and security. Privacy considerations will continue to be central to all initiatives undertaken by the Government of Canada.

Q8. Vulnerable populations are affected by COVID-19 in Canada. Will this funding meet their specific needs?

Health Canada is exploring ways to support diverse populations when rolling out virtual health services. Community partners could potentially use virtual technologies—particularly secure messaging and videoconferencing—to address the specific needs of vulnerable populations. However, important discussions with provincial and territorial partners regarding rollout of these tools are needed.

The Canada COVID-19 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, and also as a web-based app accessible from any modern laptop or desktop computer.

Q10. How does the app work?

The app is simple to use and has been designed to provide users with information and recommendations based on their personal risk. It also allows users to track their symptoms.

It provides educational information on topics related to COVID-19, such as physical (or social) distancing, hand washing, food safety, pets and other common issues, as well as links to reliable, up-to-date sources of public health information.

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

Q11. How is this app related to resources already in place in some provinces?

This app is based on the tools developed by the provinces and territories and is another valuable resource for Canadians. The mobile platform is based on a mobile app launched by British Columbia 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 who use this tool can get the information and advice they need, resulting in fewer calls to 811 and Telehealth, as well as fewer in-person visits to health care providers such as family doctors, walk-in clinics and urgent care centres.

The new Canada COVID-19 app will increase support available to Canadians by providing resources, evidence-based recommendations and up-to-date information.

EXPERT ADVICE AND RESEARCH

Q13. Do we have an emergency scientific advisory group, similar to the Scientific Advisory Group for Emergencies in the United Kingdom, that is advising ministers or the Cabinet on coronavirus? If not, are we getting all our scientific advice from the Public Health Agency of Canada?

In January, the federal, provincial and territorial governments agreed to create the Special Advisory Committee (SAC) on the 2019 novel coronavirus (2019-nCoV) to advise Deputy Ministers of Health across the country on coordination, public health policy and technical content related to the COVID-19 pandemic. The SAC consists of representatives from various federal departments and agencies as well as members of the Pan-Canadian Public Health Network Council and Canada's Council of Chief Medical Officers of Health.

This committee is supported by three expert groups that bring together senior federal, provincial and 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 been holding almost daily telephone meetings with her provincial and territorial counterparts—as has Canada's Deputy Minister of Health—in order to understand the situation in each jurisdiction and accelerate collaboration to address common needs.

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

Canada's Chief Science Advisor (CSA) has assembled a multidisciplinary Expert Panel to advise her on the latest scientific developments related to COVID-19. This group is itself made up of subgroups focusing on health systems and modelling methods. This information will help the CSA provide relevant, interdisciplinary, independent advice to the Prime Minister and the Government. The Expert Panel is composed of distinguished Canadian scientists and meets regularly to discuss available scientific data and evidence from disease modelling, risk perception, diagnostic and clinical research. The first meeting was held in March.

As announced by the Prime Minister on April 23, 2020, the Government of Canada will invest in new medical countermeasures to better understand COVID-19, and develop the infrastructure needed to fight the virus in Canada. These measures include:

The establishment of the COVID-19 Immunity Task Force that will be led 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 establish priorities and oversee the coordination of a series of countrywide blood test surveys that will tell us how widely the virus has spread in Canada and provide reliable estimates of potential immunity and vulnerabilities in Canadian populations.

Q14. **What is CanCOVID?**

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

Q15. **Could you explain the significance of Dr. Francesco Marchetti's response to the revision of OECD Test Guideline 488?**

The 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, might have led to incorrect conclusions. Germ cell mutations are associated with a range of hereditary diseases and the appropriate classification of chemicals as germ cell mutagens is important under the Globally Harmonized System of Classification and Labelling. The revised Guideline provides recommendations that should generate stronger data on the potential for chemicals to induce mutations in germ cells. It also provides a common sampling time for the simultaneous assessment of mutagenicity in somatic tissue and germ cells, which significantly reduces the number of animals required for testing.

Health Canada led the OECD Expert Group to revise the germ cell portion of TG 488. These revisions were ratified after lengthy deliberations among a number of member countries. This consensus was reached largely based on two publications from the Health and Environmental Sciences Institute Genetic Toxicology Technical Committee's Germ Cell Workgroup, chaired by Health Canada.

FUNDING

Q16. **How much money has the Public Health Agency of Canada received for COVID-19? How much of that has been used to fund COVID-19 testing across the country? What proportion has been used for public health surveillance? How much has been used for contact tracing?**

Approximately $230 million of the planned funding has been allocated to the Public Health Agency of Canada (PHAC).

Of that, the following amounts have been set aside for the following purposes:

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

Funding for contact tracing is not included in this allowance, as this is done 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?***

The funding will support the development and rollout of a comprehensive national COVID-19 public education campaign to provide Canadians with credible information that encourages behaviours to protect the health of individuals and overall public health. The campaign will include advertising, social media posts, development of information resources, partnership building and outreach activities targeting at-risk populations. This work will complement the Public Health Agency of Canada's current outreach and communication activities (e.g. COVID-19 information website, toll-free telephone line, digital advertising, regular media updates).

Educating the public plays a key role in our response to COVID-19, as that contributes to:

- improving awareness and understanding of symptoms and treatments;
- providing information on preventive measures such as self-isolation;
- countering misinformation and addressing public concerns.

Q18. **What will the $240.5 million for COVID-19 mental health tools be used for?**

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

This funding will allow for the continued development and scope of the following:

- The Canada-COVID-19 mobile app, which helps Canadians access a symptom-tracking tool, credible information sources and resources, and a self-assessment tool.

- The Wellness Together Canada portal, which provides Canadians with easy access to self-learning tools and credible information on mental health and substance abuse. This portal also connects Canadians with peer helpers, social workers, psychologists and other professionals who offer confidential chat sessions, phone calls and online counselling; and

- 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 contracted with BlueDot Inc. to enhance and develop existing expertise in this area.

In addition, the Government of Canada is working with provinces, territories and organizations such as Canada Health Infoway to support initiatives to develop virtual health services that help Canadians continue to have their routine health needs met in a safe and secure manner, by telephone, text messaging or videoconferencing, aside from in-person visits. Our government is committed to working collaboratively with all jurisdictions to determine the priorities for this investment and to identify where additional support is needed for virtual care technology and infrastructure.

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

As part of the rollout of virtual health services, Health Canada is exploring ways to serve diverse populations. Community partners could potentially use virtual technologies—specifically secure messaging and videoconferencing—to meet the specific needs of vulnerable populations. However, rolling out these tools requires important discussions with provincial and territorial partners.

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

The Government of Canada ads featured on Spotify are part of the $30 million campaign. As we have not yet received the final invoices, we are not able to provide information on expenditures.

Q20. **Which organizations funded by the $30 million COVID-19 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, in order to reach a wide range of audiences. Most of the platforms have facilities in Canada; however, exceptions have been made for certain digital platforms that effectively reach some of our specific target audiences in Canada, including Facebook and YouTube. We do not yet have the final costs of the media buy since the campaign is ongoing and final invoices have not yet been received.

Q21. **What is the cost of the contract between the Government (PSPC) and Cossette? How much is Cossette getting to do this job?**

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

Other services are provided upon request and paid for based on the work performed (Task Authorizations), in accordance with the contract's 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 Canada.ca/coronavirus and in the Canada COVID-19 app, along with Health Canada's other COVID-19 virtual tools.

Q23. Does the Government intend to make more digital COVID-19 tools and resources available to Canadians?

The portal is part of a suite of virtual products supported or funded by Health Canada to provide Canadians with information and support during the COVID-19 pandemic. The self-assessment tool and 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 during the current COVID-19 pandemic. It will offer them different levels of support tailored to their needs, ranging from information and self-assessment tools to the opportunity to speak with peer support workers and other professionals. Discussions may include a limited number of live telephone sessions.

The portal is being offered by a consortium of mental health and substance use organizations. 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. Is the information I share on this portal secure?

Crisis support links and a number of resources are accessible directly through the portal without signing up. You can sign in for additional support and resources. Resources and services included in the portal are provided by certified professionals. Any information given will remain strictly confidential.

Q26. What is the expected number of Canadians who will be able to use Wellness Together Canada? What is the portal's current capacity?

The portal provides Canadians in all provinces and territories with free, 24/7 access to evidence-based tools and resources that will help meet their mental health and substance use support needs. Through the portal, Canadians can also access the services of more than 6,000 Homewood Health and Kids Help Phone employees.
Following the SARS outbreak, it was found that over 40% of the population 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, it is expected that approximately 11 million Canadians may experience high stress levels 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 so that services can be tailored to meet the demands of Canadians.

Q27. How many psychologists, social workers, peer helpers and "other professionals" have been hired so far and how many is the Government looking to hire? How many of these employees are available full-time?

The suite of tools on Wellness Together Canada will provide Canadians with different levels of support tailored to their needs, ranging from information and self-assessment tools to an opportunity to chat with peer helpers and other mental health professionals. Homewood Health and Kids Help Phone have more than 6,000 employees who will provide psychosocial support services to Canadians by text and phone.
Although the exact breakdown of care providers is not available at this time, they represent a range of health professions—including social work and psychology—and have varied backgrounds in counselling psychology, clinical social work, rehabilitation, crisis management, child psychology and neuropsychology, sexuality, adolescent problems, marital and family therapy, and substance abuse. The vast majority of these service providers are certified mental health and substance abuse professionals.

Q28. Is the federal government paying the psychologists listed on the mental health portal that Canadians will be consulting?

The Wellness Together Canada portal is part of a suite of virtual products that are being supported or funded by Health Canada to provide Canadians with information and support during the COVID-19 pandemic. Funding for the portal goes 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 being paid for by Health Canada from funds that are also used to pay for the portal.

Q29. Will the Government of Canada be investing more in mental health and suicide prevention?

With school closures and reduced access to community resources, Kids Help Phone is experiencing an increased demand for its confidential, 24-hour, crisis support services available

online, and by phone and text messaging. In response, the Government of Canada has provided Kids Help Phone with $7.5 million in funding so it can respond to this increased demand and provide young people with the mental health support they need during this difficult time.
With this additional funding, it will be possible to offer electronic mental health services in English and French to children and youth across Canada who are experiencing the social and financial effects of the COVID-19 pandemic. This will ensure that vulnerable Canadian children and youth can find the help they need when they need it most.

Q30. **Does this portal address the specific needs of First Nations?**

During the funding process for this initiative, Health Canada asked that the portal address cultural safety and trauma. This portal is for all Canadians.

Q31. **Can people without Internet access use the portal?**

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

Q32. **There have been a lot of announcements related to mental health lately. Are people going to have trouble getting through this?**

The current situation is very difficult for Canadians. We are very pleased to see so many organizations coming forward to provide direct services, resources and funding in this area. Canadians should not worry or feel confused, no matter whom they call or what resources they use, someone will be there to help them. This portal is just one way of bringing together in one place a number of organizations that are uniquely positioned to provide a wide range of information, resources and advice.

Q33. **What is the status of 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 roll out and sustain a fully operational pan-Canadian suicide prevention service. People across Canada will be able to use the technology of their choice (telephone, text message or chat) to access a bilingual crisis support service provided 24/7 by qualified responders.

In July 2019, the Public Health Agency of Canada issued a call for funding requests targeting organizations willing to develop a pan-Canadian suicide prevention service. This process ended on October 31, 2019, and a decision is expected shortly.

Q34. **This initiative does not address the issue of a safe drug supply. As the supply of illegal drugs continues to decline because of supply-chain problems**

in the illegal market, people who traffic in illegal substances may start using harmful cutting agents, making the drug supply even more dangerous. 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 funds services such as harm reduction, treatment and housing for people who use drugs. It is committed to ensuring that provinces and territories have the tools they need to address the combined effects of the opioid overdose crisis and the COVID-19 pandemic on their populations.

- On March 19, 2020, Health Canada granted a six-month exemption for prescriptions for controlled substances (such as narcotics) under the *Controlled Drugs and Substances Act* and its regulations. This temporary exemption allows practitioners to orally give prescriptions for controlled substances, allows pharmacists to extend or renew prescriptions more easily and to transfer prescriptions to other pharmacies, and allows drugs to be delivered or collected by another person.

  This will ensure that people with a substance use disorder who are on opioid agonist therapy will continue to have access to their medication while maintaining the recommended physical distance.

- On April 6, 2020, Health Canada granted class exemptions allowing provinces and territories to establish new sites to address an urgent public health need (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 distancing and self-isolation.

  The Department will also enable community health service providers to ensure that existing supervised consumption sites can quickly adapt their operations to meet public health recommendations in the context of COVID-19. This can be done without the need to notify Health Canada or request additional authorization. Changes to operations could include new measures regarding how people move around the facilities and changes to operating hours or number of booths.

Q35. What are the current statistics on Canada COVID-19 app downloads or the number of clicks on the mental health portal? How many Canadians have been able to access mental health services through these tools?

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

Q36. What other resources are available to Canadians?

The COVID-19 pandemic is a new and unexpected phenomenon. It can be confusing. People may feel as though they are no longer in control of their own lives. It is normal that individuals and communities are experiencing sadness, stress, confusion, fear and worry.

The Government of Canada is working with the provinces and territories to expand and adapt digital platforms to help governments in their response to COVID-19 through education, information, counselling, alerts and screening tools.

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

The many resources available for people in crisis include:

Kids Help Phone - 1-800-668-6868 or text TALK to 686868 (a 24/7 resource for Canadian kids ages 5-29 who are looking for confidential, anonymous support from professional psychological counsellors).

Hope for Wellness Helpline - Call the toll-free help line at 1-855-242-3310 or connect by chat. (A resource available to all Indigenous peoples across Canada who need immediate crisis intervention).

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

GUIDELINES

Long-term care facilities

Q37. **Why are you recommending 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. They provide direct care to patients. Everyone who enters a long-term care facility, including essential visitors and volunteers, has a responsibility to prevent infections among residents of that facility, who are at high risk of serious illness and death from COVID-19.

The Government of Canada is working to ensure that health care workers have the personal protective equipment and medical supplies they need, through bulk procurement in cooperation with the provinces and territories, building national production capacity, and researching alternatives and ways to extend product life.

Q38. **Why are you telling workers not to hold multiple jobs when they may need multiple jobs to survive?**

We know that seniors are at greater risk of developing serious complications from COVID-19 because of their underlying health problems and their age.

In the case of seniors living in long-term care facilities and assisted living facilities, the risk of infection and transmission of the virus is even higher due to proximity. The movement of workers from one facility to another increases the risk of spreading the infection, meaning a higher risk of seniors contracting the virus. We need to protect seniors in these difficult times.

The guidelines recommend identifying employees who work in more than one facility and ensuring that efforts are made to prevent this from occurring where possible.

Q39. How will residents' needs be met if there is further restriction on the availability of personal support workers?

Managing long-term care is the responsibility of provincial and territorial governments. They have established a number of measures to support the provision of ongoing quality care to residents during the crisis. These measures include flexibility in staffing policies and approaches, and working with third party suppliers to provide acute care support.

The Government of Canada is working with provincial and territorial governments to respond to COVID-19. A national recruitment campaign has been launched to recruit volunteers—including individuals with health care experience—to help perform case management duties and support the cutting-edge health care system. A directory of volunteers is maintained from which provincial and territorial governments can draw as needed.

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

Q40. What is the Government doing to help low-wage workers?

The Government of Canada is taking strong and swift 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 (CERB) will help Canadian workers, both employees and self-employed workers, who, because of COVID-19, have had to stop working and have lost their income. Eligible workers will receive $2,000 per month for up to four months to help them pay their bills.

Getting Canadians the money they are entitled to as quickly as possible is a priority for the Government of Canada. We have created an online portal to share information and enable workers to apply for the new benefit.

Q41. What is the Government of Canada doing to protect the financial security of seniors?

The Government of Canada is taking steps to ensure that Canada Pension Plan and Old Age Security benefits that seniors rely on continue to be paid without delay, and that new applications for these benefits are processed quickly.

The purpose of the Old Age Security pension is to provide a guaranteed minimum income for all seniors. As a result, it is paid based on age and place of residence and is in no way tied to employment history or investment income, and continues to be paid monthly to seniors.

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

Several new measures are being implemented to further protect the financial security of seniors. Since April 9, 2020, the Government has been providing a special one-time Goods and Services Tax (GST) credit payment to low- and modest-income Canadians, including seniors. This amount will be about $400 for low-income singles and about $600 for low-income couples.

Minimum withdrawals from Registered Retirement Income Funds (RRIFs) have also been reduced by 25% for 2020. This will give seniors more flexibility and help protect their RRIF assets in the face of an unstable market.

In addition, we have extended the deadline for filing tax returns to June 1, 2020, and Canadians will have until September 1, 2020, to pay any new balance owing or instalments before interest or penalties are charged.

Q42. **What is the Government doing to protect seniors' pension plans?**

In the 2019 budget, new measures were announced to strengthen the viability of workplace pension plans in the event of corporate insolvency.

Measures that make insolvency proceedings more fair, transparent and accessible for workers and pensioners are now in place.

Stricter expectations and better monitoring of corporate behaviour have been put in place:

- Federally incorporated companies must now explicitly consider the interests of pensioners and workers when acting in the company's interest;
- Federally incorporated publicly traded companies will be required to disclose their policies regarding workers and pensioners and executive compensation, or explain why such practices are not in place.

Finally, measures protect the hard-earned benefits of Canadians by clarifying in federal pension law that if a plan is wound up, it must still pay out pension benefits just as it did when it was active.

Q43. **What steps is the Government taking to prevent elder abuse?**

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

We continue to provide seniors, caregivers, service providers and the public with information, resources and tools to recognize and respond appropriately to situations of abuse.

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

Q44. **What steps is the Government taking to protect seniors from COVID-19-related fraud and scams?**

The Government of Canada is working to implement measures to improve the lives of seniors and their families and takes elder financial abuse very seriously. Fraud and theft are offences under the *Criminal Code*.

Employment and Social Development Canada publishes real-time anti-fraud information from other government departments on its Facebook page for seniors as well as on other departmental communication channels.

In the longer term, the Government will establish a national definition of "elder abuse", invest funds to improve data collection and enforcement measures, and incorporate new penalties for elder abuse into the *Criminal Code*.

This work builds on ongoing initiatives such as the National Seniors Council's review of elder financial abuse and funding under the New Horizons for Seniors Program for community groups to help combat elder abuse.

Q45. Why did PHAC take so long to release its long-term care guidelines?

One of our priorities is protecting residents and staff in long-term care facilities, so PHAC is working with provincial and territorial governments on all aspects of the response to the COVID-19 pandemic that affect this population. In order to determine the information needed to protect residents and staff found in *Infection prevention and control for COVID-19: Interim guidance for long-term care homes*, PHAC consulted with responsible jurisdictions and other experts across the country. Scientific knowledge on the transmission of COVID-19 is evolving rapidly, so this document is a summary of the latest findings on the transmission of COVID-19.

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

Q46. How many deaths have occurred in long-term care facilities?

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

It is important to note that these figures reflect public reporting by the provinces and territories.

Additional Tips for People with Disabilities in Canada

Q47. What factors can make a person with a disability vulnerable to COVID-19?

In people with disabilities, certain factors may increase the risk of contracting COVID-19 or developing severe symptoms. In addition to age and underlying chronic diseases, these include the following:

- the nature of their disability (for example, having difficulty washing their hands or having a visual impairment that requires them to touch objects for support or information);
- living in group homes, because of the proximity to others;
- interacting with multiple caregivers and support persons, which increases the risk of exposure;

- barriers to accessing public communications about COVID-19 and response services and programs;
- receiving treatment for another health problem in the health care system;
- loss of community services and supports (employment, treatment, schools), which may cause some people with disabilities to regress.

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

To protect themselves from COVID-19 and avoid passing it on to their caregivers, people with disabilities should:

- stay home and go out only when necessary (such as for medical appointments or grocery shopping);
- ask family, a neighbour or friend to help them with essential errands;
- wash their hands often or get help washing them;
- immediately notify family, caregivers and friends if they become ill or ask someone else to notify them.

Q49. What should health workers do to meet the needs of people with disabilities?

Health workers should consider taking measures to accommodate people with disabilities and their caregivers to ensure access to their services.
People 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 people with disabilities (work arrangements, financial resources, mental health resources, other policies and procedures).

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

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

It is important that people with disabilities have access to the services of designated COVID-19 assessment centres. In particular, assessment centres should ensure accessibility (e.g. ramps, accessible parking) and provide accommodation for people who suffer from anxiety or who have a cognitive or intellectual impairment. This could also include allowing people to avoid line-ups, providing a private room, taking into account sensitivity to noise and light, or providing alternatives to swabbing people who are in cars.

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

ISOLATION, QUARANTINE (SELF-ISOLATION) AND PHYSICAL DISTANCING

Q51. **In order to ease restrictions on social distancing, will screening be required for a certain percentage of the population?**

We continue to test on a massive scale and Canada has one of the highest screening rates in the world. We know that testing is essential to find new cases and to identify and interrupt the chains of transmission. We are now running 20,000 tests a day, almost double what we were testing earlier this month, and that number continues to grow.
We do not have a precise figure for the number of tests that need to be performed each day in order to relax social distancing measures. That number will vary from jurisdiction to jurisdiction. However, increasing the number of tests performed is helping to detect new cases and their contacts early to prevent or reduce the spread of COVID-19.
Canada has maintained a positive result rate of approximately 6-7%, which is within the effective detection range for accurately targeting the spread 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 continue to expand our laboratory capacity to ensure that this continues to be the case.
The main objective is to test symptomatic individuals and those in high-risk situations such as long-term care facilities, correctional facilities, health care workers and outbreak control support in any setting.
Our priorities continue to be access to reagents, evaluation of rapid non-laboratory tests, and access to licensed test kits to ensure that the provinces and territories are equipped to expedite testing according to their requirements.

Q52. **Can asymptomatic people go outside for a walk, as long as they maintain physical distance?**

You can all go out for a walk under the following circumstances:

- you have not been diagnosed with COVID-19;
- you are not exhibiting symptoms of COVID-19;
- you have not travelled outside Canada in the last 14 days.

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

Travellers entering Canada, during their 14-day isolation or quarantine period:

- If they are in mandatory isolation, they must stay inside their place of isolation;
- if they are in quarantine (self-isolation), they can go outside for fresh air in a private area such as their yard or balcony; however, they must stay on their property and not go into a community setting.

BORDER MEASURES

ArriveCAN Mobile App

Q53. How do I get the ArriveCAN app?

The mobile app is available in the Google and Apple app stores.
It can be downloaded and installed for free on the following devices:

- iPhone running iOS 12 or higher;
- Android phone or tablet running OS 6 or higher.

ArriveCAN is also available as a web app accessible from the browser of any laptop or desktop computer.

Q54. How does the app work?

The 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 allows you to record answers (yes/no) to questions about symptoms and your self-isolation plan.

Q55. Does the Government intend to make more digital COVID-19 tools and resources available to Canadians?

The Government of Canada is working with the provinces and territories to put additional digital platforms online to respond to the COVID-19 pandemic. This includes supporting efforts to provide education, information, and mental health and substance abuse support, sending alerts, and facilitating screening.

On March 31, 2020, the Government of Canada launched its COVID-19 mobile platform, where Internet users will find:

- information and recommendations on the risks to which they are exposed;
- symptom tracking tools;
- links to reliable, up-to-date sources of public health information;
- information related to COVID-19 on topics such as:
  - physical distancing;
  - hand washing;
  - food safety;
  - pets.

ArriveCAN is a free mobile app for Apple iOS and Android phones and tablets. It is also available as a web app from any laptop or desktop computer.

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

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

The app will make it easier for travellers entering Canada to share their contact information with border services officers.

Travellers are encouraged to use the ArriveCAN app as an alternative to the paper form. The app will speed up border crossings for travellers entering Canada.

Electronic data collection will also protect travellers and border services/quarantine officers by reducing physical contact.

Q57. What is the difference between the app and the online form?

Travellers can access the online form from the browser on their laptop, tablet or Internet-connected phone. Before using the online form, the traveller must obtain a local token at the port of entry into Canada and enter it online.

The ArriveCAN app can be downloaded directly to a mobile phone. The traveller can enter information without a token before arriving at the port of entry. The token provided at the port of entry is only required for sending the information after it has been initially entered into the app.

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

Q58. Will the app be used to track travellers' movements?

The ArriveCAN app will not be used to automatically track the user's position using their phone or GPS, nor will it be used for surveillance purposes. Protecting the personal information of Canadians is a priority for the Government of Canada, and all tools used to collect personal information undergoes a rigorous privacy assessment.

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

The ArriveCAN app is not a case monitoring app and does not intersect with any existing digital or mobile solutions. In accordance with the emergency order 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 to support compliance and enforcement of the mandatory 14-day quarantine or isolation measures.
The ArriveCAN app is a digital solution that makes it easier to collect essential information, as well as simplifying the presentation of travellers' responses. The app also supports physical distancing efforts by limiting contact between travellers and border services personnel, since information can be easily and securely entered into mobile devices. The mobile app can be downloaded at any time, including before travellers leave, so that they can enter their information, making it easier and faster for them to enter Canada.

Q60. What type of information is the app collecting?

The information to be entered into ArriveCAN and paper/online forms is mandatory under the *Quarantine Act.* This information includes:

- name, date of birth, flight number and destination details;
- answers (yes/no) to questions about symptoms (cough, difficulty breathing, fever);
- answer (yes/no) to questions about preparing a self-isolation plan.

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 COVID-19 information and resources. The ArriveCAN app is only used for travellers entering Canada who are required to provide essential information in support of PHAC's mandate of regulatory compliance and the enforcement of emergency orders issued under the *Quarantine Act*.

Q62. How will the information be protected?

Personal information under the control of a federal government institution is subject to the *Privacy Act* which governs the collection, use, disclosure, retention and disposal of personal information.

Q63. How is the information used?

Information collected under subsection 15(1) of the *Quarantine Act* may be used for any of the following three activities:

1. monitor and verify compliance with the mandatory isolation order, and apply sanctions if necessary;
2. provide information to assist travellers in complying with the mandatory isolation order;
3. conduct follow-up activities related to public health.

Compliance and enforcement officers will be able to use the information to contact travellers during their period of mandatory isolation to verify that they are in compliance and remaining in their place of isolation. It is not a surveillance or monitoring tool.

Upon entry into Canada, travellers are informed of these screening and verification measures, the potential consequences of non-compliance, and the sanctions and penalties that could apply if they do not comply.

The Public Health Agency of Canada is working with the Royal Canadian Mounted Police and provincial law enforcement agencies to ensure that returning travellers comply with the mandatory isolation order. These actions reflect a risk-based approach and will be taken based on information received from travellers at the border.

Q64. Which law gives the Government the power to require personal information?

Personal information may be required 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 is more information requested in the ArriveCAN app than on the paper and online forms?

The app captures 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 entered on the current paper and online forms, the app asks for flight or border crossing data, and answers to questions about COVID-19 symptoms and the preparation of a self-isolation plan.

Although some information is not requested on the paper or online form, a border services officer will ask each incoming traveller questions about symptoms and the preparation of a self-isolation plan, and will enter the answers themselves.

Eventually, the information requested about coronavirus will be the same on the mobile app and the paper and online forms. PHAC is currently working with the operations team to ensure that all incoming travellers communicate this information consistently in all three formats.

Q66. What does the ArriveCAN online form for travellers entering Canada consist of?

Travellers entering Canada by air or land are required to provide basic information using a Traveller Contact Information Form, which is accessible through the ArriveCAN mobile app, an online form or a paper form. Access to the online form is restricted and is done using an invitation number (token) that can be obtained at the airport. Please consult the Traveller Form in English and its equivalent in French.

Travellers are informed upon arrival in Canada of surveillance and compliance activities, the possible consequences of non-compliance, and the enforcement actions and penalties to which they may be subject. Individuals who violate the mandatory isolation or mandatory quarantine requirements may be subject to a range of enforcement measures under the *Quarantine Act*, including verbal and written warnings and arrest or detention.

Alberta Government Introduces Enhanced Screening Measures at Border Crossings and Ports of Entry

Q67. Why is the Government of Canada not performing a temperature check at all ports of entry?

The Government of Canada continues to monitor measures that have proven to be effective, based on the latest science and assessments. Currently, border services officers do not perform a temperature check at ports of entry. In the past, the use of thermal imaging at Canadian ports of entry has not been effective in detecting communicable diseases in travellers. For example, during the severe acute respiratory syndrome (SARS) outbreak in 2003, thermal imaging did not detect cases of the disease in the 2.3 million travellers who were rigorously screened.

Each province or territory in Canada examines different situations and develops risk-based approaches and assessments, depending on what is happening within its borders.

Q68. If the Government of Canada believes that temperature checking is not a reliable means of reducing the spread of COVID-19 by people entering Canada, why is the Government of Canada allowing the Government of Alberta to implement this measure?

The Government of Canada works closely with provincial and territorial governments to ensure their support for measures it approves. Since the epidemiological characteristics of COVID-19 vary among provinces and territories, provincial and territorial governments will continue to develop their own risk-based approaches and assessments.

Q69. Why is the question "Do you think you have a fever" part of the Government of Canada's current border measures if there is no temperature check?

Border services officers are required to screen people arriving at Canadian ports of entry to determine whether they have symptoms associated with COVID-19. The question about signs of a fever is one of many that travellers must answer so that officers can determine whether quarantine or self-isolation is necessary. Alberta's recent decision to perform a temperature check at airports represents an additional health control measure based on an assessment of the situation in the province.

Order 10 - Emergency Order - Mandatory Isolation

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

On April 15, 2020, the Government of Canada implemented a federal Emergency Order under the *Quarantine Act*, which requires anyone entering Canada by air, land or sea to isolate for 14 days if they have COVID-19 symptoms or, in the absence of an exemption, to quarantine for 14 days if they do not have symptoms in order to limit the introduction and spread of COVID-19.

This Order applies to anyone entering Canada, with a few exceptions - whether or not they have COVID-19 symptoms.

These measures will help protect the health of these individuals, people they live with and Canadians generally, including vulnerable people, such as adults 65 years of age and older and people with known health problems, who are at the greatest risk of serious illness from COVID-19.

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

According to new scientific evidence showing that asymptomatic people can transmit the disease, all travellers entering Canada—whether they have symptoms (symptomatic) or not (asymptomatic)—are required to wear a non-medical mask or face covering when en route to their place of isolation (if symptomatic) or quarantine (if asymptomatic).

Previously, only symptomatic people were prohibited from isolating themselves in a place where a vulnerable person might be exposed.

This Order expands this directive to asymptomatic people as well. For example, asymptomatic individuals cannot quarantine in a place where they would be in contact with vulnerable people, such as adults 65 years of age and older or people of any age with a weakened immune system or an underlying health condition that makes them susceptible to COVID-19 complications.

If an asymptomatic person cannot quarantine in an appropriate location, he or she will be transferred to a quarantine facility selected by the Chief Public Health Officer of Canada.

In addition, the 14-day quarantine period begins again if the person begins to show signs or symptoms of COVID-19, or if the person is exposed to a person who is subject to the Order and shows signs and symptoms of the disease after entering Canada.

Q72. How will travellers be informed of the applicable protocol when they enter Canada?

Upon entry into Canada, travellers will be required to answer questions about their health status and symptoms, which they are required to report to a screening officer or quarantine officer. They will also have to acknowledge that they are required, under the *Quarantine Act*, to isolate or quarantine for a 14-day period, beginning on the day they enter Canada.

Travellers will receive a document informing them that they are subject to the Order, which outlines the Order's requirements and provides general public health advice, as well as a link to the Canada.ca/coronavirus website for more information.

People entering Canada are also encouraged to consult public health authorities in their province or territory for information on other measures and restrictions regarding mandatory isolation or quarantine.

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

Anybody returning to Canada must answer relevant questions asked at the border and provide any required information or records in their possession. They are also required to wear a non-medical mask or face covering upon arrival and while travelling to their place of isolation or quarantine.

In addition, the Order requires that any person entering Canada who is not exempted be placed in one of two categories: asymptomatic (no symptoms) or symptomatic (symptoms).

Asymptomatic people

People entering Canada who do not show any signs or symptoms of COVID-19 are subject to the Order and must comply with a 14-day **quarantine** upon entry into the country as they may develop symptoms or infect others.

"Quarantine" means isolating people entering Canada in order to prevent the possible spread of infection or contamination.

Asymptomatic people arriving in Canada must follow these instructions:

- go directly, without delay, to their place of quarantine and stay there for 14 days;
- quarantine in a place where they will not come into contact with vulnerable people, such as adults 65 years of age and older or people of all ages with weakened immune systems or underlying health conditions;
- be able to spend their quarantine in a suitable place where they will have access to basic necessities;
- monitor their health for signs and symptoms of COVID-19 until the end of the 14 days;
- remain at the place of quarantine at all times, except to receive medical attention;
- arrange for delivery of basic necessities such as food or medicine;
- not use public transit;
- not have visitors;
- not go to school, the workplace or any other public place;
- maintain physical distance at all times (i.e. maintain a distance of at least two metres from others).

Asymptomatic individuals are encouraged to use private transportation, such as a personal vehicle, to get to their place of quarantine. If they use public transit instead, they must wear a suitable non-medical mask or face covering while in transit. En route, they must make no stops and respect physical distancing at all times.

Asymptomatic people may be required to remain in a quarantine facility designated by the Chief Public Health Officer of Canada if they plan to quarantine at a place:

- where they would be in contact with vulnerable people;
- where they would not have access to basic necessities (e.g. food, heat, medicine);
- that is not deemed suitable (e.g. a shelter or other place where many people would be newly exposed during their stay).

It is important to note that travellers returning to Canada may be asymptomatic upon arrival, but may subsequently become ill. Unfortunately, there have been cases where an asymptomatic person has developed symptoms and his or her health has deteriorated quite rapidly.

A person who develops symptoms within 14 days must:

- self-isolate;
- Immediately call a health care professional or their provincial or territorial public health authority, then:
  - describe the symptoms and explain his/her travel history;
  - follow the procedure indicated.

The 14-day quarantine period begins again if the person begins to show signs or symptoms of COVID-19, or if the person is exposed to a person who is subject to the Order and shows signs and symptoms of the disease after entering Canada.

Anybody who develops COVID-19 signs or symptoms should follow the instructions for symptomatic people.

Symptomatic people

People entering Canada who have COVID-19 signs or symptoms or who have reasonable grounds to believe they have such signs or symptoms are subject to the Order and must remain in **isolation** for 14 days upon entry into the country as they may infect others.

"Isolation" means separating people who are infected with COVID-19 or who show signs and symptoms of the disease from others in order to prevent the spread of the virus or contamination.

Symptomatic people arriving in Canada must follow these instructions:

- 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 their place of isolation;
- go directly, without delay, to the place where they will self-isolate, and stay there for 14 days;
- self-isolate in a place where they will not come into contact with vulnerable people, such as adults 65 years of age and older or people of all ages with weakened immune systems or underlying health conditions;
- be able to spend this period of time in a suitable place where they will have access to basic necessities;
- undergo required medical examinations;
- monitor the signs and symptoms of the disease and notify the public health authority if they need further medical attention;
- stay in their place of isolation;
- remain at the place of isolation at all times, except to receive medical attention;
- arrange for delivery of basic necessities such as food or medicine;
- not use public transit;
- not have visitors;
- not go to school, the workplace or any other public place;
- maintain physical distance at all times (i.e. maintain a distance of at least two metres from others).

Symptomatic people entering Canada may be required to remain in a quarantine facility designated by the Chief Public Health Officer of Canada if:

- they need to use public transit to get to their place of isolation;
- they plan to self-isolate for 14 days in a place:
  - where they would be in contact with vulnerable people;
  - where they would not have access to basic necessities (e.g. food, heat, medicine);
  - that is not deemed suitable (e.g. a shelter or other place where many people would be newly exposed during their stay).

Q74. **What is a vulnerable person?**

Individuals 65 years of age and older and those of all ages with a weakened immune system or an underlying health condition that makes them susceptible to developing complications from COVID-19. All of these groups are at increased risk of serious illness.

Q75. **What is the difference between isolation and quarantine?**

Isolation means isolating people infected with COVID-19 or showing signs and symptoms of COVID-19 in order to prevent the spread of infection or contamination.

Quarantine means isolating people entering Canada in order to prevent the possible spread of infection or contamination.

Q76. How is it determined whether travellers meet the conditions for isolation or quarantine at home or at a place of their choice?

Upon entry into Canada, travellers are asked questions about their health and to assess their ability to meet the conditions for isolation or quarantine in an appropriate place set out in the Order.

Conditions that are considered include the person's ability to self-isolate or quarantine in a suitable place (e.g. it should not be a shelter or other place where many people might be newly exposed as a result of the person's stay), where they will have access to basic necessities and they will not be in contact with vulnerable people. If the traveller is unable to meet one or more of these conditions, he or she will be required to self-isolate for 14 days in a quarantine facility designated by the Chief Public Health Officer of Canada.

People entering Canada should also consult local public health authorities in their province or territory for information on other measures and restrictions regarding mandatory isolation or quarantine.

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

Symptoms of COVID-19 include cough, shortness of breath or fever of 38°C or higher (signs of fever may include chills, reddened skin and excessive sweating). You can also get information about COVID-19 at www.canada.ca/coronavirus or by calling 1-833-784-4397.

Visit the website for the public health authority for the province or territory where you live for information, including when to contact the public health authority.

Q78. When does the 14-day period begin? Is it from the day of entry into Canada or from the day the traveller arrives at their place of isolation or quarantine?

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

Individuals should consult the local public health authority in their province or territory for information on other measures and restrictions, such as the issuance of a provincial emergency order requiring individuals to self-isolate for 14 days when entering their province from another part of Canada.

Q79. What is considered a suitable non-medical mask or face covering?

Wearing a suitable non-medical mask or face covering is an extra step you can take to protect those around you, even if you have no symptoms. This can be useful for short periods of time to prevent respiratory droplets from contaminating others or landing on surfaces. Suitable non-medical masks and face coverings include homemade cloth masks, dust masks and scarves (bandanas).

A suitable non-medical mask or face covering consists of several layers of absorbent fabric (such as cotton) that fit snugly around the nose and mouth and are attached to the face with ties or loops. Masks or face coverings should allow easy breathing, retain their shape after washing and tumble drying, and be changed as soon as possible if they are wet or dirty.

Q80. Who determines whether the traveller is wearing a suitable non-medical mask or face covering when entering Canada?

Quarantine or screening officers determine whether travellers entering Canada are wearing suitable non-medical masks or face coverings.

If it is determined that a traveller is wearing an unsuitable non-medical mask or face covering, the traveller will be asked to remove it in accordance with the instructions provided by PHAC. The traveller will then be required to wear a suitable non-medical mask or face covering.

Q81. Can people travelling together quarantine or self-isolate together if one of them is a vulnerable person?

Under the terms of the new Order, people who have travelled together may quarantine or self-isolate together if one of them is a vulnerable person, as long as they are a consenting adult or a parent/minor in a parent-minor relationship.

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

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

Provinces and territories may implement their own statutory quarantine and isolation requirements. People entering Canada will be required to comply with the federal Order and with any measures or restrictions applied by their province or territory as long as the latter do not contradict or replace measures/restrictions in the Order (i.e. they must be more stringent than the requirements or the Order).

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

Q83. What types of masks or face coverings will be provided at borders? If all travellers entering Canada are required to wear masks, how will that affect supplies available for health care workers?

Travellers must wear non-medical masks or face coverings upon arrival. Homemade cloth masks are also accepted. Masks or face coverings may be provided on arrival, as needed.

The wearing of medical masks, including surgical masks, procedure masks and filter masks (such as N95 masks), should be restricted to health care workers and others providing direct care to patients infected with COVID-19.

Even if you wear a non-medical mask or face covering, you must maintain strict hygiene and public health measures—including frequent hand washing and physical distancing—to reduce the risk of transmission of the virus. It is also important to know that there is no evidence that wearing a non-medical mask or face covering in a social setting protects the person wearing it. Wearing a non-medical mask or face covering is an additional measure that people—including people who are not symptomatic—can take to protect others.

Q84. **Will the new requirements (e.g. travellers will have to confirm the planned place of their isolation/quarantine; getting a non-medical mask or face covering) create delays at airports?**

The adoption of the revised Emergency Order allows us to build on the measures previously implemented on March 25, 2020, to reduce the introduction and spread of COVID-19 in Canada. While it can be expected that processing travellers at the border will initially increase wait times, the additional measures implemented will then contribute to reducing the spread of COVID-19. Efforts will be made to speed up the processing of travellers at borders, while respecting public health measures and guidelines, such as physical distancing by maintaining a distance of two metres between travellers. All travellers need to contribute to the safety and security of Canadians.

Travellers With No Symptoms (Asymptomatic)

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

Yes, under the Order, travellers with no signs or symptoms are required to quarantine. They must quarantine immediately and monitor for signs and symptoms of COVID-19 until the end of the 14-day period beginning on the day they enter Canada.

Given the rapid spread of COVID-19 around the world and the widespread transmission in an increasing number of countries, individuals who have travelled outside of Canada are considered to be at risk of exposure to COVID-19. In addition, there are many examples of asymptomatic individuals entering Canada who have become ill and, based on new public health science, asymptomatic and pre-symptomatic individuals may spread COVID-19. It is therefore extremely important—for their own health and that of others—that travellers entering Canada quarantine and monitor for symptoms.

Thus, additional strict measures are needed to reduce the risk of spread by people who are not showing any symptoms. The Government of Canada has implemented an Order requiring any asymptomatic person entering Canada by air, land or sea (and who is not exempted) to quarantine for 14 days to limit the introduction and spread of COVID-19.

Q86. **Why is it that some people with no symptoms can quarantine at home or at a location of their choice, while others have to go to a quarantine facility?**

Asymptomatic travellers entering Canada will be asked to proceed directly and without delay to their place of quarantine and remain there for 14 days. If they are unable to quarantine in

accordance with the terms of the Order, they will be sent to a quarantine facility, at the discretion of the Quarantine Officer.

Conditions that are considered include the person's ability to quarantine in a suitable place (e.g. it should not be a shelter or other place where many people might be newly exposed as a result of the person's stay), where they will have access to basic necessities and they will not be in contact with vulnerable people. If the traveller is unable to meet one or more of these conditions, he or she will be required to self-isolate for 14 days in a quarantine facility designated by the Chief Public Health Officer of Canada.

Q87. **If I have no symptoms, can I quarantine at home if I have vulnerable people living with me?**

No. Asymptomatic travellers cannot quarantine at home if they live with one or more vulnerable individuals who are at higher risk of serious illness, since new scientific evidence suggests that asymptomatic and pre-symptomatic individuals might spread COVID-19.

Q88. **Why does my quarantine period start all over again if I am exposed to COVID-19 by another person subject to the Order?**

Under the new Order, the 14-day quarantine period begins again if the person begins to show signs and symptoms of COVID-19, or if the person is exposed to anybody subject to the Order who shows signs and symptoms after entering Canada.

People entering Canada may develop symptoms of COVID-19 during their quarantine and may expose others who are in quarantine with them and also subject to this Order. Since symptoms can appear up to 14 days after exposure, more stringent measures are needed to reduce the risk of spread.

Q89. **Can symptom-free travellers take public transit (including taxis) or rent a vehicle (at the airport) to get to their home or place of quarantine?**

Yes, travellers who do not have any symptoms can take public transit or rent a car to get to their place of quarantine. However, they must wear a suitable non-medical mask or face covering during the journey and proceed directly and without delay to their place of quarantine.

While in transit, people must follow the recommendations of quarantine and control officers to avoid transmitting the infection to others. For example, they must respect physical distancing– maintaining a distance of two metres from others–, and practise good hand hygiene and cough etiquette.

Under the Order, public transit includes airplane, bus, train, taxi, subway or a carpooling service.

Individuals returning home for mandatory quarantine should also consult the public health authority in their province or territory for information on additional measures or travel restrictions in their area.

Q90. Can symptom-free travellers returning home in a private vehicle have someone pick them up, or must they be the sole occupants of the vehicle? If someone drives them, does that person then have to quarantine for 14 days?

It is recommended that asymptomatic travellers do not ask anyone to pick them up.

However, if you must do so, you must at all times wear a suitable non-medical mask or face covering, make no stops on the way home and maintain physical (social) distancing. This also applies if you have to take a taxi or public transit to return home for your quarantine.

In either case, if you are buying gasoline, pay at the pump. If you want to eat, use a drive-through service. If you need to stop, use rest areas or other places where you can park and relax in your vehicle, avoiding contact with others.

If private transportation is not available, the Public Health Agency of Canada can arrange medical transportation, depending on the distance to the traveller's home or place of quarantine.

Anyone who has been in direct contact with a person who has or is suspected of having COVID-19 must quarantine for 14 days.

Q91. Why do I have to wear a non-medical mask or face covering when taking public transit to my place of quarantine if I do not have any symptoms of COVID-19?

New scientific evidence suggests that asymptomatic and pre-symptomatic individuals may spread COVID-19, which may explain the emergence of a number of secondary cases. Stricter measures are therefore needed to reduce the risk of spread by symptom-free people.

Wearing a non-medical mask or face covering is an extra step you can take to protect those around you, even if you have no symptoms. By covering your mouth and nose, you can reduce the risk of others coming into contact with your respiratory droplets. This can be useful during short periods when physical distancing is not possible in public, for example on public transit.

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

Yes, symptom-free individuals can take connecting flights to their destination for quarantine, provided they wear a suitable non-medical mask or face covering during the journey.

Quarantine or screening officers will instruct travellers to take extra precautions during their journey to their place of quarantine to avoid transmitting the infection to others. For example, they must respect physical distancing–maintaining a distance of two metres from others–, and practise good hand hygiene and cough etiquette.

Individuals returning home for mandatory quarantine should also consult the public health authority in their province or territory for information on additional measures or travel restrictions in their area.

Q93. What happens if a symptom-free Canadian traveller misses his or her connecting flight and has to spend the night in a city before boarding a

connecting flight the next day? Can they stay in a hotel, or with friends or family?

Travellers who enter Canada without symptoms may be allowed, as directed by the quarantine or screening officer, to stay in a hotel for one night before boarding their connecting flight the next day. They must wear a suitable non-medical mask or face covering when in a public place and proceed directly to their hotel without making any unnecessary stops along the way.

While staying at a hotel, travellers returning from abroad should stay in their rooms to avoid contact with others, observe physical distancing (i.e. maintain a distance of two metres from others), and practise good hand hygiene and cough etiquette. To get a meal, travellers should use drive-through or room service, provided the meal is delivered outside the hotel room door.

Staying with friends or family is not recommended, as it may be more difficult to avoid contact with others than in a hotel room.

Q94. If people arrive in Canada on a charter flight without landing at one of the four designated international airports, can they use a private vehicle to travel to their final destination in another province to isolate there?

Yes. People can continue their journey–including in a private vehicle–to self-isolate in another province.

If you need to stop, take precautions to avoid spreading the infection to others. You should wear a suitable non-medical mask or face covering, avoid contact with others (i.e. maintain a distance of two metres from others), and practise good hand hygiene and cough etiquette.

If you are buying gasoline, pay at the pump. If you want to eat, use a drive-through service. If you need to stop, use rest areas or other places where you can park and relax in your vehicle and avoid contact with others.

After you get home, use food delivery services or online shopping to buy essential items and ask family, a neighbour or friend to help you with essential errands.

Q95. What about people who come back to Canada by land? Can they spend the night in a hotel on the way home by car?

Asymptomatic people may be allowed, as directed by the quarantine officer or screening officer, to stay overnight at a hotel if necessary, but must proceed directly to their hotel without making any unnecessary stops along the way. Wearing a suitable non-medical mask or face covering is mandatory at all times in public places.

While staying at a hotel, travellers returning from abroad should stay in their rooms to avoid contact with others, observe physical distancing (i.e. maintain a distance of two metres from others), and practise good hand hygiene and cough etiquette. To get a meal, travellers should use room service, provided the meal is delivered outside the hotel room door.

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

Q96. RVs have been spotted in store parking lots near the border. Are they allowed to stop there so travellers can go shopping on the way back?

Asymptomatic individuals travelling in an RV will generally be instructed to stay overnight in their RV. Their recreational vehicle is basically their place of quarantine.

If they need to stop for the night, they should take precautions to avoid spreading the infection to others. They should remain in their RV and avoid contact with others, i.e. maintain a distance of two metres from others, and practise good hand hygiene and cough etiquette. They cannot go into stores to shop.

Q97. Can travellers stop to fill up, use a toilet or buy essential items on the way home to self-isolate?

It is important that travellers entering Canada avoid contact with others. Depending on the instructions provided upon entry to Canada, you must proceed directly and without delay to your place of quarantine and wear a suitable non-medical mask or face covering during the journey.

If you need to stop, take precautions to avoid spreading the infection to others. Avoid contact with others (maintain a distance of two metres from others) and practise good hand hygiene and cough etiquette at all times.

If you are buying gasoline, pay at the pump. If you want to eat, use a drive-through service. If you need to stop, use rest areas or other places where you can park and relax in your vehicle.

After you get home, use food delivery services or online shopping to buy essential items and ask family, a neighbour or friend to help you with essential errands, if possible.

Q98. What happens if an asymptomatic traveller is unable to travel somewhere to quarantine for 14 days?

Quarantine facilities, such as hotels designated by the Government of Canada, will be used to accommodate asymptomatic people who are unable to quarantine in a place:

- that is deemed appropriate (e.g. it should not be a shelter or other place where many people could be newly exposed as a result of the person's stay);
- where they will not come into contact with vulnerable people;
- where they will have access to basic necessities (e.g. food, heat, medicine).

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

Travellers With Symptoms

Q99. Why is it that some people with symptoms can self-isolate at home and others have to go to a quarantine facility or hospital?

Travellers entering Canada who report having COVID-19 or signs and symptoms of COVID-19, or who have reasonable grounds to suspect that they have signs and symptoms of COVID-19, will be ordered to proceed directly and without delay to their place of isolation and remain there

for 14 days. If they are unable to meet the conditions of the Order and self-isolate, they will be sent to a quarantine facility, or transported to a hospital, at the quarantine officer's discretion.

Factors to consider include the severity of symptoms or illness and whether they have a suitable place to self-isolate where they will have access to basic necessities and will not be in contact with vulnerable people. In addition, symptomatic travellers should be provided with private transportation to their home or place of isolation.

For example, if they have to make connections afterwards, if the distance home is too long for PHAC-organized medical transportation, or if they live with one or more vulnerable people, travellers will have to spend the 14 days of isolation in a quarantine facility designated by the Chief Public Health Officer of Canada.

Q100. **What is the definition of a symptomatic person?**

Any person with COVID-19 or who has signs and symptoms of COVID-19 or who has reasonable grounds to believe that he or she has signs and symptoms of COVID-19, is considered symptomatic. Signs and symptoms of COVID-19 include fever and cough or fever and difficulty breathing.

Q101. **Can symptomatic travellers returning home to self-isolate by private transportation be driven by another person or should they be the only ones in the vehicle?**

Symptomatic travellers should have private transportation to their place of isolation. They cannot ask anyone to pick them up.

If they do not have private transportation, the Public Health Agency of Canada can arrange medical transportation for them, depending on the distance to their home or place of isolation.

If the distance home is too long for PHAC-organized medical transportation, or if they live with one or more vulnerable people, travellers will have to spend the 14 days of isolation in a quarantine facility designated by the Chief Public Health Officer of Canada.

Q102. **If I am symptomatic, can I stop at a hotel on the way home by car?**

No. It is important to avoid any contact with others. Go straight to the place where you will carry out your 14-day mandatory isolation. That means you have to:

- wear a suitable non-medical mask or face covering while travelling to your place of isolation;
- travel directly to your place of isolation using private transportation (i.e. personal vehicle) and remain there for 14 days.

If you need to stop, take precautions to avoid spreading the infection to others. Wear a suitable non-medical mask or face covering, avoid contact with others (maintain a distance of two metres from others), and practise good hand hygiene and cough etiquette.

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

No. It is important that you follow the quarantine officer's or screening officer's instructions and avoid contact with others.

Once you are at home, use food delivery services or online shopping to buy essential items and ask a family member, neighbour or friend to help you with essential errands, if possible.

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

If private transportation is not available, PHAC will arrange medical transportation to the traveller's home or place of isolation, up to a maximum of 12 hours by road. If the traveller has to make connections or if the distance to return home is too long for PHAC-arranged medical transportation, the traveller will be required to spend the 14 days in isolation in a quarantine facility designated by the Chief Public Health Officer of Canada.

Quarantine facilities, such as hotels designated by the Government of Canada, will also be used to accommodate symptomatic people who are unable to quarantine in a place:

- that is deemed appropriate (e.g. it should not be a shelter or other place where many people could be newly exposed as a result of the person's stay);
- where they will not come into contact with vulnerable people;
- where they will have access to basic necessities (e.g. food, heat, medicine).

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

Compliance and Enforcement

Q105. **Who will be verifying compliance with the Order (i.e. spot checks)?**

Upon entry into Canada, travellers are required to provide their contact information to the Government of Canada for surveillance and compliance purposes.

If there is a concern that a traveller may not be complying with the requirements of the Emergency Order, peace officers may be called upon to assist in establishing contact with the traveller and confirming compliance. This may 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 confirm whether travellers returning to Canada are complying with the Emergency Order.

Q106. **What happens if someone is not complying with the Order?**

Failure to comply with the Order is an offence under the *Quarantine Act*. Individuals who violate mandatory isolation or mandatory quarantine requirements may be subject to a series of enforcement actions under the *Quarantine Act*, which include verbal and written warnings, arrest, detention or escort to a designated quarantine facility.

The Government of Canada will conduct 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 to determine the most appropriate action in each circumstance. In addition, anyone who, by willfully or recklessly contravening this Act or the regulations, exposes another person to imminent danger of death or serious injury, is liable to a fine of up to $1,000,000, or imprisonment for up to three years, or both.

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

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

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

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

The information needed to follow up with travellers is collected at the border and shared with provincial law enforcement agencies.

As a result of regulatory amendments made under the *Contraventions Act*, police authorities, including the Royal Canadian Mounted Police and local or provincial police forces, can now issue tickets to individuals who fail to comply with orders under the *Quarantine Act*, such as orders requiring people to self-isolate after international travel.

Q108. **How many Canadians have been penalized under the *Quarantine Act*? Of those, how many were fined? How many were sentenced to prison?**

PHAC recommends a graduated, risk-based approach to compliance, recognizing that authorities will exercise their discretion in responding to violations. Amendments to the *Contraventions Act* now allow greater flexibility in the enforcement of offences under the *Quarantine Act*. Law enforcement agencies, including the Royal Canadian Mounted Police (RCMP) and local and provincial police forces, may issue tickets to individuals who are subject to fines ranging from $275 to $1,000, depending on the seriousness of the non-compliance with the *Quarantine Act* and the Order.

Based on the information we have received from the police so far:

- no penalties have been imposed under the *Quarantine Act* or under amendments to the *Contraventions Act* since the implementation of the two mandatory isolation orders (issued on March 25 and April 14, 2020). Three Canadians have received verbal or written warnings from peace officers.
- a fine of $1,000 was issued under amendments to the *Contraventions Act*;

- no subpoenas, summonses, recommendations for prosecution, or prison sentences have been issued under the *Quarantine Act*.

Essential Service Workers

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

Mandatory quarantine does not apply to certain people who regularly cross the border to ensure the continued flow of essential goods and services, or to people who receive or provide other essential services to Canadians, as long as they do not have symptoms of COVID-19 at the time of entry into Canada.

Canada Border Services Agency officers will assess whether people crossing the border can be exempted from the Order.

People exempted from mandatory quarantine are still required to comply with the intent of the Order—to minimize the spread of COVID-19 in Canada—including wearing a suitable non-medical mask or face covering when entering Canada, and during transport or in public places. They will receive a document at the border advising them to monitor their health for symptoms of COVID-19, to be aware of and follow the public health advice and instructions of the area where they are travelling or are located and the link to the Canada.ca/coronavirus website, where they can get more information.

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

Adults 65 years of age and older represent one of the populations most likely to get seriously ill from COVID-19. Recent circumstances have highlighted the fact that residents of long-term care homes are vulnerable to infections because of their common living spaces, shared health care providers, outside visitors and transfers from other care facilities.

Individuals entering Canada whose work requires them to provide direct care to people 65 years of age or older must undergo a mandatory 14-day quarantine to reduce the possibility of spread of COVID-19.

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

Employers have an important role to play in helping to prevent the introduction and spread of COVID-19. It is important that employers do not prevent 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 ill after the quarantine period. If a worker develops symptoms at any time, the employer must immediately take the necessary steps to completely isolate the worker from others and contact local public health authorities. It is also suggested that the employer contact the appropriate consulate.

Like all Canadians, employers are required to report violations of the *Quarantine Act* committed by a worker who is in quarantine or isolation to local authorities. This includes workers who do not comply with the mandatory quarantine or isolation period.

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

The employer must house asymptomatic quarantined workers in premises separate from workers not under quarantine. It may be necessary to find alternative accommodation (e.g. a hotel) if this condition cannot be met. Appropriate quarantine facilities should provide an environment that ensures access to basic necessities (e.g. food, water, heat) while preventing exposure of vulnerable populations.

Quarantine facilities (e.g. hotels designated by the Government of Canada) may be used to accommodate symptomatic or asymptomatic individuals who cannot self-isolate or quarantine because they do not have suitable accommodation.

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

Q113. **Why is Canada accepting refugee claimants during a pandemic?**

Canada is committed to ensuring the health and safety of Canadians while continuing to meet its international obligations to refugee claimants. The Order maintains the prohibition against entry for foreign nationals seeking to come to Canada temporarily from the United States to make a claim for refugee protection, with some exceptions. Asylum claims from individuals covered by these exceptions will be processed.

Q114. **In response to the pandemic, the Government of Canada has put in place exceptional border and domestic restrictions for foreign nationals, permanent residents and Canadians. What steps are being taken to mitigate any public health risks that may result from the reopening of the border to asylum seekers?**

Foreign nationals who enter Canada other than at an official land port of entry to make a claim for refugee protection will still be refused entry unless they are covered by an exception or exemption to the prohibition.

Individuals who are ineligible to make a claim for refugee protection under the STCA will be returned to the United States, a designated safe third country, and individuals who are barred from entering Canada to make a claim for refugee protection will have to return to the United States. Although international travel has decreased as a result of the pandemic, this change in policy on refugee claimants could lead to an increase in the number of people entering Canada. All foreign nationals entering Canada, including refugee claimants, must still comply with the requirement to self-isolate for 14 days after their arrival in Canada.

Where claimants are unable to self-isolate or quarantine adequately, the federal government will work with them to find a suitable place for them to quarantine. Discussions are taking place between PHAC, IRCC and CBSA to establish an effective border procedure.

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

The exceptions in the Safe Third Country Agreement are based on principles that take into account the importance of family unity, the best interests of the child and the public interest.

There are four types of exceptions:

- Exception for family members
- Exception for unaccompanied minors
- Exception for document holders
- Public interest exceptions

Even if an asylum claimant falls under one of the above exceptions, all other eligibility criteria under Canadian immigration law apply. For example, a claim for refugee protection from a person who is considered inadmissible to Canada on grounds of security, human or international rights violation, or criminality will not be eligible.

Q116. **What are the exceptions to the prohibition against entry for foreign nationals arriving in Canada between land ports of entry or at an airport?**

Foreign nationals who enter Canada other than at an official land port of entry (including those arriving at an airport or between official land ports of entry) to make a claim for refugee protection will still be redirected to the United States, a designated safe third country, with the exception of:

- unaccompanied minors;
- U.S. citizens and stateless individuals ordinarily resident in the United States.

NOTE: Parents and guardians of U.S. citizens under the age of 18 were covered by an exception in Order 9. However, this is not in line with the STCA and this exception was removed in Order 11.

Q117. **Can an asylum claim be made at an airport?**

The prohibition against making an asylum claim at an airport or at any port of entry other than a land entry is maintained unless the claimant is an unaccompanied minor, a U.S. citizen, or a stateless person who ordinarily resides in the United States.

Quarantine Facilities

Q118. **How will the Public Health Agency of Canada accommodate and feed incoming travellers who are not allowed to return home for 14 days?**

The Government of Canada has designated quarantine facilities, such as hotels, to prevent the possible spread of COVID-19. Quarantine facilities will be used to accommodate travellers entering Canada who are unable to self-isolate or quarantine because they cannot meet the conditions of the federal Emergency Order (e.g. if they are symptomatic but live with a

vulnerable person or have no private transportation). 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 individuals, who are the people most likely to become seriously ill as a result of COVID-19.

PHAC is working with its partners to provide travellers who will be isolating in a designated quarantine facility with the necessary essentials, including food and any medical care or equipment.

Q119. **If a traveller returns to Canada and has to quarantine in a quarantine facility, will he or she be required to reimburse the costs associated with his or her stay?**

Costs associated with quarantine facilities will not be charged to travellers who are directed by a quarantine officer to quarantine or self-isolate in a designated quarantine facility. Transportation to the facility is provided free of charge.
During their stay at the quarantine facility, travellers receive three meals a day and other essential items, provided under contract with the Canadian Red Cross. All items are delivered to their rooms. A toll-free telephone number (Canadian Red Cross) is also available so they can indicate any essential items they need.

Q120. **How will my medical needs be met if I have to stay in a quarantine facility?**

People 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 at 8:00 p.m. EDT on May 3, 2020, the total number of travellers who were accommodated in 2020 was 387. This number does not include travellers quarantined at Canadian Forces Base Trenton or the Nav Centre in Cornwall.

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

The Government of Canada has established designated quarantine sites that provide accommodation for travellers entering Canada who either have known symptoms of COVID-19 or are asymptomatic and do not have suitable housing for self-isolating. To protect travellers' privacy and security, the locations of designated quarantine sites are not being made public.

MODELLING AND SURVEILLANCE

Q123. **What is predictive modelling?**

Predictive modelling uses mathematical equations to estimate the number of cases that may occur in the coming weeks or months. Many of the variables included in the calculation are based on what we know about the population affected, the disease, the virus and its spread. We

can then modify the calculations to show how public health measures would reduce transmission and assess how effectively these measures may control the epidemic.

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

The goals are to:

- predict the number of potential COVID-19 cases for the coming weeks or months;
- evaluate the best methods to control the epidemic in Canada.

Projections help us decide what public health actions we need to take, and how to prepare the health care system for the projected number of patients who may have COVID-19.

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

There are two broad categories of models:

- Predictive models: Predictive models are based on our knowledge of the evolution of the epidemic in Canada and other parts of the world over the past few days and weeks to predict the number of new cases we can expect to see in the coming week or so. These models are based on the assumption that the number of infections will continue to increase at the same rate as it did in the preceding days and weeks.

- Dynamic or mathematical models: Dynamic or mathematical models are based on knowledge of the virus responsible for COVID-19 (the SARS-CoV-2 virus), and its spread, derived from studies conducted by researchers around the world. This knowledge is used to produce a mathematical representation (model) of the potential spread of COVID-19 in the Canadian population based on public health measures taken to control the disease. These models are valuable planning tools, and are modified as data on the actual progress of the epidemic becomes more accurate. The resulting forecasts will change over time.

Q126. **What public health measures taken by communities are being used to model potential effects on the epidemic?**

The modelling is trying to measure the effect of the following key public health measures:

- Social distancing or physical distancing: Adopting measures such as closing schools, universities, and gathering or meeting places, as well as teleworking, to reduce the possibility of transmitting the virus from one person to another.
- Detecting and isolating cases: Finding infected people through testing and public health surveillance and isolating them (at home or in hospital) so they cannot spread the infection to anyone else.
- Contact tracing and quarantine: Tracing people who have been in contact with someone with COVID-19 and ensuring that they remain in isolation for 14 days (or longer if they develop symptoms) so that they do not spread the virus to others.

All of these public health measures are aimed at curbing community transmission.

Q127. **How reliable is the data?**

Our knowledge of COVID-19 is constantly evolving around the globe. The epidemic in Canada also continues to evolve and new case data is communicated every day. Model predictions will be updated and modified as the science evolves and as new data on cases in Canada becomes available to us. The models will also be updated to reflect changes in the public health measures being used to control the epidemic.

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

The actions taken by Canadians every day will continue to affect forecasts and actual data.

Q128. **Why offer two different models? One is not enough? What is the difference between the two models and what are their limitations?**

Predictions are based on data on the actual evolution of the epidemic in Canada, and allow us to understand its short-term trends based on the situation in Canada and other countries so far.

Dynamic models provide us with a long-term view of the potential evolution of the epidemic and help us identify public health measures that will minimize its impact on Canadians.

Q129. **Are the projections different among provinces and territories that have published their modelling data? If so, why?**

We are using comparable methods to predict the number of cases that could occur in the coming weeks, and to model the effects of various public health measures. However, our forecasts and models focus on Canada as a whole, while the provinces and territories consider what is happening locally. Since provincial models are based on data from cases that occurred in their jurisdiction, their predictions will be different and will relate to the changing situation in that province.

Q130. **Which external experts are involved in this work?**

The Public Health Agency of Canada (PHAC) has established an external advisory group to support its efforts to model and forecast the COVID-19 epidemic. The advisory group is composed of 37 experts in modelling and infectious disease epidemiology from provincial and territorial public health agencies and universities across Canada. The group meets twice a week.

PHAC participates in the World Health Organization’s modelling group to learn from studies around the world and compare their results with our own studies.

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

Modelling studies conducted outside of PHAC have been published and widely distributed. PHAC is committed to scientific excellence and will provide details of these study results in reputable scientific publications. Publication is already underway and PHAC will make them widely available as soon as possible after publication.

Additional Resources

COVID-19 in Canada: Using data and modelling to inform public health action

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

Q132. **Will these models tell us if we are achieving our goals?**

Models provide an indication of what will happen if different types of public health measures are taken, and the effectiveness of those measures will be shown in surveillance data. We continually assess the impact of our public health measures on the number of cases reported through surveillance. If necessary, we are adjusting these measures in collaboration with our provincial and territorial partners. We should not forget that the effects of public health measures are not visible in our surveillance data until about two weeks later. This is due to the time between when a person is infected and when his or case is reported to the Public Health Agency of Canada as a confirmed case.

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

The Public Health Agency of Canada (PHAC) and provincial and territorial public health authorities are working collaboratively to provide Canadians with the best, most accurate information available, including the number of cases and deaths related to COVID-19. Every effort is being made to ensure that data is reported in a timely manner but, as with any disease surveillance and given the heavy burden that COVID-19 is currently placing on provincial/territorial staff, there are some delays in reporting data to PHAC, particularly for deaths. The Centre for Immunization and Respiratory Infectious Diseases (CIRID) program area is working on a data strategy that includes a number of complementary indicators, including more current data on deaths, to complement what can be found in the current case report forms for COVID-19 and more.

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

As of April 22, 2020 (noon EDT), the median age for deaths related to COVID-19 was 84. Median age is based on the analysis of 764 COVID-19 case report forms reporting a death outcome and for which age information was complete.

Q135. **In the daily epidemiological report, only about one third of COVID-19 cases include hospitalization data. Why is that? Did some provinces fail to provide hospitalization data? If so, which provinces and why?**

While every effort is being made to obtain information in a timely manner, there are delays inherent in collecting information in a surveillance system covering both local and national. PHAC and provincial/territorial public health authorities are working closely together to provide the most accurate information possible to Canadians. As noted, detailed case data has been received nationally from provinces and territories for approximately 65% of reported cases. Data on these cases is preliminary and may have missing values for characteristics of interest or may be coded

"unknown". In most cases, when hospitalization information is not available on the case report form, it is because the hospitalization status was coded "unknown".

Q136. **Is the total number of deaths attributable to COVID-19 in Canada higher than the reported number and will modelling based on aggregate death statistics be required after the end of the pandemic 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 deaths related to COVID-19 reported in Canada, for a clinical mortality rate (CMR) of 3.3%. CMR is a commonly used method proposed by the World Health Organization and represents the number of deaths divided by the total number of cases.

As we have seen in all countries, this measurement varies over time during an epidemic. At the beginning of the epidemic, a lower estimate is usually obtained because people usually die late in the course of their illness. Other emerging factors, such as recent outbreaks in vulnerable populations in long-term care facilities, as well as other factors which affect data reporting may influence this estimate at any time. We expect the accuracy of the CMR to increase as we move through the epidemic.

Our knowledge of COVID-19 continues to evolve every day. Model-based forecasting will be updated and adjusted as the science evolves and as new data on cases in Canada become available.

Data Modelling - April 28, 2020

Q137. **What are the modelling numbers at the moment? How do they compare to the numbers that were initially published?**

Based on current modelling, it is estimated that the cumulative number of cases in Canada will be 51,196 to 66,835 and the cumulative number of deaths will be 3,277 to 3,883 by May 5.

In the model we presented on April 9, we estimated that there would be a cumulative total of 22,580 to 31,850 cases by April 16. The actual cumulative number of deaths reported on April 16 was 29,826.

The number of deaths attributable to COVID-19 was expected to be in the range of 500 to 700 on April 16. The actual cumulative number of deaths reported on April 16 was 1,048. Modelling has now been adjusted to correct for the underestimation of deaths in the latest model released.

Q138. **What does the large gap between the most optimistic and most pessimistic scenarios suggest about the value of this modelling exercise?**

The goals of modelling are to help predict the potential number of COVID-19 cases that might occur in the coming weeks or months, and to evaluate the best methods to adopt in order to

control the epidemic in Canada. As a result, the models provide information on what might happen in various scenarios, so that we can prepare for the worst and guide public health measures to achieve the best possible outcome. These various forecasts help us decide what public health measures we should use and how to prepare the health system for the expected number of patients with COVID-19.

Q139. **Two weeks ago, you miscalculated the number of deaths you were expecting. Why should we believe these numbers are accurate now?**

The Public Health Agency of Canada (PHAC) predicts the number of deaths within a statistical range based on a case-fatality rate of 2.2%, which is the ratio of deaths to cases. The World Health Organization also uses this ratio.

We need to accept that models have inherent limitations. The estimated case-fatality rate is usually low at the beginning of an epidemic because the increase in the number of confirmed cases in the denominator is much faster than the increase in the number of deaths in the numerator during this period.

Emerging factors, such as recent outbreaks among vulnerable populations in long-term care homes, were not included in our calculations. Model predictions are also very sensitive to changes in the actions we take (e.g. the extent to which people obey physical distancing guidelines).

Q140. **Have you fine-tuned your method to make forecasts more accurate?**

Models cannot predict what will happen, but they can help us understand what *might* happen. As part of the dynamic modelling approach, models are constantly updated as information emerges about transmission of the virus that causes COVID-19. For weekly forecasts, the method will depend on what most closely matches the course of the epidemic—based on the number of reported cases and deaths in the previous weeks.

Short-term forecasting of cumulative caseloads has proven to be effective. Short-term forecasts of the number of deaths are based on a different method. In the first release, the fatality forecast was based on a fixed value for the calculated case-fatality rate, which did not account for rate fluctuation over time. The case-fatality rate was particularly impacted by the large number of deaths in long-term care facilities. We believe that the new method will produce more accurate forecasts.

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

Predictive modelling uses mathematical equations to estimate the number of cases of a disease that may occur over the coming few weeks or months. The calculation involves many variables based on what we know about the population affected, the disease, the virus and how it is spread. We can then modify the calculations in ways that represent how public health measures would reduce transmission and assess the extent to which these measures may control the epidemic.

The method used to make these predictions uses the course of the epidemic, here, cases and deaths that have been reported in the previous weeks. Using this dynamic modelling approach, we can try to predict the potential total number of cases during the entire epidemic based on levels of control considered in different scenarios.

These total numbers are then used to estimate how many Canadians may be mildly or severely affected, and how many may die, based on global estimates of the differences in severity between different age groups, taking the age profile of the Canadian population into account. To assess caseloads and health care needs by province, university partners are developing models that take local data on underlying health problems, age and gender into account.

Q142. **On what dates are the modelling projections based?**

The Public Health Agency of Canada (PHAC) periodically updates its modelling, which includes national projections of the total number of cases. The projection presented on April 9 was produced on April 6, for the 10-day period ending April 16. Similarly, the projection presented on April 28 was produced on April 24, for the 10-day period ending May 5.

Projection modelling based on data collected up to April 18 resulted in a projected range, for a 10-day period, of 39,950 to 47,235 cumulative reported cases and 2,330 to 4,017 cumulative deaths as of April 28.

Q143. **Dr. Tam keeps saying that the course of this pandemic is not the same in all regions of the country, nor in all demographic groups. Are you developing demographic models or providing models that cover specific vulnerable populations, such as individuals living in LTC homes or who are homeless?**

PHAC is using a range of modelling methods to assess and understand how COVID-19 might spread in Canada over the coming weeks and months. We know from the data that the provinces and territories have provided about cases reported in their jurisdictions that the patterns of spread and populations affected are different in each jurisdiction.

We do not have a specific model of transmission in long-term care homes. However, while we are making model-based predictions for the country as a whole, we are also developing models that take the range of differences among provinces and territories, municipalities and vulnerable populations into account.

Models like these, which can account for local demographic variations, reflect the complexity of epidemics in each province and are more useful for planning at the provincial and local levels.

PHAC is committed to scientific excellence and will provide details of its modelling results in leading scientific publications. The publishing process for these publications is already underway. PHAC will widely disseminate these results as soon as possible after their release.

Q144. **Do you collect data based on race and ethnicity, including Aboriginal populations? Would that not make your modelling more accurate?**

There is no evidence that race or ethnicity is a risk factor for COVID-19. Circumstances or contexts are what make it difficult to apply public health measures, such as physical distancing, which impact the risk of spread.

The national COVID-19 case report form collects data on Aboriginal (First Nations, Métis and Inuit) status. However, data on the Aboriginal status of COVID-19 cases reported by the provinces and territories is incomplete.

Q145. **Modelling data from British Columbia and Ontario show that they have already peaked in cases of spread within communities and that the numbers appear to be decreasing. Is this true for Canada as a whole? As provinces see a reduction in the number of cases and begin to relax restrictions, how will this affect the modelling data?**

Surveillance data suggests that, overall, the public health measures implemented in Canada are having a significant impact and are slowing the epidemic. The degree of control of the epidemic varies greatly from one jurisdiction to another. We are monitoring 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. Models are also updated to reflect any changes in the public health measures being used to control the epidemic.

Modelling allows us to assess the potential impact of public health measures over time, to adapt the calculations to reflect how public health measures reduce transmission, and to evaluate the extent to which these measures may control the epidemic. Modelling data presented takes changes in public health measures (e.g. when, what, where) into account. Modelling data also shows when we can reopen schools, workplaces and other places and when, if necessary, restrictions need to be tightened again.

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

Q146. **Have you accounted for the reopening of some provinces and territories, many of which have started to announce their plans? Could there be repercussions to and from other more affected areas?**

Surveillance data suggests that, overall, the public health measures implemented in Canada are having a significant impact and are slowing the epidemic. The degree of control of the epidemic varies greatly from one jurisdiction to another. We are monitoring 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. Models are also updated to reflect any changes in the public health measures being used to control the epidemic. PHAC is working with university partners to explore the potential effects of removing public health measures.

Modelling allows us to assess the potential impact of public health measures over time, to adapt the calculations to reflect how public health measures reduce transmission, and to evaluate the extent to which these measures may control the epidemic. The modelling data presented takes changes in public health measures (e.g. when, what, where) into account and examines when we can reopen schools, workplaces and other places and when, if necessary, restrictions need to be tightened again.

It is important to remember that we must not let our guard down, that we must be realistic and recognize that we are still at the beginning of this epidemic. If public health measures are relaxed too quickly, the epidemic is likely to return with a vengeance very quickly.

Q147. **How can a government talk about reopening the economy when these figures show 3,277 to 3,883 deaths by May 5 if current measures are not maintained?**

While PHAC has undertaken model-based projections for the country as a whole, we recognize that the nature of the epidemic is different in different parts of Canada. Each region will have a different timeline for relaxing current public health measures.

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

We continuously monitor the impact of our public health measures by reviewing and analyzing case and outbreak surveillance data. In addition, we are adapting our surveillance systems as needed, in collaboration with our provincial and territorial partners.

Q148. **The lack of recent high-quality data was presented as a problem for developing this modelling. Did you experience any problems in the last cycle? Are there any vulnerabilities in the information you are submitting to us due to lack of data?**

Every effort is made to have up-to-date information, but there are inherent delays in collecting information in a surveillance system that extends from the local to the national level. The epidemic in Canada also continues to evolve and new case data becomes available every day. Model-based projections continue to be updated and adjusted as the science evolves and new data on cases in Canada becomes available. PHAC and provincial and territorial public health authorities will continue to work closely together to provide Canadians with the most accurate information.

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

For the dynamic modelling approach, models are constantly being updated as new information on the transmission of the virus that causes COVID-19 becomes available. The expected number of cases and deaths is constantly updated using forecasting methods, which include analyses of the pattern of cases and deaths reported in the previous weeks.

Short-term projections for cumulative cases have proven to be effective. Short-term projections for deaths are based on a different method. In the first version, the projection of deaths was based on a set value of the calculated case fatality rate, which did not take into account rate fluctuations over time. The case fatality rate was particularly influenced by the large number of deaths in long-term care facilities. We believe that the new method will be more accurate.

Q150. **A significant decline has been reported in emergency room visits across the country for non-COVID-19-related illness. Do you have any numbers on how many** Canadians are at risk of dying because they are afraid to go to the hospital and of catching the virus?

At this time it is not possible to estimate or model the reasons for changes in emergency room use; therefore, this information is not included in our modelling data. The provinces and territories may have more detailed information on the situation in their respective jurisdictions.

We recognize that many Canadians may be concerned about going to a doctor's office or hospital in light of the current pandemic. However, we must stress that it is very important that Canadians continue to seek treatment and to consult a health professional if they are not feeling well.

Q151. **Are you presenting numbers that are higher than you think, just to scare people into abiding by the restrictions in their daily lives?**

Models cannot predict what will happen. But they can help us understand what *could* happen. The purpose of disseminating the modelling is not to provide distorted or inaccurate images to scare Canadians into compliance with public health measures. The modelling is intended to help us understand and see the possible number of COVID-19 cases that could occur in the coming weeks or months, and to assess the effect that 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 will continue to help slow the spread of COVID-19 if they are maintained.

PHAC continually assesses the impact of public health measures that aim to break the chains of community transmission. It is important to remember that we mustn't let our guard down, and that we must be realistic and recognize that the fight against this epidemic is still ongoing. If public health measures are relaxed too quickly, the epidemic is likely to return with a vengeance very quickly.

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

To date, the available data do not suggest that the expected temperatures in Canada during the summer will influence virus transmission. The short-term projections released today do not take the season (temperature) into account.

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

The models provide information on what might happen in various scenarios to ensure we can plan for worst cases and drive public health action to achieve the best possible outcome. The possible scenarios presented in the Government of Canada's modelling are a synopsis of modelling studies, including those conducted by the Public Health Agency of Canada (PHAC) and other epidemiologists and modellers in Canada and around the world. The three possible scenarios presented were: "no controls" where an unrestricted outbreak occurs and infects a very large proportion of Canadians, "weaker controls" where the epidemic is not controlled by public health measures but is delayed and the peak reduced by public health action, and "stronger epidemic control" where the epidemic is controlled through a combination of public health measures. These scenarios are used for planning purposes and are not forecasts. Studies conducted outside PHAC have been published and are widely available, while those conducted within the Agency will be released in the coming weeks.

We are working with federal, provincial and territorial governments and universities to explore the potential spread of COVID-19 in Canada and to estimate a range of possible cases, hospitalizations and deaths that might occur over the next few weeks and months given different public health intervention scenarios. Our COVID-19 predictive modelling requires us to make assumptions based on incomplete data and evolving scientific data. These assumptions change as new information about the virus and more data about the epidemic in Canada become available. We are continually improving the models to provide Canadians with the best possible information on the possible scenarios.

The work cited by Mr. Attaran is consistent with our own studies and those of other groups. In the absence of public health measures, 70% or more Canadians may become infected. If public health measures are put in place and then relaxed suddenly or too quickly, the epidemic will simply resume. While public health measures are not enough to halt the epidemic, they may nonetheless help to reduce the percentage of Canadians who need to become infected and immunized in order to create "herd immunity" to stop the epidemic.

Additional work by the Agency and other modellers, and which is consistent with observations from other countries, suggests that low percentages of infected Canadians (1% to 10%) could be achieved through high public health efforts. These efforts would include sustained public health measures to prevent reintroduction of transmission, to detect and isolate cases in Canada, and to trace and quarantine people who have come into contact with cases.

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

The Public Health Agency of Canada (PHAC) has established an external advisory group to support our efforts to model and forecast the COVID-19 epidemic. This advisory group includes

more than 40 experts in infectious disease modelling and epidemiology from provincial and territorial public health agencies and universities across Canada. This collaborative group meets twice a week. The Agency is also committed to ensuring that scientific research and information produced by PHAC is made available to the public in a timely manner and in accordance with the Government of Canada's Directive on Open Government, including a daily epidemiological report and preliminary data tables of confirmed cases. In some cases, PHAC may not be able to transfer certain data if they are third party owned or if there are compelling reasons to limit disclosure, such as for privacy reasons. Our knowledge of COVID-19 continues to evolve on a global scale. The epidemic in Canada also continues to evolve and new case data becomes available every day. Model-based forecasting will be updated and adjusted as the science evolves and as new data on cases in Canada become available.

FLUWATCHERS

Q155. **Prior to COVID-19, what was the FluWatchers program responsible for? Can you also give us some numbers, such as the number of Canadians who volunteered to participate in the FluWatch program in 2018 and 2019?**

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

Traditional flu surveillance programs such as laboratory and hospital-based surveillance only target those who seek medical care or test positive for the flu, and therefore miss many potential cases of the flu. For this reason, the Public Health Agency of Canada (PHAC) launched FluWatchers to detect flu-like illnesses in individuals who do not seek medical attention or get tested for the flu. This program provides a more accurate picture of flu cases in Canada during the typical flu season. The FluWatchers program also provides valuable additional surveillance indicators, such as the number of symptomatic individuals who see a doctor, the number of people tested and their results.

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

Q156. **When did the FluWatchers program start monitoring COVID-19, and why?**

PHAC has been monitoring FluWatchers data since the beginning of the pandemic in Canada for signs of an unusual increase in the number of Canadians with a cough and fever. Minimal changes were made to the questionnaire toward the end of March 2020 to include specific COVID-19 questions. PHAC uses FluWatchers to track COVID-19 for the same reasons that the program is used to track the flu. The vast majority of people are unlikely to seek treatment or testing; therefore, a large portion of the population will not be included in the traditional surveillance methods currently in use. The FluWatchers program will also give us an idea of how many symptomatic people are seeing a doctor and how many people are being tested and their results. We hope that this program will provide Canada with a better picture of COVID-19 cases in the country, as it does for the flu.

Q157. **How can you tell the difference between the flu and COVID-19 in the responses you are receiving now?**

Syndromic surveillance programs such as FluWatchers are used for signal detection. If the program reports something, we usually use it as a trigger to look at our other surveillance data streams to validate the signal we are observing. We are able to validate the results we get from FluWatchers against data from our other flu surveillance programs. For example, currently, according to our laboratory surveillance data stream, there are very few flu viruses or other seasonal respiratory viruses circulating in Canada. Our other flu indicators, such as hospitalizations and outbreak surveillance, also show very low flu activity. We can use this knowledge to differentiate the data reported by the FluWatchers program. If flu circulation was high, we suspect that the responses from FluWatchers would likely be the flu. Given that circulation of the flu (and other respiratory viruses) is currently very low and that we are seeing the end of the flu season, we can assume that the FluWatchers responses could be attributed to COVID-19.

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

PHAC began increasing promotion of the FluWatchers program on social media on April 3, 2020, to recruit additional participants. Since then, our weekly participation rate has increased from 3,200 to 8,700 participants per week. The higher the number of participants reporting, the more accurate the data.

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

ROLE OF GPHIN IN SURVEILLANCE

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

The Public Health Agency of Canada'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 around the world who conduct public health surveillance. GPHIN is a significant contributor to the World Health Organization's Epidemic Intelligence from Open Sources.

Every day, about 7,000 articles are captured in the GPHIN system. The web-based application in the GPHIN system continuously scans and acquires news sources of information worldwide in nine (9) languages (Arabic, Persian, English, French, Portuguese, Russian, Spanish, 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 aggregator 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 data are in the GPHIN system, they are processed, validated, and assessed.

Q160. **How are GPHIN threat assessments and analysis compiled?**

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

Every day, approximately 7,000 articles are entered into the GPHIN system. Once the data is in the GPHIN system, it is processed, validated and evaluated and then included in reports, including the daily situational awareness report published every morning.

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

On December 31, 2019, at 5:16 a.m. EST, an article called "China probes mystery pneumonia outbreak amid SARS fears" was published by Agence France-Presse and uploaded in the GPHIN system at 5:42 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 review recognized the potential importance of this issue and highlighted it in the Daily GPHIN report, which was distributed at 7:50 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 mysterious pneumonia outbreak amid SARS fear (Media)**
>
> Authorities are investigating an outbreak of viral pneumonia in central China amid online speculation that it might be linked to Severe Acute Respiratory Syndrome (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 central Hubei province, the city's health commission said in a statement. Seven patients were in a critical condition.

Q163. **Have Chinese officials already briefed Canadian officials on COVID-19? If so, when were they briefed and what did they say?**

Canada and China have been exchanging information on a regular basis since the outbreak in early 2020. This has included discussions between the health officials of both countries and numerous exchanges between health and foreign affairs officials involving our respective embassies in Ottawa and Beijing. Interactions have also taken place in multilateral processes such as the G20.

Minister Champagne has discussed COVID-19 issues with his Chinese counterpart, State Councillor and Foreign Minister Wang Yi, on three separate occasions, on 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

Early in the year, as part of his regular contacts with the Chinese Embassy, Paul Thoppil, Assistant Deputy Minister, Asia-Pacific at Global Affairs Canada, also had several meetings with Chinese Ambassador Cong Peiwu on related issues to discuss the evolving outbreak. Beginning in January, other Global Affairs Canada officials in Ottawa and at the Canadian Embassy in Beijing, including Ambassador Dominic Barton, also participated in several COVID-19-related conversations with Chinese officials. Initial conversations focused on sharing information about the progress of the outbreak and the evacuation of Canadian citizens from Wuhan, followed by discussions about Canada's offer to provide personal protective equipment (PPE) to help China combat the epidemic.

Recent high-level discussions in both Ottawa and Beijing have focused on the provision of medical supplies from China to Canada and global lockdown measures.

Q164. **What is the GPHIN Renewal Project? Why was this renewal undertaken in stages?**

The GPHIN Renewal Project aimed to develop an enhanced web-based platform that complies with Government of Canada information technology policies to increase the automated collection, aggregation 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 was a collaboration between PHAC and the National Research Council of Canada.

The GPHIN Renewal Project achieved the following objectives:

- The platform is compliant with information technology policies, guidelines and standards, and the Government of Canada has the capacity to make further improvements and innovations to the system.
- GPHIN can take advantage of the variety, volume and velocity of available data—including data from social media and a wider range of websites—and provide a visual representation of events in time and space through an integrated analysis and evaluation capability and automated article summaries.
- The system's AI can learn and improve the accuracy of its index of relevance.

A phased approach allowed PHAC to develop, create, implement and test functionality. A post-rollout review of Release 1 identified quality and functionality issues that were addressed in Release 2, allowing for further enhancements to the system.

Q165. **Have there been any complaints about GPHIN's search system after the Release 1 update of the NRC system? And about the fact that search results were sometimes missing and had to be entered manually?**

After the initial launch of the renewed system in August 2016, analysts noted a decline in search function speed. In the summer of 2017, NRC brought in an industry expert to analyze the issues and recommend changes. These changes were implemented in mid-2018 and the evaluation measures showed clear improvements.

Q166. **Has Shared Services Canada directed the Global Public Health Intelligence Network (GPHIN) to transfer servers outside of government to a private system for integration with the Government of Canada system?**

A Request for Information issued by Public Services and Procurement Canada to engage private sector companies to upgrade the GPHIN platform went unanswered. In collaboration with the National Research Council Canada (NRC), the platform was updated within scope and budget.

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

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

Q168. **Is there a ban on sharing information with registrants?**

The sharing of information with registrants is not prohibited. GPHIN continues to provide information to its users on a regular basis. In addition, GPHIN provides users with special COVID-19 reports to respond to needs identified by organizations such as the World Health Organization.

Q169. **Can you explain how the work of GPHIN analysts is assigned? How many are responsible for national health surveillance (e.g. vaping, Lyme disease) and how many are responsible for global surveillance (e.g. COVID-19, avian flu)?**

GPHIN analysts work collaboratively on national and global surveillance. While analysts focus on regions and countries that match their language capabilities, they all share responsibilities for national monitoring. This practice has been in place for many years.

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

GPHIN's annual budget is approximately $2.8 million, which includes human and operating resources.

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

GPHIN consists of two essential components:

- A professional multidisciplinary team of life science analysts, reviewing information in nine (9) languages and conducting rapid risk assessments to detect public health threats; and
- An Information Management Tool that uses machine learning and natural language processing to facilitate the work of the analysts.

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 provided by volunteer "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 necessary, and often add comments or context before posting. ProMED is one of many data sources of GPHIN.

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

BlueDot is a private company for which you need to pay a subscription to access the 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 identify potential threats and provide early warning.

Q172. **Does the Government of Canada use the BlueDot AI for COVID-19 contact tracing of individuals?**

The Public Health Agency of Canada and Health Canada have contracts with BlueDot. None of these contracts relate to the use of AI for contact tracing.

Q173. I have confirmed with Ontario Public Health 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 Public Health Canada does not collect this kind of data either. Could you confirm that?

It is true that the COVID-19 Case Report Form does not include questions on race or ethnicity, but it does include a section for the purpose of identifying and classifying cases as Aboriginal peoples (First Nations, Métis, Inuit). This section is only completed when the individual indicates that they belong to one of the three categories of Aboriginal peoples. Data in this section is often incomplete or missing.

Q174. Are there plans to add other social determinants of health (such as education or income) as risk factors to the case report form used for COVID-19 data collection?

The Case Report Form contains information on age and known risk factors, such as having a pre-existing medical condition or being a resident of a long-term care facility. This data is analyzed regularly and included in an epidemiological summary.

There are no plans at this time to add social determinants of health (education or income) as risk factors to the COVID-19 Case Report Form. If a revision to the form were to be considered, the Public Health Agency of Canada would involve a national advisory committee of provincial and territorial public health experts to discuss the issue, as the responsibility for data collection rests with provincial and territorial health authorities.

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

Understanding a patient's history is essential to providing safe and appropriate care. That is why the sharing of health information between health care providers, protected by strict confidentiality and data security requirements, can produce better outcomes through better informed, coordinated and integrated care. A system that meets the needs of patients can also make it easier for them to access information about their own health. Health Canada is working with its provincial and territorial partners, as well as key national data organizations, to support improved patient access to health data while ensuring the privacy of health information.

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

At present, the Public Health Agency of Canada is not aware of any Canadian studies that have been conducted in Canada that collect wastewater samples for the detection and identification of COVID-19.

It is too early to consider this type of analysis because more research is needed to understand its usefulness. The Public Health Agency of Canada is keeping abreast of the science in this area.

As part of the Canadian 2019 Novel Coronavirus (COVID-19) Rapid Research Funding Opportunity recently funded by the Canadian Institutes of Health Research, a project led by Dr. Jeffrey Joy of the University of British Columbia will collect environmental samples to better understand the epidemiology and course 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, it is not yet known whether wastewater samples will be part of this project.

Q177. *Why was the emerging infectious disease events surveillance platform project initiated and what is its scope?*

The Emerging Infections Surveillance Platform (EISP) was designed to improve internal processes for managing and evaluating data on emerging infectious diseases. Launched in 2016, the pilot project was limited to data on zoonotic and vector-borne diseases. The pilot project provided guidance on how to improve processes and informed the development of new tools and mechanisms that have been put in place.

PHAC's readiness to manage emerging infectious diseases is supported by:

- A Data Innovation Centre fully dedicated to meeting PHAC's data needs and using numerical tools to enable rapid data access and analysis;
- The Global Public Health Intelligence Network, which constantly reviews and analyzes global information sources to detect early warnings of public health threats and triggers rapid risk assessments based on this information;
- The implementation, in conjunction with the provinces and territories, of national disease surveillance programs that monitor infectious diseases and risk factors and alert us to trends that could signal areas of increasing risk;
- Laboratory detection of signals that exceed expected baseline levels of pathogen circulation and the use of technologies, such as full genome sequencing, to identify clusters of infection and support a rapid public health response;
- International collaboration under the Global Health Security Initiative (GHSI) for real-time communication of public health risk assessment, detection methods and data collection approaches.

The results of this pilot project have been shared with GHSI as part of the regular and continuous exchange of information.

Q178. **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 is collected through daily communication between federal, provincial and territorial epidemiologists who work together to collect and share information. Case data 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. We supplement this information with publicly available data sources. Data on outbreaks in long-term care facilities is reported by local public health authorities to their P/T public health counterparts, who summarize this information, report it publicly and implement control measures. We are currently working on a standardized data set for long-term care facilities. PHAC also publishes information on possible exposure to the virus, for example in long-term care facilities, on its website.

NML's RESPONSE TO OUTBREAK

Q179. **Why did NML scientists go to the level 4 laboratory at the Wuhan Institute of Virology?**

The Institute requested viral samples of the Ebola and Henipah viruses and in 2019, the Public Health Agency of Canada responded to the request by sending samples for scientific research. The National Microbiology Laboratory (NML) exchanges samples with other public health laboratories, as they do with the NML, in order to contribute to the advancement of science. Transfers are subject to strict protocols including the requirements of the *Human Pathogens and Toxins Act*, *the Transportation of Dangerous Goods Act*, the Canadian Biosafety Standard and NML Standard Operating Procedures.

The NML also provides training to international laboratory professionals and has already trained scientists from many countries, including China.

If pressed...

For confidentiality reasons, we will not comment on individual employees.

Any speculation about the role of Public Health Agency of Canada (PHAC) scientists in the emergence of the novel coronavirus has no basis in fact.

Q180. **Do the Government of Canada and PHAC support examination of the possibility that a breach or accident at the Wuhan laboratory may be somehow connected to the pandemic outbreak? Will the Government of Canada provide updated information on concerns about the level 4 laboratory in Saskatchewan and the potential for espionage or security breaches by Chinese researchers?**

Coronaviruses are naturally occurring and are known to be transmitted from animals to humans. There is no evidence to suggest that another source of the novel coronavirus causes COVID-19.

No speculation about the role of Public Health Agency of Canada scientists in the emergence of the novel coronavirus is based on fact. Our COVID-19 response will continue to be based on science.

TESTING AND CASE CONFIRMATION

Q181. **How does Canada currently detect COVID-19 in patients?**

Canadians can have confidence in the methods and capabilities of Canada's NML.

The NML is world-renowned for its scientific excellence.

Provincial public health laboratories can test forCOVID-19 with a very high degree of accuracy.

The NML provides laboratory reference services to all provinces and territories. These screening services provide various forms of support to provincial and territorial laboratories across Canada, including confirmatory testing, quality assurance testing and in-depth analysis of difficult-to-diagnose samples.

Q182. **What is the Public Health Agency of Canada's testing capacity?**

We continue to test on a massive scale and Canada has one of the highest screening rates in the world. We know that testing is essential to find new cases and to identify and interrupt the chains of transmission. We are now running more than 20,000 tests a day, almost double what we were running in April, and that number continues to grow.

We do not have a precise figure for the number of tests that need to be performed each day in order to relax social distancing measures, and these figures vary from one jurisdiction to another. The target of 60,000 tests per day is based on what we can achieve by maximizing current public health laboratory capacity, and is useful for planning purposes. The provinces continue to increase their screening capacity based on their needs. Some days, in some provinces, the capacity exceeds the number of people looking to get tested.

Canada has maintained a positive result rate of approximately 6–7%, which is within the effective detection range for accurately targeting the spread 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 relatively sensitive screening system. We continue to expand our laboratory capacity to ensure that this continues to be the case.

The main objective is to test symptomatic individuals to detect cases and quickly trace contacts. Another key objective is to increase testing in high-risk situations, including long-term care facilities, health care facilities and correctional facilities, to support outbreak control in all settings.

Our priorities continue to be access to reagents, evaluation of rapid non-laboratory tests, and access to licensed test kits to ensure that the provinces and territories are equipped to expedite testing according to their requirements.

Q183. **Does PHAC recommend temperature screening prior to entry to public places? If not, why not? Will this be implemented when activities begin to gradually resume?**

In Infection prevention and control for COVID-19: Interim guidance for long-term care homes, the Public Health Agency of Canada (PHAC) recommends the implementation of staff screening measures, including a twice-daily temperature check. However, fever is not usually the first symptom of COVID-19, and in some cases, infected individuals do not develop a fever, so it is not recommended to implement measures focused solely on fever detection.

During the outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003, there were more than 6.5 million screening interactions for inbound and outbound travellers at Canadian airports, including 2.3 million travellers screened by thermal scanning. Despite these intensive screening efforts, this method did not detect a single case of SARS. For this reason, it is not recommended that temperature checks be conducted at borders prior to entry into Canada.

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

Members of the Special Advisory Committee, which includes Canada's Chief Medical Officers of Health, continue to work closely together to develop a coordinated response to the epidemic based on the best available scientific knowledge and evidence.

Q184. **What are the specific tests currently authorized in Canada for COVID-19 screening?**

With the implementation of new diagnostic testing for the novel SARS-CoV-2 virus, Canadian public health laboratories have used the collective strengths of their network to evaluate these new tests to ensure their accuracy, while promoting the ability to rapidly distribute testing capacity across Canada.

After the publication of the genetic sequence of the virus in January, it became possible to immediately develop multiple molecular tests (polymerase chain reaction) that detect specific genetic traits of the virus. The Canadian laboratory network has recommended that molecular tests targeting two different traits of the virus be used to diagnose infections, and that for some cases (such as travel from countries that have not yet reported COVID-19 infections), additional tests include genetic sequencing to provide definitive evidence of the presence of SARS-CoV-2. Through the use of multiple testing methods and multi-site testing, such as when tests were presumed positive in the provinces and then confirmed by the National Microbiology Laboratory, Canada was able to ensure that each confirmed case was a real case.

We have a certain level of confidence in the tests, but we need to streamline their approach so that they can be conducted in additional laboratories in Canada. The case definition was therefore successively adjusted to allow cases to be confirmed as positive using a single molecular test. Selection of this test was based on knowledge of the performance of the different tests conducted in different Canadian laboratories. The most sensitive targets are now regularly used.

With regard to false negative results, there is a need for a better understanding of COVID-19 infections and the course of the virus during infections. It is conceivable that either very early or very late in an infection, the amount of detectable virus may be low and that current molecular testing does not detect these cases. However, as the response to this epidemic shows, laboratories will continually strive to improve their testing approach based on the evidence.

Furthermore, the current molecular tests used across the country, which are the result of the collective sharing of information and tools by laboratories, will soon become the benchmark for comparison and implementation of the next phase of testing, as rapid point-of-care tests are implemented to allow testing in health care facilities, rather than requiring specimens to be sent to a laboratory for testing.

Q185. **Are Spartan tests an effective way to diagnose COVID-19? What are the false positive and false negative rates?**

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

Health Canada's review is in line with international best practices and ensures that devices meet standards such as those described in applicable guidance documents, including:

i) the Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency issued by the US FDA on March 16, 2020;

(Ii) the EUA [Emergency Use Authorization] Interactive Review Template for Molecular-Based Tests for SARS-CoV-2 That Causes COVID-19 (guidance on emergency use authorization) issued by the US FDA on March 12, 2020.

Q186. **Does the Public Health Agency of Canada plan to deploy Spartan Bioscience's portable COVID-19 test kits at Canada's land borders?**

The Public Health Agency of Canada plans to use the available COVID-19 test kits produced by Spartan Bioscience Inc. to support screening in rural and remote communities. Screening kits should not be deployed at Canada's land borders at this time.

Q187. **What are Health Canada's requirements for screening machines that have not been approved by Health Canada? Does Health Canada advise against the use of unauthorized COVID-19 screening machines? Do swab results from unauthorized test kits need to be confirmed in another laboratory (using Health Canada-approved test kits)?**

Only diagnostic tests authorized by Health Canada can be imported into or sold in Canada. Unauthorized tests have not been reviewed by Health Canada and their accuracy has not been validated. Health Canada has confirmed that the authorized COVID-19 tests are backed by evidence that they will provide accurate and reliable results. A list of diagnostic devices authorized for use in the fight against COVID-19 is available here.

The Xpert Xpress SARS-CoV-2 was authorized under the Interim Order (IO) on March 24, 2020.

The BD SARS-CoV-2 reagents for the BD Max system were authorized under the IO on April 19, 2020. They will be added to the list of authorized devices within the next two days.

Health Canada has no pending applications for a COVID-19 screening device manufactured by Altona. The Department contacted the Prince Edward Island provincial laboratory to confirm that Altona's PCR kit was marketed and sold to them for research purposes and internal use only. Based on the information obtained to date, no non-compliance with the Medical Device Regulations was found.

The Department encourages anyone who has information about the sale or potentially misleading advertising of any health product that claims to treat, prevent or cure COVID-19 to report it using the online complaint form.

Q188. **Will the tests be accessible to anyone who wants to take them?**

Rapid and accurate screening is an essential component of the public health response to this pandemic. It enables the early detection of cases to help 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 laboratories and other diagnostic laboratories have the resources necessary to screen people infected with COVID-19. Several commercial reagents approved by Health Canada can be used for COVID-19 infection screening. However, there is a global shortage of many of these reagents, and this affects the analytical capacity of laboratories. We need Canadian solutions to tackle this problem. The shortage is affecting Canada's screening capacity. The Public Health Agency of Canada's (PHAC) National Microbiology Laboratory (NML) has developed a reagent to help address this shortage. This reagent is mass-produced by LuminUltra Technologies Ltd., a New Brunswick-based company. Even with increased capacity, screening priorities will need to be respected in order to achieve appropriate public health goals.

Q189. **Does the shortage of sampling and analytical equipment prevent more tests from being carried out?**

The Government of Canada has ordered over 11 million swabs from various domestic and international suppliers that are delivered in batches every week. The Government purchases and produces other laboratory supplies needed to support provinces and territories in their overall laboratory analysis efforts. We are also exploring options to ensure a continuous supply of sterile swabs, including the possibility of producing swabs in Canada.

Q190. **What is the greatest challenge to overcome to increase screening capacity and test a larger proportion of the population?**

The Government of Canada is investing $150 million in support of federal public health measures such as enhanced surveillance, increased analytical capacity at the NML, and continued support to First Nations and Inuit community preparedness. This important work will

support the delivery of diagnostic tests across Canada, research, testing and implementation of new diagnostic tests and methods, and coordination of the procurement and distribution of reagents and laboratory supplies with provincial and territorial authorities to increase screening capacity across the country.

Q191. **Which universities and manufacturers are currently involved in the development of sampling or testing equipment or otherwise contribute 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 assess how they can meet the urgent needs of Canadians and front-line health care workers. Canadian industry plays a major role in increasing national screening capacity. It is important to note that LuminUltra (New Brunswick) provides extraction reagent to federal and provincial laboratories across the country and is continually expanding the capacity to conduct diagnostic testing. As well, Spartan Bioscience offers a Health Canada approved non-laboratory diagnostic test that will support screening in rural and remote areas.

Q192. **How does Health Canada's list of COVID-19 symptoms compare to the CDC's list? Is the list updated and how important is it to Canadians who are monitoring for signs of illness at home?**

Public health is a shared responsibility in Canada. Canadian public health guidelines for COVID-19 are evolving as the body of evidence grows and the novel virus is better understood. We continually review the latest science 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 modify or revise it as new information is received.

With respect to the differences between the federal government's self-assessment tool and the Ontario self-assessment tool, 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 availability of health services. With respect to the differences between the Canadian government's list of symptoms and that of the U.S. Centers for Disease Control, each country develops its own guidelines based on a variety of factors, including epidemiological data and risk assessments.

Q193. **How do laboratories report information about positive test results to public health authorities?**

The means used by provincial public health officials to collect and disseminate information about positive test results for COVID-19 varies from province to province. The provinces are in the best position to provide additional information on the methods they use.
However, the provinces and territories report their laboratory test results to the Public Health Agency of Canada (PHAC) for national surveillance.

Canadian public health laboratories collaborate through the Canadian Public Health Laboratory Network (CPHLN), which brings together federal, provincial and territorial public health laboratory professionals working together to strengthen Canada's public health system through coordinated laboratory services and sound management. It is through the CPHLN that the provinces and territories report their lab results for COVID-19 on a daily basis using a variety of tools.

One such tool is an online platform, the System for Analysis of Laboratory Testing (SALT) which is a component of the Canadian Network for Public Health Intelligence (CNPHI). CNPHI is a public health scientific informatics and biomonitoring platform designed and managed 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, including real-time visual analysis.

Remdesivir for COVID-19 treatment

Q194. **Can remdesivir be used for any patient infected 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. There is some evidence to suggest that remdesivir may have the potential to reduce the duration of disease symptoms in some hospitalized patients with advanced COVID-19. Patients who received remdesivir had a 31% faster recovery time 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 in intravenous form.

Q195. **Are there clinical trials underway to determine the effectiveness of remdesivir?**

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 give Canadians access to new treatments to treat COVID-19 and provide the medical community with an opportunity to systematically collect information on the effectiveness of treatments and associated risks. To date, Health Canada has approved two clinical trials for remdesivir associated with COVID-19 in Canada: the CATCO remdesivir trial, which is part of the World Health Organization's SOLIDARITY study, and Gilead's open-label remdesivir trial. Access to remdesivir through clinical trials is available at several sites across the country. More information on approved tests is available on our website.

Health Canada is also aware of several international clinical studies on remdesivir in the treatment of COVID-19. Some of these studies have been completed or are in the process of being completed. Health Canada is closely monitoring the progress of clinical trials and new findings on remdesivir.

Q196. **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 has granted emergency use authorization for remdesivir, an investigational antiviral drug for the treatment of COVID-19. According to information published by the U.S. FDA, "the authorization is temporary and does not take the place of the formal new drug application submission, review and approval process. The EUA allows for the distribution and emergency use of remdesivir only for the treatment of COVID-19; remdesivir remains an investigational drug and has not been approved by the FDA." Additional information on the FDA's EUA for remdesivir is available on theFDA website.

Testing at-home

Q197. **What type of tests have been proposed for home use?**

To date, Health Canada has not approved any diagnostic tests or sample collection kits that can be used by the general public to detect or self-diagnose COVID-19.

Lateral flow antibody tests, commonly known as "rapid tests", have been illegally offered for home use. This type of test does not require any laboratory equipment and the results are presented as a colour strip 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 also follow the advice of a medical professional on how to care for themselves and how to reduce the spread of COVID-19 by self-isolating. Furthermore, public health authorities must have access to the results of all tests in order to make decisions to counter the spread of COVID-19 in Canada.

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

Q198. **What is Health Canada doing to prevent the sale of unauthorized COVID-19 tests?**

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

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

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

Q199. **Are COVID-19 home test kits available in other countries?**

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

It was recently mentioned in the media that the FDA approved its first home test kit, but that is not true. The FDA has approved the COVID-19 RT-PCR test for which only a fluid sample is taken at home. After collection, the swabs should be sent to a laboratory for analysis. They are subject to stringent transportation requirements.

Q200. **What type of COVID-19 tests have been approved by Health Canada or are under consideration?**

Health Canada has only authorized the sale and importation of COVID-19 diagnostic tests for the exclusive use of qualified heath care professionals or technicians.

Health Canada has received submissions for serological testing for COVID-19 and is currently reviewing them. The Department has published an industry guideline on the requirements for serological antibody testing submitted under the COVID-19 Interim Order.

Amendments to the Spartan test kit authorization

Q201. **What is the Spartan kit and how does it work?**

The Spartan test kit consists of a portable analyzer called the Spartan Cube. The Cube carries out the test with Spartan COVID-19 detection cartridges and Spartan-exclusive swabs. COVID-19 can be diagnosed in less than an hour using the kit without having to send the sample to a laboratory.

Q202. **Could there be similar problems with other medical devices approved under the Interim Order?**

Each product is examined individually depending on the technology, and different requirements related to evidence standards may be necessary. While no problems are anticipated at this time, Health Canada will not hesitate to take appropriate action should problems arise.

Q203. **Have any kits been used to diagnose patients?**

Spartan Bioscience has informed the Department that none of the tests were used for diagnostic purposes. As part of the voluntary recall requested by Health Canada, the company will need to reconfirm whether kits were used for diagnostic purposes.

Q204. **Why is the Spartan test no longer approved for use other than for research? How and when did the problem arise?**

On March 26, 2020, Health Canada issued conditional approval to Spartan Bioscience Inc. for its Spartan Cube for research use only. 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 through an expedited scientific review process, based on minimum requirements.

On April 11, 2020, Health Canada completed its scientific review to ensure that the device was supported by evidence that it met safety and effectiveness requirements. Health Canada's scientific review was based on analytical data from laboratory studies provided by the company and took into consideration

that additional clinical validation would be conducted by public health laboratories to determine performance in a clinical setting. Health Canada has amended the conditions of the authorization, allowing the sale of Spartan Cube, but requiring that data be provided from additional technical studies and sales information.

On May 1, 2020, the Public Health Agency of Canada's National Microbiology Laboratory (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 to identify any performance problems that go undetected in a laboratory. The report indicates that although the Spartan Cube functioned in the laboratory according to the manufacturer's specifications, performance problems were identified during the clinical trial. These problems appear to be related to the patented swab, which may not collect enough mucous material for testing.

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

Health Canada will continue to work with Spartan to meet the regulatory requirements to allow the use of the point-of-care test kit.

Q205. **Why didn't Health Canada wait for the results of the clinical studies before authorizing the sale of the Spartan kit?**

The scientific review of the Spartan test kit was fast-tracked as part of the Interim Order announced on March 18, 2020.

Health Canada's regulatory decision was based on laboratory testing of the kit and not on clinical trial data on its effectiveness. The review took into consideration that further validation would be conducted by public health laboratories to determine performance in a clinical setting. This is consistent with the approach taken by other reputable regulators.

As planned, Health Canada continued to monitor and evaluate the safety and effectiveness of these rapid field test kits to ensure that they function properly and provide accurate results. In light of the clinical results, Health Canada has amended the conditions of the product's authorization to restrict the sale of the product for research purposes only, until the company can provide adequate evidence of the kit's clinical performance.

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

Serology

Q206. **Does the Public Health Agency of Canada agree that the best way to understand COVID-19 transmission and progression is through serological testing for antibodies? Is Canada working on a serological test for COVID-19?**

Antibody-based serological tests will be essential for understanding the immune response to the viral infection and will play a key role in a number of public health investigations to determine the immunity status of infected individuals. The Public Health Agency of Canada's National Microbiology Laboratory and its partners are working on developing a number of serological

tests in addition to evaluating various commercial serological tests for COVID-19. This pan-Canadian collaboration includes members of the Canadian Public Health Laboratory Network, clinical researchers in front-line health care facilities and Canadian Blood Services, all of whom are working to develop the equipment needed to evaluate and then implement serological testing.

Serological tests detect the presence of virus-specific antibodies in patients' blood and allow public health professionals to identify individuals who have been infected with the virus that causes COVID-19. These studies will provide an understanding of community transmission and COVID-19 exposure rates.

It is important to note that serological tests have not been validated as a routine diagnostic approach and that molecular testing methods will continue to be the diagnostic standard. For the time being, plans are underway to conduct pilot studies, followed by larger-scale studies to investigate immunity in health care workers and other selected populations.

Q207. **Is the Public Health Agency of Canada concerned about the availability of serological testing? Are there any risks?**

This is a new virus and the body's immune response to it is not well known at this time. The results of serological tests depend on the body's immune response. There are concerns about the usefulness of serological technologies for clinical diagnosis because of the time required for antibody development (i.e., the seroconversion process) and the potential for cross-reactivity with antibodies to other viruses. Using a diagnostic test that produces false or inaccurate results may put individuals and the Canadian public at risk. Health Canada is ensuring that the serological tests are scientifically reviewed based on validation results from trusted laboratories in Canada and abroad.

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

Antibody-based serological tests will be essential for understanding the immune response to viral infection and will play a key role in a number of public health investigations to determine the immunity status of infected individuals.

Q208. **Do you have an update on serological tests being developed in Canada? Or a time frame for beginning serological studies?**

As of April 17, 2020, Health Canada had not authorized any serological testing. A list of pending applications is available here.

Only diagnostic tests authorized by Health Canada can be imported into or sold in Canada. Unauthorized tests might not produce accurate results and may result in misdiagnosis. The COVID-19 tests authorized by Health Canada are well supported by evidence that they will provide accurate and reliable results.

Developing and implementing validated and effective serological tests for COVID-19 is an important step in Canada's public health response. This is a new virus and the body's immune

response to it is not well known at this time. The Public Health Agency of Canada's National Microbiology Laboratory is analyzing various commercial COVID-19 tests.

Using a diagnostic test that produces false or inaccurate results may put individuals and the Canadian public at risk. Canada is being vigilant to ensure that serological tests are used appropriately in conjunction with other laboratory tests.

Q209. What is the difference between swab tests 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. Conversely, the traits of the virus itself (rather than the human immune response) form the basis for the molecular tests currently used to diagnose COVID-19 from swab samples.

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

Using serological tests to diagnose COVID-19 infections is not recommended, given that antibodies are unlikely to develop until later in the infection, often resulting in false negative results. For diagnostic tests, it is best to test directly for the presence of the virus while the infection is active.

Q210. Is the government considering the possibility of issuing serological or immunity certificates or passports to allow immunized persons to move freely again?

We are expanding our knowledge of COVID-19 every day by keeping abreast of the rapid growth of new scientific evidence as it emerges. This is essential for decision making.

There is an active international effort to assess whether people who have recovered from the disease can safely resume their daily activities. No decision has yet been made in Canada as to whether the immunity status of individuals can be certified.

COVID-19 is an emerging virus, which means we need more data before we know if those who have recovered will have lasting protective immunity.

At this time, we do not know whether people who have recovered will have immunity, how long this immunity will last, whether it is possible for people to contract COVID-19 twice, or whether they will have milder or more severe symptoms if they contract COVID-19 a second time.

We recognize that it may be difficult to wait for scientific results, but while we learn more about COVID-19, we must use public health measures that we believe to be effective.

We continue to advise Canadians to stay in their homes, practise good hand hygiene and, if they must leave their homes, practise physical distancing. These are proven public health measures that work.

We are working to improve our understanding of COVID-19 across Canada so that we can continue to adapt our response to slow the spread of the virus.

Q211. **Other countries are offering the BTNX blood test; why isn't Canada? When do you think the review process for this test will be completed?**

Canada has maintained a science-based approach to pandemic management, including maintaining pre-market authorization requirements for diagnostic tests. Health Canada will continue to focus its work on the health and safety of Canadians and to distribute safe and effective COVID-19-related health products as quickly as possible.

The COVID-19 tests authorized by Health Canada are well supported by evidence that they will provide accurate and reliable results. Only diagnostic tests authorized by Health Canada can be imported into or sold in Canada. Unauthorized tests might not produce accurate results and may result in misdiagnosis.

Serological tests are used to determine whether a person has previously 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. Unlike the tests currently authorized in Canada that analyze swab samples from the nose or throat, serological tests do not diagnose active COVID-19 infection.

The results of serological tests are very useful in determining infection rates and the prevalence of people with protective antibodies in certain settings or communities. These results are also important to better understand the overall immune response to the virus, including providing data for developing vaccines against COVID-19.

Health Canada is collaborating with the Public Health Agency of Canada's National Microbiology Laboratory and provincial public health laboratory partners to build on their studies of immune responses and serological technologies underway in Canada and internationally. Health Canada's position on the use of serological testing is consistent with the World Health Organization's view that serological testing will play an important role in research and monitoring, but it is not currently recommended for early case detection.

Serological tests are not currently authorized for sale in Canada because there is no evidence that they can provide reliable and accurate results. These tests can provide false negative results if used for diagnostic purposes. False negative results could be detrimental to those tested if they delay seeking medical treatment because they believe they are not infected. This could also lead to increased community spread of the disease by those misinformed about their infection status. For this reason, priority has been given to authorizing diagnostic tests based on nucleic acid technology.

Health Canada is reviewing applications for serological diagnostic devices and may authorize them for specific purposes other than diagnosis when sufficient evidence is obtained.

Contact tracing

Q212. **Can you tell me more about the federal government's program to recruit people to do contact tracing?**

As part of the overall federal, provincial and territorial government response to COVID-19, the Government of Canada is supporting provinces and territories by providing a virtual directory for recruiting and mobilizing qualified Canadians to provide peak capacity in key areas.

To assist the provinces and territories, the Government of Canada is working with them to determine their needs. They identified contact tracing and case registration as areas where they need assistance. As a result, required skills include case management, data collection and management, public awareness and telephone interviewing skills. Further 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 stages. The first and second stages are already underway. The first step consisted of bringing in qualified federal public servants, who are not currently in essential positions for ongoing federal work, to work in jurisdictions that are feeling the most pressure. The second step involves building on the directory developed as part of a volunteer recruitment campaign for COVID-19 and contacting health, public health and science faculties across the country to issue an open call to those interested in joining the directory. The third step will be aimed at retirees or people who are not currently participating in the COVID-19 response from all health and health science professional associations.

Q213. **How many volunteers will be accepted for the National COVID-19 Volunteer Recruitment Campaign and how many will be accepted for contact tracing? When will they be deployed in the field?**

By the time the process closed on April 24, over 53,769 volunteers were registered in the directory. Volunteer lists have been circulated to several jurisdictions, primarily to support long-term care activities. Each jurisdiction will decide when and how it will deploy volunteers. Please contact the provincial and territorial governments to learn more about their specific plans.

Q214. **Is the Department considering the use of digital data technologies, such as mobile phone applications, to improve contact tracing? What type of digital data model is the Department considering?**

Mobile applications can help promote physical distancing by enabling Canadians to change their activities and reduce risk behaviours. They could complement public health measures to flatten the curve, including:

- avoiding crowded areas and non-essential gatherings;
- frequent hand-washing with soap and water for at least 20 seconds;
- avoiding touching your eyes, nose or mouth without washing your hands.

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

Q215. **A company partially based in Canada has developed a smartphone application that helps with contact tracing, similar to the one in place in Singapore. Would the government consider adopting this type of technology to facilitate contact tracing?**

Contact tracing is an important public health measure to identify people potentially exposed to COVID-19 and to ensure that they take precautions (such as self-isolation and symptom monitoring) to avoid exposing others. Contact tracing is a provincial and territorial responsibility and has been ongoing since the beginning of the COVID-19 outbreak. Although it is an essential public health tool, contact tracing is resource-intensive. Telephone applications using location or proximity data to help alert those who have been in contact with patients with COVID-19 can be a useful tool to fight this epidemic. Please direct questions about specific provincial or territorial contact tracing policies or regulations to the appropriate provincial or territorial public health authorities.

DRUGS, HEALTH PRODUCTS AND MEDICAL SUPPLIES

Availability of medical devices

Q216. **Does Canada have a sufficient number of diagnostic tests**?

We expect there to be enough diagnostic kits.

Health Canada is working with manufacturers to allow market entry for commercial diagnostic devices to increase COVID-19 diagnostic capacity in Canada.

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

As a result of the Interim Order, two new diagnostic tests are now readily available in Canada:

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

This measure will help improve access to medical devices that could make it easier and faster to screen patients in Canada.

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

Q217. **Is Health Canada looking to the cannabis industry for additional COVID-19 testing?**

A number of options are being evaluated to increase screening capacity to support provincial and territorial public health authorities. As part of this work, Health Canada is working to identify what laboratory capacity may be available across the country in various areas, including licensed cannabis production sites, to help support COVID-19 testing. On March 26, Health Canada sent an email to all licence holders, asking those with laboratory capacity who are

interested in helping to inform the Department by email. Several laboratories responded indicating their willingness to assist. The Department is currently confirming next steps, including whether they have the appropriate equipment, certifications and protocols to help.

Q218. **Is the government considering increasing the supply of flu vaccines for the next flu season in light of the demand resulting from the COVID-19 pandemic?**

The Public Health Agency of Canada (PHAC) is preparing for the possibility of simultaneous outbreaks of influenza and COVID-19 in Canada this fall. To help minimize the challenges that this 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 diseases.

PHAC is involved in coordinating and overseeing the distribution of flu vaccines for public programs in collaboration with Public Services and Procurement Canada, Health Canada, vaccine manufacturers and federal, provincial and territorial partners. PHAC does not decide the number of vaccines that provincial and territorial governments purchase for their respective populations; the decision is made by each provincial and territorial government based on past experience, flu season forecasts 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. Orders can still be increased before final commitments are made.

Q219. **Is Health Canada aware of a potential shortage of medical devices due to COVID-19, and what is being done to monitor supply?**

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

The Department has encouraged stakeholders in the medical devices industry to look for any early signs that could indicate supply problems, and none has been reported to date. Health Canada is continuing to monitor the situation and will take appropriate action, if necessary, to mitigate the impact on Canadians.

Q220. **Can 3D-printed medical devices be used to reduce supply shortages in Canada during this pandemic?**

Health Canada is aware that groups here in Canada and in other countries (e.g., the United Kingdom, United States, Italy and China) may use different manufacturing techniques to address supply issues.

Health Canada, in collaboration with other federal organizations and the private sector, is facilitating an assessment of the current 3D-printing capacity in Canada and will help define next steps to increase capacity where needed.

It is important to note that Health Canada remains the regulatory authority for all medical devices intended for sale or import and has processes in place to rapidly assess the safety, effectiveness and quality of medical devices manufactured in response to COVID-19, including those manufactured using 3D printing.

Health Canada has communicated with its reliable 3D-printing network within the medical device industry, hospitals, universities, colleges and industrial manufacturing facilities. As of March 20, we had received a response from 34 organizations with experience in 3D printing who are willing to help.

Q221. **Is there an estimate of the number of critical care beds that Canada will need when the epidemic peaks, and how many critical care beds are currently available?**

According to the Canadian Institute for Health Information (CIHI), Canada (excluding Quebec, Nunavut and Yukon) had 3,902 critical care beds in 2017–2018. This is the most recent and comprehensive data available. More information can be downloaded from the CIHI website. Provincial and territorial health system officials are closely monitoring the capacity of their respective health systems, including the supply and demand for essential goods, such as critical care beds and ventilators, as the number of COVID-19 cases increases. The situation continues to evolve as many jurisdictions are taking a variety of measures, including cancelling elective surgeries and relocating patients receiving other levels of care to other sites to improve their acute care capacity in hospitals.

Health Canada is currently in discussions with provincial and territorial officials on intensive care unit capacity and ventilator availability.

Q222. **How many ventilators does Canada currently have? How many will be needed when the pandemic reaches its peak?**

The supply order between the federal, provincial and territorial governments also includes ventilators. The federal government has entered into contracts for more than 1,500 ventilators and is working to help acquire additional ventilators to assist the provinces and territories.

Global demand for these items is high, and the Public Health Agency of Canada will continue to assess needs with the provinces and territories as the epidemic progresses.

Q223. **What is the federal government doing to increase the number of available ventilators and masks?**

The Government of Canada is currently investing $2 billion for the purchase of personal protective equipment (PPE), including bulk purchases with the provinces and territories. This includes masks and face shields, gowns, ventilators, test kits and pads, and hand sanitizer.

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), discussions are ongoing regarding avenues to explore PPE procurement and increased domestic production with Canadian companies, such as Thornhill Medical and Medicom. To ensure that these production lines meet the appropriate technical specifications for use in front-line interventions, Health Canada and the Public Health Agency of Canada are currently conducting technical assessments. This includes the Minister of Health's recent signing of an Interim Order to allow accelerated access to medical devices related to COVID-19. The list of approved COVID-19 screening devices (with approval dates) is posted here, and medical devices approved in Canada are on the current list of authorized medical devices.

Q224. **Is Health Canada using the three Royal Canadian Mounted Police (RCMP) forensic laboratories to provide personal protective equipment to health care workers?**

The Government of Canada has not asked the RCMP to provide personal protective equipment to health care workers. It works directly with the provinces and territories to determine needs and makes bulk purchases to take advantage of their collective purchasing power. The Government is also accepting donations, increasing domestic industrial capacity and speeding up the regulatory process to ensure that urgently needed products come onto the Canadian market.

Q225. **Is the federal government considering a plan to speed up the evaluation process for donations of medical supplies to address the medical equipment shortage?**

The Public Health Agency of Canada and Health Canada are working closely with the Canada Border Services Agency to expedite access to donated medical supplies.

In response to the COVID-19 pandemic, Health Canada implemented interim measures to expedite the importation of medical equipment and products, including disinfectants, hand sanitizer, personal protective equipment (masks, gowns) and swabs. More information can be found here.

Q226. **Does Canada have a stockpile of syringes, needles or other equipment that would be needed for a pandemic vaccination campaign?**

Currently, the National Emergency Strategic Stockpile (NESS) stores goods to respond to a variety of threats and risks that could be used for a pandemic vaccination campaign, such as sterile needles, syringes and gauze pads, as well as personal protective equipment (PPE). These supplies could be used to supplement provincial and territorial supplies. It is not NESS practice to disclose specific quantities of its stocks. PHAC is working with the provinces and territories on an ongoing basis to assess all pandemic-related needs and to ensure that every effort is made to maintain an adequate supply in Canada.

Q227. **Will Health Canada ensure adequate immunization supplies are ready for when a COVID-19 vaccine becomes available?**

The Public Health Agency of Canada (PHAC) and Health Canada are currently working with key partners and stakeholders to identify in advance any supply chain risks or capacity gaps that could impact Canada-wide mass vaccination campaigns against COVID-19.

PHAC will continue to work with its provincial and territorial partners to identify potential gaps in the supply chain and will be ready to support the rapid supply of additional commodities such as needles, syringes, as well as the personal protective equipment and medications that will be required for mass COVID-19 vaccination campaigns in Canada.

Q228. **What is the current waiting period for Canadian personal protective equipment (PPE) manufacturers (not importers) to obtain authorization to sell and distribute their products to health care facilities? How many companies are currently waiting for these certificates?**

Canada's *Medical Devices Regulations* (MDR) establish a system for classifying medical devices into one of four classes, with Class I representing the lowest risk and Class IV, the highest.
Health Canada issues two types of licences for medical devices:

- Medical Device Licence (MDL) - a 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) - a licence issued to Class I manufacturers, as well as Class I-IV importers or distributors, authorizing the importation or distribution (sale) of a medical device in Canada.

The regulatory review process for authorizing medical devices has been modified in response to 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 allows for an expedited review of medical devices required for COVID-19 diagnosis, treatment, mitigation and prophylactic measures without application review fees.

Health Canada has received a significant number of applications under the Interim Order for PPE as well as MDEL applications.

Applications received under the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19

Currently, 359 applications are being processed for PPE under the Interim Order. Most of these applications are on hold as Health Canada is awaiting additional evidence to demonstrate that the devices meet the necessary requirements. The time required to authorize a COVID-19-related application is highly dependent on the quality of the application and the supporting information provided to Health Canada. It currently takes about nine days on average to process an application that is without issue. The list of diagnostic devices authorized by Health Canada to counteract COVID-19 can be found on the following Health Canada webpage: 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 therefore considered low-risk compared to other classes. Companies looking to manufacture, import or distribute PPE must obtain an MDEL if they do not have an authorization number under the Interim Order. Health Canada's usual service standard for issuing an MDEL is 120 days. However, our goal is to process COVID-19-related MDELs as quickly as possible to facilitate access to needed medical devices.

In light of the current demand for medical devices to help combat COVID-19 and the high number of companies working to provide these products in Canada, Health Canada is facing an unprecedented increase in MDEL applications.

As of April 27, 2020, Health Canada had expedited issuing over 750 MDELs (e.g., masks, gowns and respirators), with approximately 450 applications still pending.

To facilitate timely access to supplies needed to help combat COVID-19, Health Canada has implemented a temporary discretionary measure by assigning MDEL applicants a temporary submission number while MDEL applications continue to be processed as quickly as possible. Submission numbers allow applicants to carry out licensable activities pending the issue of the MDEL. As of April 27, over 380 submission numbers had been assigned to applicants while their MDEL applications were 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 all requirements set out in the MDEL and must ensure that the Class I-IV medical devices they sell comply with the safety and effectiveness requirements set out in sections 10 to 20 of the MDR. Health Canada has adopted a risk-based approach to compliance and enforcement, the primary objective being to mitigate the risk associated with non-compliance. The Department uses a range of compliance and enforcement tools to verify compliance and takes immediate action to stop the importation or sale of any non-compliant product. Examples of compliance and enforcement tools include written notices (regulatory or warning letters), inspections, public notices, seizures or impoundments at the border, and recalls, as outlined in Health Canada's *Guidance on Medical Device Compliance and Enforcement (GUI-0073).*

All authorized MDELs are listed on the following website: *Medical devices establishment licence listing*.

Additional information regarding the Department's actions to increase the supply of PPE is available on the following Health Canada web page: COVID-19 personal protective equipment (PPE)

Q229. **What has been the response to the federal government's call to address the need for medical supplies (http://www.ic.gc.ca/eic/site/080.nsf/eng/00048.html)?**

On March 18, the Minister of Health signed the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19 as an emergency public health measure to allow for the expedited processing of medical devices related to COVID-19. The Interim Order will help to ensure that medical devices related to COVID-19 are available to treat, mitigate or prevent COVID-19, if required.

As part of the COVID-19 pandemic response, the Government of Canada passed the *COVID-19 Emergency Response Act* on March 25. Amendments to the *Food and Drugs Act* allow Health Canada to implement robust tools to support efforts to mitigate and, where possible, prevent shortages. 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 necessary to prevent or mitigate the effects of shortages directly or indirectly related to COVID-19.

The Interim Order allows for the exceptional importation of specific drugs that may not fully meet Canadian regulatory requirements (e.g., bilingual labelling) but that are manufactured to comparable standards, to ensure Canada's drug supply and protect Canadians' health during this period.

We are aware of the PPE and medical supplies shortage in Canada and we are committed to doing what is necessary to protect the health of Canadians, particularly front-line health care workers, from COVID-19. The Government of Canada is continuing to work with 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. To meet these needs, we are purchasing large quantities of equipment and supplies, working with Canadian companies to increase their manufacturing capacity to produce additional supplies, and investing in COVID-19 testing. We have also received donations from national and international organizations. Health Canada has also considered conservation strategies, including decontaminating respirators and using expired masks, to ensure the continued availability of these devices.

The Public Health Agency of Canada, Health Canada and the National Research Council of Canada conduct technical reviews to verify that products comply with the Government of Canada's technical specifications for COVID-19, as outlined on Public Services and Procurement Canada's Buy and Sell website.

Q230. How has Canada solved the mask shortage when the United States has not?

The Government of Canada is working with provincial and territorial governments to continually assess the need for personal protective equipment (PPE), such as masks.

To meet these needs, the Public Health Agency of Canada (PHAC) is working with Public Services and Procurement Canada to process bulk supply orders and allocating PPE and medical supplies to provinces and territories according to an approach agreed to by federal, provincial and territorial Ministers of Health. PHAC also deploys PPE and ventilators from its National Emergency Strategic Stockpile (NESS) to provinces and territories that have requested assistance. The objective of NESS is to help complement provincial and territorial resources by providing additional support.

PPE shortages are an ongoing concern as global demand remains high, which is why, in addition to acquiring PPE and increasing domestic manufacturing capacity, the Government of Canada is promoting various measures, such as frequent hand washing and physical distancing, to flatten the epidemiological curve.

Distribution and quality control

Q231. When did Canada begin procuring personal protective equipment (PPE) and supplies for COVID-19?

In January 2020, the Public Health Agency of Canada (PHAC) began monitoring the coronavirus outbreak in China and assessing the National Emergency Strategic Stockpile (NESS). That same month, PHAC began working with Public Services and Procurement Canada to obtain the supplies needed to respond to a potential outbreak in Canada and placed bulk orders for medical supplies in addition to orders for NESS.

Q232. **How much personal protective equipment (PPE) was exported to China from mid-January to March 31 through all known (i.e., institutional, retail and community) channels?**

As announced on February 9, 2020, the Government of Canada has donated approximately 16 tonnes of PPE to China, in collaboration with the Canadian Red Cross and the Red Cross Society of China. More information on these donations can be found here.

Q233. **Where will medical supplies be stored before they are distributed to hospitals by Canada Post or Purolator?**

Amazon will work directly with Canada Post to supply warehouses and leverage its existing third-party distribution channels through Canada Post and Purolator to deliver products to provincial and territorial health authorities across the country for use by front-line health care workers.

Q234. **As of May 1, how many shipments of personal protective equipment (PPE) to the provinces were sent through Amazon Canada?**

To date, each province and territory has received five shipments of PPE through Amazon.

Q235. **Do you have any doubts about the quality of medical equipment donated to Canada?**

The Government of Canada is receiving medical supplies donated by companies in Canada and abroad and is working to make them available to front-line health care workers.

The Public Health Agency of Canada (PHAC) currently manages donations. Partners are helping PHAC to handle all donations received as efficiently as possible and to distribute them as widely as possible.

When the federal government receives a donation, it must assess its quality. The goal is to complete this process as quickly as possible so that products that meet specifications can be distributed to the provinces and territories without delay.

PHAC and Health Canada use a pre-established list of product specifications for this purpose. They have also created a technical review team to facilitate the process.

A multidisciplinary interdepartmental technical evaluation committee has been established to evaluate donated medical supplies. The committee verifies that they comply with the Government of Canada technical specifications for COVID-19, which can be found on Public Services and Procurement Canada's "Buy and Sell" website. The evaluation process varies depending on the medical device.

The multidisciplinary interdepartmental technical evaluation committee is composed of representatives from PHAC, including the National Microbiology Laboratory, Health Canada and the National Research Council of Canada.

Q236. Has the Public Health Agency of Canada (PHAC) rejected any donations of supplies following quality control? Has any equipment failed quality control tests in the past two months?

Personal protective equipment (PPE) and medical supplies received by the Government of Canada, whether donated or purchased by Public Services and Procurement Canada (PSPC), are verified by PHAC to ensure that they meet the Government of Canada's technical specifications for COVID-19. If PHAC cannot report on quality, this equipment will not be allocated to the provinces and territories for front-line health care.

To date, PHAC has received some supplies that do not meet Government of Canada specifications for health care facilities. Although these supplies do not meet the specifications for front-line health care intervention, they are subsequently evaluated for potential use in non-health care settings.

For example, items can sometimes be damaged in transit, and PHAC ensures that these items are not distributed to the provinces and territories. As part of the COVID-19 response, PHAC had a small amount of PPE that was not distributed because it was damaged in transit, and PHAC continues to verify PPE as it is received. The same applies to donations received by PHAC.

If pressed for further details:

Given the intense global competition for PPE and medical supplies, countries are working with a number of new and diverse suppliers and manufacturers to meet the demands of the COVID-19 response efforts. As a result, PHAC is exercising due diligence on products purchased by PSPC by verifying the quality of the supplies purchased and provided upon receipt. Thus far, PHAC has reported approximately one million KN95 masks that do not comply with specifications for health care facilities. These masks have not been distributed to the provinces and territories for front-line health care, and the possibility of using these masks in non–health care settings is being evaluated at a later date.

Q237. What happens to items that do not pass inspection? Are they destroyed? Are they sent back to the donor country?

Personal protective equipment (PPE) requirements for health care workers are more stringent than those that apply to a non–health care setting. Equipment that does not meet specifications for health care facilities will be further evaluated for possible use in the community.

Q238. How many of the N-95 masks received are still being tested?

The number of N95 and equivalent respirators (e.g., KN95 respirators) received changes daily, as does the number of respirators tested. Of the 5.342 million respirators received, 2.3 million are still awaiting final test results.

If pressed:

Of the 5.342 million respirators received, 2.0 million were deemed non-compliant with specifications for health care facilities.

Q239. **Does the government require medical supplies used by local health agencies to meet certain standards? If so, what are they?**

The Public Health Agency of Canada (PHAC) encourages suppliers to go online for information on specific products, including product specifications and details on the current expedited process.

Q240. **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 that are delivered in batches every week. We are also exploring options to ensure a continuous supply of sterile swabs, including the possibility of producing swabs in Canada. The Government purchases and produces other laboratory supplies needed to support provinces and territories in their overall laboratory analysis efforts.

PHAC has shipped over 700,000 test swabs for distribution in Canada. PHAC anticipates weekly deliveries of approximately 500,000 swabs through orders placed with various companies. PHAC is working to allocate these swabs to the provinces and territories on a per capita basis without delay.

Q241. **Recent media coverage has reported that during the week of April 6, Canada received 320,000 mould-contaminated swabs from China. What measures are being taken to ensure that this does not happen again? Are we set to receive other medical supplies from China that may be unusable because they do not meet Health Canada criteria?**

When the provinces and territories identified problems with the swab stocks in question, the product was recalled by the company, who committed to taking corrective action and replacing the swabs.

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 over 11 million swabs and is supporting the provinces and territories in their laboratory testing efforts, including ensuring that the demand for swabs is met.

The Public Health Agency of Canada (PHAC) reviews personal protective equipment (PPE) and other medical supplies received by the Government of Canada (whether donated or purchased) to ensure compliance with the Government of Canada's technical specifications for COVID-19 before the equipment is shipped to the provinces and territories. If PHAC cannot report on the quality of the equipment or supplies, it does not distribute them for front-line health care. The verification process varies depending on the medical device. For example, KN95 respirators (an accepted alternative to N95 respirators) are visually inspected for any design or manufacturing

defects and tested to confirm that they meet filtering facepiece specifications. Surgical gowns and 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 meet requirements for front-line health care interventions but are subsequently evaluated for potential use in non-health care settings.

Q242. **Has an investigation been initiated to determine why ESBE Scientific's contaminated scientific equipment was sent to Canada?**

ESBE Scientific shipped 380,000 EZ PRO swabs to various locations in Canada between March 28 and April 3, 2020. On April 11, 2020, the company issued an urgent recall notice due to a swab contamination issue. The company recalled the product and committed to taking corrective action and replacing the product. Provincial and territorial public health laboratories were immediately notified of the recall. Health Canada worked with the company to ensure that the recall went smoothly. The Department posts all health product recalls in its recall and safety alert database. Information on the EZ PRO swab recall can be found here.

ESBE Scientific has a valid Medical Device Establishment Licence (business no. 103659). Health Canada will continue to work with the manufacturer to ensure that it takes the necessary corrective actions and adheres to appropriate protocols.

It was determined that ethylene oxide can be used to sterilize the swabs. All provincial public health laboratories were notified on April 13, 2020. The Public Health Agency of Canada (PHAC) immediately made arrangements with a company to sterilize the swabs. Health Canada has authorized this sterilization process under the Interim Order signed on March 18, 2020. Provinces and territories have a choice between discarding the swabs and re-sterilizing them.

The Government of Canada has ordered over 11 million swabs from various suppliers and is supplying or producing other items needed for laboratory testing to support the provinces and territories. It is currently reviewing ways to ensure a continuous and safe supply of sterile swabs, including options for producing and sterilizing swabs in Canada.

A contract has been 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 to place bulk orders. Public Services and Procurement Canada is continuing to identify all suppliers capable of meeting Canada's needs.

Q243. **If these products do not meet all of Health Canada's regulatory requirements, should Canadians be concerned about their safety?**

No. While these products are generally subject to certain regulatory requirements (e.g., licensing and bilingual labelling), Health Canada is allowing the distribution of these low-risk products in Canada to meet the current unprecedented demand to help slow the spread of COVID-19.

The expedited process requires companies to complete and submit a notification form to allow Health Canada to maintain a record of all hand sanitizers, disinfectants and personal protective equipment sold in Canada under this Interim Measure. 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 appropriate action to protect the health and safety of Canadians when necessary.

Health Canada will continue to use all tools at its disposal to expedite the provision of safe and effective health products related to COVID-19. However, the Department is not providing blanket approval for unauthorized drugs or devices.

We will keep Canadians informed of any new information as it becomes available.

Consumers and patients are encouraged to report any adverse events associated with health products to Health Canada.

Q244. **Have Health Canada or the Public Health Agency of Canada (PHAC) received complaints about a batch of masks provided to Albertan health care facilities?**

PHAC is not aware of the circumstances surrounding this purchase and is therefore unable to comment. We have contacted the Province of Alberta to see if we can provide assistance.

Q245. **Are there concerns about 3D-printed medical devices without the usual quality control or certification processes?**

Medical devices sold, imported or distributed in Canada must meet the safety, effectiveness and quality requirements of the *Medical Devices Regulations* or the Interim Order in the case of devices related to COVID-19. Regulated devices include medical devices manufactured by 3D printing. Health Canada is the regulatory authority for all medical devices intended for sale or importation and has processes in place to rapidly assess the safety, effectiveness and quality of medical devices manufactured in response to COVID-19.

There are risks if instruments like personal protective equipment are not of sufficient quality to adequately protect patients and health care workers. We are working with traditional medical device manufacturers and certified 3D-printing organizations on device specifications and quality to ensure that Canadians have quick access to safe, effective and high-quality medical devices.

Q246. **What steps are being taken to provide the necessary equipment and products to food production and processing businesses?**

The Government of Canada is coordinating with provincial and territorial governments to quickly assess the need for personal protective equipment (PPE) for health care professionals (e.g., N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing), as well as medical supplies (e.g., disinfectants, ventilators, swabs and test kits). To meet these needs, we purchase large quantities of equipment and supplies, and work with Canadian companies to increase their manufacturing capacity to produce additional supplies.

The priority of the Public Health Agency of Canada (PHAC) and 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 COVID-19 transmission in the workplace. The most important measures are physical distancing, strict hand hygiene, respiratory etiquette, cleaning and disinfecting surfaces and objects, using physical barriers and restructuring the workspace to allow for physical distancing.
The Government of Canada is working to assess the needs in essential service sectors and to increase national capacity to manufacture PPE.

Invitation to submit an expression of interest in providing logistics services

Q247. **What tasks will be assigned to the logistics service provider?**

The logistics service provider will be responsible for managing customs documentation, secure storage, inventory management, reporting, and transportation of personal protective equipment to various locations in each province and territory.

The logistics service provider will be required to manage shipments by all modes of transportation, including receiving and transporting goods from seaports, airports, railway stations and commercial transition points.

Q248. **What is the length of the contract?**

Logistics services shall be provided for one year and may be extended. Questions regarding the contract and the tendering process should be directed to Public Services and Procurement Canada.

Q249. **How does the Government of Canada currently manage the importation and distribution of personal protective equipment (PPE) in Canada?**

The Government of Canada is using existing National Emergency Strategic Stockpile (NESS) locations and resources. In addition, on April 1, 2020, a contract was awarded to Amazon to facilitate the distribution of large quantities of PPE and medical supplies to support the fight against COVID-19.

Q250. **A few weeks ago, the Government of Canada announced an agreement with Amazon and Canada Post for the receipt and distribution of PPE in Canada. What is the status of this agreement and why do we need to enter into another one with this new expression of interest?**

On April 1, 2020, the Government of Canada awarded a contract to Amazon to facilitate the distribution of PPE and medical supplies to support the fight against COVID-19. Amazon is working directly with the Government of Canada and Canada Post to manage warehousing and with Purolator to deliver products for front-line health care workers to provincial and territorial health authorities across the country.
This new expression of interest is for a different end-to-end logistics solution than the one provided for in the current agreement with Amazon. The goal, however, is that this new solution will complement the services offered by Amazon and that the selected service provider will be able to use Amazon’s technology.

Q251. **What is the role of the National Emergency Strategic Stockpile (NESS) in storing personal protective equipment (PPE) and distributing it to the provinces and territories?**

Canada's NESS contains supplies that provinces and territories can request in emergencies—such as, infectious disease outbreaks, natural disasters and other public health incidents—when their own resources are insufficient. The purpose of NESS is to provide emergency 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

Q252. **What are the risk factors for drug shortages?**

Several factors can affect the availability of a drug and increase the risk of a shortage, including a manufacturing interruption, lack of ingredient availability, supply chain disruptions and increased demand. Health Canada is working with companies and partners to identify the root cause of shortages and mitigate any impact on patients as quickly as possible. Recently, the Department advised Canadians not to buy more drugs than they need, and health care professionals to not prescribe or supply more drugs than they need in order to prevent shortages caused by increased demand.

Q253. **What's the difference between an "actual drug shortage" and a "potential drug shortage"?**

An actual shortage refers to a situation in which a market authorization holder of a drug cannot meet the demand for the drug in question. A potential shortage refers to a situation in which a marketing authorization holder of a drug can meet the short-term demand, but anticipates supply disruptions.

Q254. **What is the extent of drug shortages related to COVID-19 and what measures have been taken to address them?**

Health Canada is actively monitoring the impact of the COVID-19 pandemic on the supply of drugs in Canada and is aware that increased demand has resulted in supply limitations and reported shortages. The Department is proactively reviewing the Canadian supply chain to identify areas where supply may be vulnerable and to address these vulnerabilities before shortages occur. These enhanced surveillance efforts include regular communication with provinces and territories, industry, health care and patient groups, in some cases on a daily basis. Health Canada is also working with international regulatory partners, including the European Medicines Agency, the U.S. Food and Drug Administration, the Australian Therapeutic Goods Administration and the World Health Organization to share information regarding any indication of global supply disruptions. This mobilization has allowed us to better identify early signs of shortages and possible mitigation strategies, and to coordinate the response.

As part of the government-wide response to the COVID-19 pandemic, the *COVID-19 Emergency Response Act* was adopted on March 25. Amendments to the *Food and Drugs Act* enable Health Canada to put in place more robust tools to support efforts to mitigate shortages that do occur and to prevent shortages wherever possible. For example, on March 30, the Minister of Health signed an Interim Order to help prevent or mitigate shortages related 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 and labelling requirements, but are manufactured in accordance with comparable standards. Information for companies on how to request that a drug be added to the *List of Drugs for Exceptional Importation and Sale* is available on Health Canada's website.

Drug shortages that have been designated as Tier 3 shortages can be added to the *List of Drugs for Exceptional Importation and Sale*. Tier 3 shortages are those that have the potential to have the greatest impact on both the drug supply and the Canadian health care system, and are actively managed by Health Canada, in cooperation with the provinces and territories, industry and health care professionals, in order to identify measures to mitigate the impact on patients. Currently, the Tier 3 list includes medications that are used to help patients with COVID-19, such as muscle relaxants, inhalers, sedatives, blood pressure stabilizers, antibiotics and analgesics, and will be updated as needed. Tier 3 assignments are determined based on a recommendation from a Tier Assignment Committee, which includes federal, provincial and territorial governments, health professionals and industry stakeholders.

Health Canada's top priority is to work with industry to address current shortages and mitigate the impact on patients. The Department is also examining options for long-term stability. As part of these efforts, the Government of Canada issued four Requests for Information (RFIs) on April 19, 2020, and three on April 21, 2020, asking companies to indicate whether they have access to additional stocks of these essential drugs.

The RFIs will be used to identify additional supplies not already set aside to meet Canada's current needs. The Government of Canada is not seeking information on products already identified to mitigate a current supply limitation or shortage, but rather, additional products to strengthen overall supply. RFIs have been published for salbutamol, cisatracurium, injectable fentanyl, 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 with high levels of demand. The government will also 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 medications they need during the COVID-19 pandemic now and as the situation continues to evolve.

Q255. **When you say you work with drug suppliers, what do you actually do?**

Health Canada is working with industry, the provinces and territories and other health partners to mitigate the impact on Canadians of any shortages related to COVID-19. When Health Canada is made aware of a potential or actual shortage, the Department works with companies throughout the supply chain to better understand the root causes, the plans to address the shortage, and what can be done to mitigate the impact on Canadians. In the case of a critical

national shortage, Health Canada works with the company reporting the shortage, as well as with other companies supplying the Canadian market, in order to explore all opportunities to meet Canadian demand. This includes options to facilitate access to alternative sources of supply on an as-needed basis and working with businesses that are able to increase supply for Canadians.
Health Canada works with other federal departments, provincial and territorial governments, international partners and industry to ensure that Canadians have access to the drugs and medical devices they need during the COVID-19 pandemic.

Q256. **How can the provinces and territories watch for potential shortages in their jurisdictions?**

Looking to solve the complex problem of drug shortages is a multilateral responsibility requiring the concerted action of the provinces and territories, manufacturers, distributors, health care professionals and the federal government. Health Canada works closely with the provinces and territories, which notify it of any shortages that may be problematic.

In the event of a critical shortage of a given drug in Canada, Health Canada works with stakeholders throughout the drug supply chain to coordinate communication of information and identify mitigation strategies. The Department analyzes factors such as whether or not the shortage is national in scope, the availability of alternative sources of supply, and the medical importance of the drug to be able to determine the potential impact and what action should be taken. More information on roles and responsibilities regarding drug shortages can be found on our website.

Q257. **Can you confirm whether or not Health Canada is looking at alternative sources for Salbutamol or Ventolin?**

Health Canada is aware that an increase in demand has led to shortages for a certain number of salbutamol inhalers, including Ventolin. Information on these shortages is available at www.drugshortagescanada.ca.

Health Canada is working closely with industry, other federal departments, provinces and territories, and other stakeholders, such as the Canadian Thoracic Society to identify and implement mitigation options. This includes working with companies that can increase supplies to the Canadian market and exploring international supplies to ensure a continuous supply in Canada.

The Department recently advised Canadians not to buy more drugs than they need, and asked health professionals to avoid prescribing or dispensing more drugs than necessary, to ensure that all Canadians continue to have access to the drugs that they need and to prevent shortages caused by increased demand.

Q258. **What is the supply of the following drugs: chloroquine and hydroxychloroquine; ritonavir/lopinavir; and ritonavir/lopinavir and interferon beta?**

Health Canada closely monitors the supply of any potential treatment for COVID-19 and works with companies to ensure a continuous supply in Canada, including working with companies that are able to increase the 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.; none of these companies have reported a shortage of this drug.

Chloroquine is marketed in Canada by Teva, which has reported a shortage of this drug with an expected end date of December 31, 2022, due to a shortage of one active ingredient.

Ritonavir/lopinavir is marketed in Canada by AbbVie, which currently reports no shortage of the drug.

Interferon beta is marketed in Canada by EMD Serono Canada and Biogen Canada Inc. Neither company has reported a shortage of this drug.

Health Canada will continue to closely monitor the supply of these drugs in Canada and will continue to take the necessary steps in cooperation with industry, provinces, territories and other stakeholders to ensure that Canada's drug supply is not interrupted. Manufacturers are in the best position to provide information on the supply of a drug and should be contacted for any questions about the market situation and availability of a given drug. Canadians can also visit www.drugshortagescanada.ca for the latest information on reporting drug shortages in Canada.

Q259. **What is Canada doing to ensure that there is an adequate supply of Remdesivir in Canada? Do you have any now or are you planning to obtain some? Would you consider a mandatory licence if there's a shortage here?**

Remdesivir is an experimental drug administered by intravenous infusion to some hospitalized patients with COVID-19. Health Canada is closely monitoring the development of various treatment options for COVID-19, including remdesivir. Clinical trials are the best way to access investigational therapies that could be used to treat COVID-19. Clinical trials provide Canadians with access to new treatments to prevent or treat COVID-19, and the health care community will have the opportunity to gather information on the effectiveness of the treatments and the associated risks.

In Canada, access to remdesivir is available through two mechanisms: approved clinical trials and the Special Authorization Program (SAP).

To date, two clinical trials have been approved in Canada for remdesivir in the context of COVID-19 at several locations across the country. More information on approved tests is available on our website. Information from these clinical trials can help support a submission to Health Canada. The Department has been in constant communication with Gilead Sciences regarding access to remdesivir and future plans to submit an application for review. Once Gilead Sciences Canada, Inc. has filed a remdesivir submission with Health Canada, the Department will exercise the regulatory flexibility needed to expedite the review of the submission to ensure that Canadians have faster access, while ensuring drug safety, efficacy and quality. Health Canada is also working with international regulatory agencies, including the U.S. Food and Drug Administration, to share scientific information on drugs and vaccines for COVID-19, such as remdesivir, and to harmonize safety and efficacy requirements, where possible, in order to expedite the review and approval process.

Prior to the authorization of clinical trials, and for certain groups who may not have been eligible to access remdesivir as part of the trials, remdesivir was available through Health Canada's Special Access Program (SAP). The SAP for drugs is another mechanism that allows Canadians to access health products on a case-by-case basis. The SAP can provide emergency access to unauthorized and non-marketed drugs to individual professionals treating a patient with a serious or life-threatening illness when traditional therapies have failed, are unsuitable or unavailable. In some situations, it is possible to apply for a non-marketed drug, such as remdesivir, through the SAP. Each SAP request is considered on a case-by-case basis. To date, Health Canada has authorized twelve requests for remdesivir under the SAP.

Misinformation

Q260. **What is Health Canada doing about cases of advertising or sale of products with false or misleading claims regarding COVID-19?**

As of April 15, Health Canada has followed up on nearly 200 cases of health products making false or misleading claims related to COVID-19, which have been identified through proactive monitoring or through the complaints received.

Health Canada has contacted all parties involved in non-compliant advertising and asked them to immediately stop making illegal, false or misleading claims and to withdraw the advertising. In the event of refusal by the party concerned, Health Canada would have to take subsequent, stronger action, which could include stopping the sale of the product subject to the claims, site visits, public communications, recall, or seizure of products and advertising material.

Health Canada has not approved any products to treat or cure COVID-19. In Canada, the sale or advertising of health products with false or misleading claims is illegal, as stated in the *Food and Drugs Act*.

On March 27, Health Canada issued a notice to warn Canadians about the risks associated with products making false or misleading claims about COVID-19. The Department encourages anyone who has information about potentially non-compliant advertising of any health product that has not been approved by Health Canada to report it to the Department using the online complaint form. To keep Canadians informed, Health Canada will continue to update its online table of proven non-compliant products along with the corresponding companies or advertising media.

When Health Canada becomes aware of possible non-compliance with the *Food and Drugs Act* or its regulations, it takes action to check for non-compliance and takes action based on the risk to the health of Canadians. The Department will continue to monitor the situation and take action as necessary to ensure that health products with false and misleading claims related to the diagnosis, prevention, treatment or cure of COVID-19 are removed from the market.

Q261. **Is there a list of offending parties available to the public?**

As part of its commitment to transparency, Health Canada publishes a weekly updated list of products for which the Department has taken or is taking action on non-compliant advertising, as well as the parties involved in non-compliant advertising activities. Health Canada considers several factors in determining the appropriate action to take in the event of non-compliance,

including a company's history of compliance. The Department will continue to use the most appropriate measures to address non-compliance and reduce the risks to Canadians.

Q262. **Has Health Canada been made aware of any misinformation or misrepresentation about alcohol-based hand sanitizers?**

In Canada, alcohol-based hand sanitizers are considered natural health products. Hand sanitizers authorized for sale by Health Canada will be labelled with an eight-digit Natural Product Number (NPN).

Health Canada has received complaints about health products with false or misleading claims about COVID-19. The Department is currently addressing these cases and has ordered companies to remove these claims from their websites and advertising materials. Health Canada continues to monitor websites for products with false or misleading claims and is working with online retailers to have them removed. It is illegal to sell or advertise health products using false or misleading claims. The Department takes this issue seriously and will not hesitate to use all mechanisms and tools at its disposal to put a stop to these activities.

On March 18, 2020, in light of the unprecedented demand and urgent need for products that could help limit the spread of COVID-19, Health Canada issued a notice announcing that it would temporarily facilitate access to products that do not fully comply with current regulatory requirements. The products covered are hand sanitizers, disinfectants and personal protective equipment (such as masks and gowns), as well as swabs. Although these products are usually subject to regulatory requirements, such as registration and bilingual labelling, as part of this interim order, the Department is allowing the sale in Canada of certain products that do not meet all requirements. The Health Canada website makes available to consumers an updated list of products sold in Canada as a result of this measure.

Health Canada is also expediting product approvals, as well as establishment and site licensing related to these types of products. A list of more than 550 registered hand sanitizers has been published on the Department's website. This list is updated daily and contains information on Health Canada-approved alcohol-based hand sanitizers and alcohol-free hand sanitizers. If consumers notice a hand sanitizer or antiseptic on the market that makes false or misleading claims, they are encouraged to inform Health Canada through its online complaint form.

You can find more information here to help inform Canadians about the safe purchase and use of drug and health products.

Q263. **Did Health Canada send masks for testing to ensure that they are safe and not fraudulent?**

Given intense global competition for personal protective equipment (PPE) and other medical supplies, countries have had to hire a 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, face shields, 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 checks the quality of purchased supplies upon receipt. To date, PHAC has not found any fraudulent products. However, it has evaluated certain items that do not meet the technical specifications

for use in health care settings for COVID-19. These items are not distributed to provinces and territories for primary health care intervention, and are subsequently evaluated for use in non-health care settings.

The Canada Border Services Agency (CBSA) may, at its discretion, refer imported health products to Health Canada for examination. When Health Canada receives a product, it evaluates it to determine whether 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 related to false and misleading COVID-19 claims. Health Canada remains committed to managing risks to the public and implemented processes 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, allegedly effective in protecting consumers from COVID-19, were being sold illegally online and in some stores. Health Canada encourages Canadians to report potentially non-compliant imported health products or those making false and misleading claims related to COVID-19. The Department takes this issue seriously and will not hesitate to use all the tools at its disposal to stop such activities.

Q264. **Will Immune-Tami be authorized for sale in Canada?**

Health Canada has not authorized any Immune-Tami-branded products, and has not received any licence applications from MeOn Supplements.

Health Canada has opened a file after receiving a complaint about this product and will take action to address any confirmed non-compliance with the *Food and Drugs Act* or Regulations.

Q265. **Does MonaLisa Healing have a licence to produce/is it authorized to produce products containing CBD in Canada?**

MonaLisa Healing is not licensed to carry out cannabis-related activities in Canada. The 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 possible unlicensed cannabis activities and the non-compliant promotion of cannabis.

In its response to Health Canada, MonaLisa Healing confirmed that it has completely suspended all activities related to Hemp CBD that require a licence, including unlicensed promotion, that it will not conduct any such activities without a valid licence, and that it will not engage in any non-compliant 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 users of its website that MonaLisa Healing's CBD is not a cure or preventative measure for COVID-19.

If other instances of non-compliance with the *Cannabis Act* are identified, the Department will take action as appropriate.

Q266. **Has Health Canada seen other examples of claims made about CBD with regard to COVID-19?**

Health Canada is continually monitoring the promotion of cannabis. No other promotions of cannabis products with regard to COVID-19 have been identified at this time.

Each week, Health Canada publishes an updated list of health products and companies/electronic commerce platforms that do not comply with the *Food and Drugs Act* (F&DA). If Health Canada becomes aware of false or misleading advertising about products subject to the F&DA, 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 its 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. 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 about acts that do not comply with the *Cannabis Act* or evidence of such acts by using this contact information.

Is Health Canada aware that MonaLisa Healing was selling CBD-infused products without a licence and that the company was making a health claim in an email about products being able to 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 erroneous impression about the product characteristics, including its health effects or health risks. This 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 considers each situation on a case-by-case basis. When a potential violation of the prohibitions of promotion, as defined under the Act, has been identified, Health Canada works with the individuals or companies concerned 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 when identifying appropriate measures to prevent or address non-compliance, based on a review of the situation and all relevant information, including the risk to health or safety and the compliance history of the individual or corporation.

These measures range from compliance promotion and education, which is aimed at providing information about and preventing 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 departmental order, or imposing administrative monetary penalties (up to $1 million).

The Department took action when it found out that MonaLisa Healing claimed that its CBD product could help prevent OOVID-19.

On March 24, 2020, Health Canada sent a warning letter to MonaLisa Healing to express its concern about what appears to be unlicensed cannabis-related activities and non-compliant promotion of cannabis.

In its response to Health Canada, MonaLisa Healing confirmed that it has completely suspended all activities with Hemp CBD that are subject to licensing, including non-compliant promotion, that it will not conduct any activities with Hemp CBD requiring a licence with without a valid licence, and that it will not conduct any non-compliant 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 visitors that "MonaLisa Healing CBD is not a cure or preventative for COVID-19, Coronavirus".

If other instances of non-compliance with the *Cannabis Act* are identified, the Department will take action as appropriate.

Reagents

Q267. **What is the extent of Canada's need for chemical reagents for COVID-19 diagnostic tests?**

Canada's response to COVID-19 depends on laboratory tests designed to quickly detect infection and effective public health measures to reduce the spread. Canadian public health laboratories work together within the Canadian Public Health Laboratory Network to facilitate the diagnosis of COVID-19 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 responds to provincial needs for testing reagents by developing reagents in-house as an interim solution, and by working with industry to obtain bulk supplies as soon as reagents become available. Our priorities are access to test reagents, evaluation of point-of-care rapid tests, and access to licensed test kits so that provinces and territories are equipped to scale up testing according to their needs.

Q268. **Is the bioMérieux reagent the only one you've made? Are you going to reproduce 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 respond to the health product needs of Canadians. In particular, the Department has worked diligently with manufacturers in Canada to commercialize products 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 formulations have been published that can be used with current testing devices, laboratory plastics or newer models of nasopharyngeal (i.e. nasal) swabs.

Q269. **Has bioMérieux submitted its proprietary formula to the Public Health Agency of Canada?**

In 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 licence. 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 functions.

Q270. **Does Canada pay for bioMérieux's temporary licence?**

The Public Health Agency of Canada has signed a temporary licence agreement with bioMérieux Canada, at no cost, to receive the rights and formulation of their reagents used in COVID-19 diagnostics. The production systems for the products used to manufacture these reagents are in various stages of development and testing with the aim of alleviating some of the reagent shortages in the near future. If successful, this will improve access to COVID-19 test kits.

Masks

Q271. **Has Health Canada approved the use of KN95 masks in Canada? If not, why not?**

Yes, Health Canada has approved the use of KN95 full-face respirator masks in the context of the pandemic as equivalent to standard N95 respirators.

Q272. **Is the KN95 respirator mask approved by NIOSH? Does it meet another equivalent medical standard?**

No. KN95 respirator masks are not NIOSH-approved. They comply with GB2626-2006, a standard equivalent to NIOSH-42CFR84. For more information on equivalent products for masks and other supplies, please visit https://buyandsell.gc.ca/specifications-for-COVID-19-products

Q273. **Can you 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 it is clearly indicated on the product label that they are for non-medical use (e.g., “not intended for medical use”, “industrial use only”), masks and respirators are not considered medical devices and are therefore not regulated by Health Canada.

Q274. **What is the status of Health Canada’s review of the “WOODBRIDGE INOAC MASK” and its suitability for use in hospitals?**

Health Canada authorized “WOODBRIDGE INOAC MASK” on April 4, 2020. It is designed to reduce the user’s exposure to hazardous particles. This is not an NG5 respirator; it is a Tier 3 surgical mask that can be used in the hospital environment according to the manufacturer’s instructions.

Decontamination and reuse - N95 masks

Q275. **What are the possible decontamination methods under evaluation?**

Several proposed decontamination systems are being evaluated in Canada and around the world. Previously approved decontamination systems (e.g., Stryker Sterizone VP4 Sterilizer, Sterrad Sterilization Systems, Steris Sterilization Systems, Clean Works Clean Flow Healthcare Mini System and Bioquell Hydrogen Peroxide Steam 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 evaluates the proposed methods to ensure that they meet the standards for safety, quality and efficacy, and that the requirements for key performance and safety parameters to ensure the integrity of N95 masks are maintained after reprocessing up to the validated limit of reprocessing cycles.

Q276. **Is there evidence to support these methods?**

Although the virus causing COVID-19 is a novel virus, evidence from previous studies using similar viruses supports the safety and efficacy of some reprocessing methods.

Manufacturers will be required to provide evidence demonstrating the safety and effectiveness of the selected 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;
- demonstration of maintenance of filter performance and respirator fit;
- evidence that there is no residual chemical hazard associated with reprocessing;
- adequate labelling that describes the validated methods and reprocessing conditions applied to the respirator.

Q277. **What are the disadvantages of reprocessing compared to using new masks?**

Health Canada recognizes that the reprocessing of single-use masks is one possible solution to provide continued access to masks for health care workers who rely on them for protection.

The instructions provided by each manufacturer of an authorized decontamination device must be followed.

Mask fit is an extremely important aspect of using the N95 mask. The disadvantage of the reprocessed N95 mask compared to the new mask is that the nose has been folded and may not allow for a good fit. Therefore, PHAC recommends that the respirator be returned to the original user to increase the likelihood of a good fit. If the reprocessed mask is put back into general circulation, it becomes very important to perform the standard leak check for the user and to use only those masks that are suitable for the user's face.

Q278. **Have other regulatory agencies approved decontamination methods? Do we take that into account too?**

Health Canada is aware that a number of devices have received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration for the reprocessing of N95 masks (link). Health Canada continues to evaluate guidelines from other agencies such as the U.S. Centers for Disease Control and Prevention (CDC) in order to optimize the reuse of respirators.

Chloroquine

Q279. **Has Health Canada been informed of the amount of chloroquine that has been imported to 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 Services Agency (CBSA) to ensure that imported health products meet the regulatory requirements of the *Food and Drugs Act* and its regulations.
The CBSA may, at its discretion, refer imported health products to Health Canada for examination. When Health Canada receives a product, it evaluates it to determine whether 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 used to treat malaria and extraintestinal amoebiasis. Under the *Food and Drug Regulations*, prescription drugs can only be imported by a practitioner, drug manufacturer, wholesale druggist, 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 one 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 meet the legislative or regulatory requirements were refused entry to 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 this unprecedented period, Health Canada remains committed to managing risks to the public and has adopted processes to ensure the continued delivery of essential services to Canadians.

The Department encourages anyone who has information about the non-compliant importation, sale or advertising of any health product to report it through the online complaint form.

Q280. Is chloroquine authorized in Canada? Do you have any evidence of its effectiveness in preventing the coronavirus? What advice would you give about using this medicine?

Currently, there are no drugs specifically authorized in Canada to treat or prevent COVID-19. Health professionals may prescribe drugs outside their approved indications (off-label use), relying on other sources of information such as medical literature. This is within the practice of medicine and is regulated at the provincial level.

Clinical trials are the best way to access investigational therapies that could be used to treat COVID-19. Health Canada encourages drug manufacturers to work with researchers so that these drugs can be made available to COVID-19 patients in the context of clinical trials. Clinical trials provide Canadians with access to new treatments used to prevent or treat COVID-19, and the health care community will have the opportunity to gather information on the effectiveness of the treatments and the associated risks.

To date, no clinical trials have been approved in Canada for chloroquine in the context of COVID-19. However, Health Canada has approved other possible therapies to treat patients with COVID-19, including three clinical trials on the use of hydroxychloroquine. A list of approved clinical trials on the prevention or treatment of COVID-19 can be found on the Health Canada website.

Although Health Canada issues market authorizations for drugs and approves the conditions for which drugs are to be used (called the indication), it does not issue treatment guidelines or recommendations.
In Canada, Teva Canada Limited is authorized to market chloroquine for the treatment of malaria and extraintestinal amoebiasis. Instructions on the conditions for which the drug is approved can be found in Health Canada's Drug Product Database by entering "chloroquine" in the "Active Ingredient(s)" field. Teva Canada Limited reports currently experiencing a shortage of chloroquine due to a shortage of an active ingredient, which is expected to end by December 31, 2022. For more information on this shortage and the current state of supply, you can contact the company directly.
Health Canada closely monitors all potential therapeutic treatments and vaccines, diagnostic tests and medical devices, as well as disinfectants currently available and under development in Canada and abroad. The Department is aware of international reports on the use of chloroquine as a drug to treat COVID-19. These reports are based on preliminary data.

Q281. Has Health Canada investigated or charged anyone selling chloroquine or hydroxychloroquine for the treatment of COVID-19? Has Health Canada seized unauthorized hydroxychloroquine or chloroquine supplies?

Health Canada has not approved any products to treat or cure COVID-19. The sale and advertising of health products that are unauthorized or make false or misleading claims are illegal in Canada under the *Food and Drugs Act* (F&DA). It is also illegal to directly or indirectly promote investigational therapies or the off-label use of authorized drugs.

Health Canada has undertaken proactive monitoring of websites to identify 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 found 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 Services Agency (CBSA) to ensure that imported health products meet the regulatory requirements of the F&DA and its regulations. The CBSA may, at its discretion, refer imported health products to Health Canada for examination. When Health Canada receives a product, it evaluates it to determine whether 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.

As a result of a dispatch of products from the CBSA, Health Canada seized a shipment of chloroquine that did not comply with applicable legislation.

Canadians should not take any prescription drugs that have not been prescribed by a health care professional who can assess and advise the patient about possible side effects—including serious side effects—and about 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 buying health products online can put their health at risk and that it is risky to buy health products that claim—without authorization—to prevent, treat or cure COVID-19.

The Department takes this issue seriously and will not hesitate to use all the tools at its disposal to stop such activities. When Health Canada determines the existence or is notified of a potential non-compliance with the F&DA or its associated regulations, it takes action to confirm whether non-compliance has occurred and then acts 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.

The Department will continue to monitor the situation and to 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 concerning the sale or advertising of potentially non-compliant 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.

Q282. **Given the known health effects of chloroquine, if this drug is taken inappropriately or mixed with another drug with which it should not be taken, 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 promote investigational therapies or the off-label use of authorized drugs. If Health Canada becomes aware of the illegal promotion of an investigational therapy, the Department will contact the party involved to immediately stop the promotion and take all enforcement action required to ensure compliance, which could include seizure of the promoted product in question.

Canadians should not take any prescription drugs that have not been prescribed by a health care professional who can assess and advise the patient about possible side effects—including serious side effects—and about 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 buying health products online can put their health at risk and that it is risky to buy health products that claim—without authorization—to prevent, treat or cure COVID-19.

Q283. **How many Canadians have become ill from taking chloroquine?**

Health Canada received 1,305 adverse reaction reports involving hydroxychloroquine as a suspect active ingredient between January 1, 2020, and April 24, 2020. Of the 1,305 reports received, only one had the active ingredient—hydroxychloroquine—indicated for COVID-19. The number of adverse reaction reports received can be attributed to:

- reporting by manufacturers who have patient support programs (PSPs)
    - PSPs provide direct interaction with patients, caregivers and health care professionals to support patient care with a specific health 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 notifier submits an adverse reaction report to a number of manufacturers when more than one product is suspected of being responsible for the adverse reaction or when a manufacturer becomes aware of a notification about its product as a suspect product through, among others, another manufacturer or the Canada Vigilance Adverse Reaction Online Database.

Warning:

- It is often impossible to determine whether an adverse reaction reported to Health Canada is the result of the use of a specific health product. Other factors that could contribute to the reaction include a person's health problems or other health products they are using at the same time.
- Adverse reaction reports are suspected associations reflecting the opinion or observation of the notifier. The information does not reflect Health Canada's assessment of the relationship between the health product and the reaction(s).
- Please see the following link for additional warnings regarding interpretation of information on suspected adverse reactions collected by the Canada Vigilance Program.

Q284. **Has Health Canada been following the global discussions on chloroquine and how the studies in Brazil failed?**

Health Canada is monitoring the trials and is aware of the CloroCovid-19 study in Brazil on the use of chloroquine for the treatment of COVID-19. The Department also collaborates with international organizations in global discussions on the safety and efficacy of chloroquine for the treatment of COVID-19. Health Canada will take appropriate and timely action if new health risks are identified.

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

Q285. **How will Health Canada assess the safety, security and effectiveness of these health products?**

The Interim Order allows for the importation and sale of drugs, medical devices and foods for special dietary use that support Canada's response to the COVID-19 pandemic.
As with all pharmaceuticals and medical devices, Health Canada will assess and monitor the safety, security, quality, and effectiveness of all products allowed to be imported and sold under the Interim Order.

Drug and medical device manufacturers will be required to comply with strict monitoring requirements.

Q286. **Is Canada assured of receiving an adequate supply of these items?**

Difficulties in the supply of medicines, medical devices or foods for special dietary use may arise at any time. As a result, Health Canada monitors the supply of prescription drugs, medical devices and various other health products, such as hand antiseptics, to ensure that Canadians have continued access to these products.

Q287. **How does the Interim Order compare to the interim measure that the Department announced last week that allowed the importation of disinfectants, hand sanitizers, personal protective equipment and cotton swabs that do not fully meet Health Canada's requirements?**

This Interim Order applies to a wider variety of products, including prescription drugs and foods for special dietary use, and makes it mandatory to report shortages of medical devices.

Q288. **And how does the Order compare to the shortage provisions in the legislative amendments?**

Both the Interim Order and the legislative amendments contain provisions that permit the sale of products not normally authorized for sale in Canada, subject to certain restrictions.

The legislative amendments provide greater flexibility with respect to the products that may be imported and provide additional powers, such as the ability to authorize another company to manufacture, use or sell a medicine or medical device protected by a patent to meet demand

when the necessary supplies cannot be obtained from the patent holder, subject to certain conditions, as set out in the Interim Order.

Q289. **What are the new requirements for reporting medical device shortages?**

Manufacturers and importers will be required to inform the Department of shortages of medical devices considered essential during the COVID-19 pandemic. Manufacturers and importers will have up to five days to inform Health Canada of an existing or anticipated shortage from the time they become aware of it. This obligation is comparable to that already imposed on pharmaceutical companies.

A manufacturer may allow an importer to report information on its behalf to avoid duplication.

Understanding existing and anticipated shortages of medical devices and drugs will help the Department select products to be authorized for importation and sale.

Q290. **How will the Interim Order affect personal importation?**

The Interim Order will not affect Health Canada's position, policies or existing legislation with respect to personal importation.

Q291. **What does the phrase "special dietary use foods" in the Interim Order refer to, besides infant formula?**

Special dietary use foods include foods that are specially designed to meet the needs of consumers with a variety of health problems, such as low-protein foods for people with kidney disease. It can also include foods that are a person's main or sole source of nutrition, such as infant formulas and liquid formulas designed for those who cannot adequately feed themselves from solid foods.

Q292. **How will access to hand sanitizers and antiseptics be accelerated?**

The Interim Order amends a requirement that applied to applications for the approval of biocidal drugs (hard surface disinfectants and certain hand antiseptics) to expedite the review and authorization process. In addition, the Interim Order removes the requirement to hold an establishment licence for certain hand antiseptics that are regulated under the *Food and Drug Regulations*.

Q293. **What is the government currently doing to address any shortages of drugs and medical devices that may be related to COVID?**

Health Canada is closely monitoring the potential impact of the COVID-19 pandemic on the supply of drugs and medical devices in Canada.

The Department continues to dialogue with the pharmaceutical and medical device industry and the provinces and territories to identify any signs of supply disruptions in Canada. The Department is also working with its international regulatory partners, including the European Medicines Agency, the United States Food and Drug Administration, Australia's Therapeutic

Goods Administration and the World Health Organization, to share information on any signs of global supply disruptions.

Canadian regulations require pharmaceutical companies to report publicly on current and anticipated shortages and terminations of drug sales within a specified period of time at drugshortagescanada.ca. Provinces and territories, health care professionals or the public can also inform Health Canada of signs of shortages of drugs and medical devices.

Health Canada has contacted all drug establishment licence holders in Canada to remind them of their obligation to report current or anticipated drug shortages and to inform Health Canada of any situation that could affect the quality, safety or efficacy of a drug. Medical device establishment licence holders were also asked to report shortages to Health Canada.

Health Canada also closely monitors the supply of any potential treatment for COVID-19 and works with companies to ensure a continuous supply in Canada, including working with companies that are able to increase the supply for the Canadian market.

The Department will continue to monitor this situation closely and take appropriate action in collaboration with industry, provinces, territories, and other stakeholders to ensure that Canada's drug supply is not disrupted.

Q294. **How will these changes help the government increase its capacity to manage drug shortages?**

These amendments will allow the Government of Canada to put in place better tools to help prevent and address shortages. For example, the amendments are helping the government use the Interim Order to put in place a regulatory framework to authorize the importation of drugs and medical devices required to prevent or address a shortage related to COVID-19.

Q295. **Will Health Canada use amendments to the *Patent Act* to circumvent patent protection (sometimes called compulsory licensing) and allow other companies to produce patented medicines?**

The Government of Canada respects patent rights and their importance to business, and knows that industry will do everything in its power to meet the needs of Canadians.

In response to a pandemic such as the COVID-19 pandemic, the Commissioner of Patents may authorize the Minister of Health to allow another company to manufacture, use or sell a drug or medical device protected by a patent to meet the demand, when the necessary 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 situations, and include several safeguards to protect the interests of patentees, including guarantees that patentees will receive adequate remuneration for the use of their patents and the imposition of limits on the duration of the authorization.

The Minister of Health will be able to seek authorization for third-party manufacturers to produce any necessary patented inventions until September 30, 2020.

To date, the Minister of Health has not had to exercise the powers provided in Bill C-13 in relation to amendments to the *Patent Act*.

Expediting Access to Hand Sanitizers, Disinfectants and Personal Protective Equipment and Swabs

Q296. **Were these changes made through new regulations?**

These are interim measures that have been implemented due to the unprecedented demand and urgent need for products that can help limit the spread of COVID-19. They include hand sanitizers, disinfectants and personal protective equipment (e.g. masks and gowns). This is not a new regulation.

Q297. **What does this new regulation mean?**

It is an interim measure and a fast-track approach. It will facilitate access to imported hand sanitizers and disinfectants that do not fully meet the regulatory requirements of 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 approved for sale in Canada, but do not fully comply with Health Canada requirements (e.g. labelling in only one official language, different packaging from what was approved);
- products that are not approved for sale in Canada, but are approved or registered in other countries with similar regulatory and quality assurance frameworks.

Health Canada will authorize the distribution of these low-risk products in Canada to address the current supply shortage. A certification form must be completed to implement the expedited process. This form 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 appropriate action to protect the health and safety of Canadians when necessary.

Q298. **Is Health Canada actively reaching out to manufacturers to get more products imported?**

Information regarding this expedited process has been shared with all drug, natural health product and medical device establishment and product licence holders in Canada, as well as relevant industry associations.

Products approved for sale under this interim measure are being added to the list posted on the Health Canada website. When the notice was posted on March 18, only hand sanitizers and disinfectants had met the sales criteria for this interim measure. Since then, medical devices have been sourced and will be added to the list in the coming days.

Q299. **How are medical devices regulated in Canada? What is a Class I instrument?**

Canada takes a risk-based approach to the regulation of medical devices, where the level of pre-approval review depends on the risk posed by the use of the device. Canada takes a risk-based approach to the regulation of medical devices, where the level of pre-approval review depends on the risk posed by the use of the device. This approach balances the need to provide the health system with quick access to new and innovative technologies with the level of surveillance and time required to assess safety and effectiveness.

There are four classes of medical devices in Canada: Class I devices present the lowest potential risk (e.g. masks or gowns) and Class IV devices the greatest potential risk (e.g. pacemakers). Class II, III and IV medical devices must be licensed to be sold in Canada. Companies that sell Class I medical devices in Canada are required to hold a Medical Device Establishment Licence (MDEL). However, during the current situation of the pandemic, Class I to IV devices may be approved pursuant to the Interim Order Respecting the Importation and Sale of Medical Devices for Use in Relation to COVID-19.

Health Canada is currently expediting the review of licence applications for any COVID-19 medical device. In addition, as is the case for hand sanitizers and disinfectants, Class I medical devices that may not fully meet all regulatory requirements and that are reported to Health Canada under this interim measure are allowed on the market.

Q300. **How can consumers tell the difference between a fraudulent product and a product imported under this interim measure?**

An updated list of products sold in Canada under this measure will be posted on the Health Canada website.

There is an eight-digit Drug Identification Number (DIN) or Natural Product Number (NPN) on the product label of hand sanitizers and disinfectants approved for sale by Health Canada. These products are listed in Health Canada's Drug Product Database or Licensed Natural Health Products Database.

Class I medical devices are not licensed by Health Canada, but companies that import or manufacture them must obtain a Medical Device Establishment Licence from Health Canada. These products are posted on the Health Canada 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 listed in the notice, or if they become aware that a company is importing or manufacturing a Class I device without the required licence, they are encouraged to report this to Health Canada.

COVID-19 medical devices approved for sale by Health Canada are posted on the Health Canada website.

Q301. **What other steps is Health Canada taking to improve the supply of health products during the COVID-19 pandemic?**

On March 18, 2020, the Minister of Health signed an interim order to expedite access to COVID-19 medical devices. The list of COVID-19 medical devices approved under this interim order is posted on the Health Canada website.

Q302. **Is it possible to access medical devices and drugs that have not been approved in Canada but are available in other countries?**

Health care professionals can request access to COVID-19 medical devices that have not yet been approved in Canada and drugs used to treat patients with COVID-19 through Health Canada's Special Access Program (SAP). Applications are assessed on a case-by-case basis.

If you have any questions regarding the SAP for medical devices, please email your questions to the program.

Interim Order Respecting Medical Devices for Use in Relation to COVID-19

Q303. **When will Health Canada be in a position to approve the first COVID-19 test kits as medical devices?**

Health Canada is working with manufacturers to enable commercial diagnostic devices to enter the market in order to strengthen Canada's COVID-19 diagnostic capacity.

On March 13, 2020, Health Canada received two applications for diagnostic devices: one from Roche Diagnostics and one from ThermoFisher Scientific. These applications were fast-tracked for approval. Health professionals now have access to these instruments through our Special Access Program (SAP).

Health Canada will immediately provide the relevant laboratories, the Public Health Agency of Canada and the provincial and territorial departments of health with information on the availability of these diagnostic devices.

Health Canada is also working with many other companies that are preparing information to be reviewed by the Department. These applications will also be fast-tracked.

Q304. **What is the timeframe for reviewing COVID-19 screening test applications send to Health Canada?**

Health Canada is working to increase access to screening tests in Canada through an expedited review process. The list of approved COVID-19 screening devices (with approval dates) is posted here, and medical devices approved in Canada are on the current list of authorized medical devices.

On March 18, the Minister of Health signed an interim order to allow expedited access to COVID-19 medical devices, including test kits, for use by health care providers. This is an important development in the fight against COVID-19. The interim order will promote faster and more flexible approval of the importation and sale of medical devices, including test kits, required as part of Canada's COVID-19 response.

Q305. **Is Health Canada looking at following the United Kingdom's lead and allowing antibody tests to be performed at home? Can you tell us how effective these tests are?**

On March 18, the Minister of Health signed an interim order to give health care providers expedited access to COVID-19 medical devices, including diagnostic test kits. The interim order will give Health Canada the flexibility it needs to more quickly approve the importation and sale of medical devices, including test kits, required as part of Canada's COVID-19 response. The list of approved COVID-19 devices (with approval dates) is posted here, and all licensed medical devices are posted at Current list of licensed medical devices.

Public health laboratories across Canada and around the world are using tests that detect the presence of the virus that causes COVID-19. Health Canada is reviewing these tests on a priority basis to increase the number of tests available in Canada to detect any active COVID-19 infections.

Serological tests – like the home tests being evaluated in the United Kingdom – have limitations. They do not detect the virus itself. Instead, they detect the antibodies produced in response to an infection. Although these tests are also accepted for examination, the World Health Organization does not currently recommend the use of serological tests for clinical diagnosis, and Health Canada is following this recommendation. Research on serological testing is ongoing in Canada and around the world. The Department is working with the National Microbiology Laboratory and consulting firms to validate testing and research to provide confidence in test results.

Q306. **How will these new kits help screen more patients?**

The interim order facilitates and expedites the importation and sale of certain medical devices, such as laboratory diagnostic kits, into Canada. It will help provide access to medical devices that will allow faster and more convenient screening because the samples will not have to be sent to the National Microbiology Laboratory in Winnipeg. Test results will therefore be available more quickly.

Point of care diagnostic tests are being developed and could be used as a result of this interim order. This would allow patients to be tested more quickly and conveniently. Early results will allow health professionals and patients to take prompt action to help reduce the spread of the disease.

Q307. **How often are interim orders used?**

In recent years, interim orders had to be made on a few occasions to allow quick access to health products in exceptional circumstances to mitigate a significant health or safety risk.

The last interim order was made in August 2018 to facilitate the immediate importation and sale of AUVI-Q epinephrine auto-injectors as an emergency measure during a significant nationwide shortage of epinephrine.

Another interim order was made in July 2016 to allow immediate temporary access to naloxone nasal spray until a Canadian approval review was completed.

Q308. **How will Health Canada ensure that these kits are safe and effective?**

The interim order creates an appropriate approval stream for the importation and sale of medical devices that support Canada's COVID-19 response. This order and the associated approval process provides the Minister with the flexibility to consider urgent circumstances surrounding the need for the device, approvals issued by foreign regulatory authorities, or potential new indications for use of medical devices already approved in Canada.

As with any drug or medical device, Health Canada will assess and monitor the level of safety and effectiveness of all products approved under this interim order, and will take immediate action to protect the health and safety of Canadians, if necessary.

Manufacturers will be required to comply with stringent post-market safety requirements, including mandatory problem reporting, recall procedures and complaint processing.

Q309. **Does Canada have a guarantee that it will receive a sufficient supply of diagnostic kits?**

We expect to have a sufficient number of diagnostic test kits. It will be up to the company to provide kits if demand exceeds supply.

Q310. **Why does the Altona Realstar SARS-CoV-2 PCR kit comply with medical device regulations if its actual use is related to COVID-19 diagnostic tests?**

The *Medical Devices Regulations* apply only to the importation and sale of medical devices. The use of medical devices, including in laboratories, is regulated by the provinces.

Q311. **Why are tests labelled "for research purposes only" exempt from the *Medical Devices Regulations*?**

Tests labelled "for research purposes only", such as the Altona device, do not meet the definition of a medical device and are exempt from the Regulations. For more information, please refer to Health Canada's guidance document entitled Guidance for the Risk-based Classification System for In Vitro Diagnostic Devices (IVDDs).

National Emergency Strategic Stockpile (NESS)

Q312. **Who manages the NESS? Where are the NESS storage facilities located?**

The Public Health Agency of Canada (PHAC) manages the National Emergency Strategic Stockpile (NESS). The NESS facilities consist of a central depot in the National Capital Region and warehouses strategically located across Canada. For security reasons, we do not publish their locations.

Q313. **Is PHAC responsible for stockpiling PPE for the NESS?**

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 locally. The role of the federal National Strategic Emergency Stockpile (NESS) is based on this shared responsibility.

NESS provides surge capacity for emergencies when local and provincial/territorial resources have been depleted. It is the only provider of niche resources needed for rare public health events. As a result, NESS stores a moderate amount of personal protective equipment. However, in response to COVID-19, the Public Health Agency of Canada (PHAC) has been working to secure additional supplies. This includes making bulk purchases and working with domestic suppliers to support production. This also means playing a key role in coordinating the Government of Canada's pandemic response efforts by organizing the distribution of incoming shipments to the provinces and territories that require them immediately for health care delivery. This work is performed in conjunction with various federal departments, including Public Services and Procurement Canada, Health Canada, Innovation, Science and Economic Development Canada and Indigenous Services Canada, and with the provinces and territories.

Q314. **How large is the stockpile and how will supplies be allocated and distributed?**

The Public Safety Agency of Canada (PHAC) does not disclose details of the stockpile contained in the National Emergency Strategic Stockpile (NESS).

The NESS contains personal protective equipment and ventilators. In the current situation, the amount of inventory is constantly changing as supplies are redistributed at the request of provinces and territories to help them meet peak demands.

Bulk orders for PPE and medical supplies have been delivered, and the Government of Canada is allocating supplies to provinces and territories in a timely manner according to the allocation formula agreed to by the federal, provincial and territorial ministers of health. In addition to responding to requests for assistance from the National Emergency Strategic Stockpile (NESS), the Government of Canada supported the distribution of 6.8 million Medicom surgical masks that were shipped directly to the provinces and territories. Ontario received their masks on April 3. In addition, 1.7 million nitrile gloves are in transit to the provinces and territories.

In accordance 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/covid19-industry/medical-devices/personal-protective-equipment/medical-masks-respirators.html>, the NESS also shipped nearly 300,000 expired N95 masks to the provinces and territories.

Q315. **Which provinces and territories have obtained supplies from the NESS? What supplies have been delivered?**

To meet immediate short-term needs, PHAC distributes NESS supplies based on requests for assistance. As of April 6, the National Emergency Strategic Stockpile had received and processed 23 requests for assistance from the provinces and territories. Items shipped through NESS included N95 masks, surgical masks, face shields, gloves, gowns and ventilators. To maintain the NESS inventory, a portion of the federal, provincial and territorial collaborative supply is maintained there to provide surge support for urgent provincial and territorial needs.

Q316. **Modelling data from Alberta indicate that Alberta is waiting for the Public Health Agency of Canada to deliver 6 ventilators. Are they from NESS or another source?**

The Public Health Agency of Canada (PHAC) continues to deploy personal protective equipment and ventilators from the National Emergency Strategic Stockpile (NESS) to provinces and territories in response to requests for assistance. As part of this process, PHAC can confirm that six ventilators have been sent to Alberta.

Q317. **How many surgical masks and N95 masks does Canada currently have? How many will be needed when the pandemic reaches its peak?**

The National Emergency Strategic Stockpile contains personal protective equipment (PPE), including N95 respirators, to provide surge capacity to the provinces and territories.

Based on the needs identified by the provinces and territories, collaborative federal, provincial and territorial efforts are focused on procuring large quantities of PPE, such as N95 respirators. Orders for PPE are starting to come in, and governments are discussing approaches for allocating this equipment that will ensure that the health system provides an effective response to COVID-19.

To date, the federal government has ordered more than 200 million surgical masks and N95 masks.

The Public Health Agency of Canada receives shipments of PPE at various locations across Canada; more than one million masks have been delivered to a warehouse in Hamilton. Once deliveries have been confirmed, the PPE will be distributed quickly to provinces and territories for use by front-line health care workers.

The provinces and territories will be consulted to continue to assess demand as the pandemic evolves.

The safety of health care workers is a top priority. The Government of Canada continues to work with partners in the provinces and territories to address the COVID-19 outbreak. This includes ensuring that health care workers have the PPE they need to protect their health and the health of their patients.

Q318. **Why is the Regina NESS facility closed and have the masks and gloves been replaced?**

The Regina warehouse was closed as a result of an independent evaluation of the National Emergency Strategic Stockpile (NESS) federal warehouse network, which found that using six warehouses instead of nine across Canada would ensure more efficient distribution without sacrificing response capability. For example, Canada’s transportation infrastructure has improved since the NESS was created. This makes it easier to maintain the same 24-hour delivery target with fewer warehouses.

In addition to masks and gloves, other expired 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 have also considered the value of supplies compared to the cost of shipping the supplies elsewhere.

Q319. How many masks and gloves were discarded and why?

The National Emergency Stockpile System (NESS) regularly reviews its inventory of materiel and, as part of this review, expired materiel 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 discarded when the National Emergency Strategic Stockpile (NESS) warehouse in Regina closed. The masks and gloves were purchased in 2009 and had exceeded the five-year expiry date recommended by the manufacturer.

Although the World Health Organization allows personal protective equipment to be donated, it requires that all donated equipment must be supported by the manufacturer for at least two years. This means that personal protective equipment must be donated two years before it expires.

The Public Health Agency of Canada (PHAC) follows strict equipment deployment guidelines. If the Agency cannot confirm the quality of the equipment, it will not deploy it. Even in the current circumstances of the COVID-19 pandemic, where Health Canada guidance allows expired personal protective equipment to be deployed, the Agency would look very closely at any equipment that is five years old or older. This practice is consistent with manufacturers' recommendations.

Q320. How many other NESS warehouses have been closed and how much stock has been discarded in Canada in recent years? How many warehouses are left?

In recent years, NESS has reduced the number of warehouses it operates in Canada from nine to six. The independent evaluation found that the six strategic locations would allow NESS to continue to deliver support supplies in a timely manner.

Q321. Has the number of PPE supplies decreased because there are fewer NESS warehouses or has the same level of PPE supplies simply been stored at fewer locations?

The quantity of personal protective equipment supplies stored by the National Emergency Strategic Stockpile is not directly correlated to the number of warehouses in Canada. When a warehouse was closed, everything that could be used 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.

Q322. Why doesn't Ottawa have a plan to deliver NESS medical supplies to other users before they expire (i.e. provincial health care systems)?

NESS's mandate is to provide the provinces and territories with support, as well support for federal populations such as the Correctional Service of Canada. The 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 insufficient.

Most supplies have a specific shelf life and must be discarded after the expiry date. As part of the normal life cycle management of NESS inventory, expired products may be disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel. NESS will examine ways to optimize product lifecycle management in order to minimize the disposal of obsolete inventory, while continuing to focus on end-user safety.

Q323. **How is personal protective equipment distributed and what are the distribution priorities?**

The Government of Canada and the provinces and territories have agreed on a personal protective equipment distribution strategy.

Based on the needs identified by the provinces and territories, joint federal, provincial and territorial (F/P/T) procurement actions focus on purchasing large quantities of PPE and medical supplies, including N95 respirators, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, disinfectant, artificial respirators, and screening supplies. A collective (F/P/T) decision on allocating these supplies is helping Canada's health care system respond to the COVID-19 outbreak.

In addition, to provide surge support to the provinces and territories, the Public Health Agency of Canada (PHAC) distributed items from the National Emergency Strategic Stockpile (NESS). These include specific types of PPE such as surgical masks, gloves and N95 respirators, as well as other items such as artificial respirators, disinfectants and hand sanitizer.

To receive NESS items, provinces and territories must submit a Request for Assistance (RFA). PHAC responds to RFAs when they are received and allocates supplies to provide surge support to the provinces and territories while maintaining a prudent stock in NESS for surge support purposes. In the current situation, due to the high worldwide demand for PPE, it is recommended that provinces and territories submit RFAs for short timeframes (e.g. peak needs for one or two weeks) with the option of sending additional RFAs as the pandemic unfolds.

Q324. **Is the Government of Canada responsible for replenishing the National Emergency Strategic Stockpile or does that responsibility lie with the provinces or territories?**

NESS's mandate is to provide crisis support to the provinces and territories, as well as federal agencies such as the Correctional Service of Canada.

PHAC, in conjunction with Public Services and Procurement Canada, has placed bulk PPE orders to meet the needs of the provinces and territories that are working very hard to ensure that they have the necessary equipment for front-line health care workers.

Canada receives orders for supplies and redistributes most of them to the provinces and territories, but retains a small portion to replenish the NESS for future peak demands.

Q325. **Have NESS stocks been increased since the COVID-19 outbreak**

Orders for personal protective equipment (PPE) and medical supplies were placed early by the federal government and the provinces and territories to supplement their current inventories. On March 9, the Prime Minister and the Deputy Prime Minister wrote to all provincial and territorial

Premiers to announce that the federal government planned to place a bulk order for health supplies needed for the COVID-19 pandemic.

PHAC has been working for some time with Public Services and Procurement Canada to place bulk PPE orders to meet the needs of the provinces and territories that are actively trying to secure the equipment they need for front-line health care delivery.

Canada is receiving supply orders and governments are working together to ensure that the health system can deal with COVID-19 while replenishing NESS stocks to meet peak demands.

We continue to do our best to keep the public informed of the highly variable quantities of PPE. However, our priority is to obtain this protective equipment and distribute it to the provinces so that it will be available to the health care workers who need it most.

Q326. **Is NESS fully integrated with other medical device depots in Canada?**

NESS's mandate is to provide emergency assistance to the provinces and territories, as well as to federal populations such as the Correctional Service of Canada. However, as part of the COVID-19 response, PHAC is also willing to distribute donations of medical supplies from other government departments, companies or countries.

In addition, under Canada's Plan to Mobilize Industry to fight COVID-19, the Government of Canada is directly assisting companies to expedite production or restructure their assembly lines so that products, such as personal protective equipment and other essential medical supplies, can be manufactured in Canada.

The Government of Canada created the Strategic Innovation Fund to provide ready assistance to Canadian companies conducting large-scale research with promising future results and development projects aimed at finding medical countermeasures to fight COVID-19 including vaccines and essential medical supplies.

Q327. **Was the recent notice on the Government Buy and Sell website a call for applications to find additional suppliers for the NESS?**

The Government of Canada is exploring all options to obtain medical supplies, including personal protective equipment (PPE), to prepare for and respond to the COVID-19 outbreak.

The notice published on the Buy and Sell website to find additional suppliers will benefit federal, provincial and territorial governments, including the National Emergency Strategic Stockpile (NESS).

More information on the Government of Canada's response is posted here.

Q328. **Does PHAC have to use a competitive bidding process to renew NESS supplies, or can PHAC use the emergency rule to purchase directly?**

PHAC follows appropriate legislation, policies and guidelines governing the procurement of supplies or goods for the NESS. Competitive procurement practices, such as established supply arrangements or requests for proposals, are commonly used to access the supply chain.

On March 14, 2020, PHAC requested, and was granted, 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 follow a competitive process to renew NESS supplies and will work with Public Services and Procurement Canada to determine the best procurement strategy.

Q329. **A 2010 audit found that PHAC did not have a complete and up-to-date inventory of its emergency medical supply stockpile, designed for distribution to provinces during public health emergencies such as this one. Does the federal government now have a complete inventory of its stockpile of emergency medical supplies? Has it shared this inventory with the provinces or the public? Can you provide proof of inventory?**

Following the 2010 audit, the Public Health Agency of Canada (PHAC) implemented an electronic inventory system to track the National Emergency Strategic Stockpile (NESS) inventory. The provinces and territories are aware of NESS resources; however, for security reasons, PHAC does not disclose the NESS inventory to the public.

Q330. **What has changed since the 2011 NESS evaluation report?**

Since the 2011 evaluation, the NESS has taken steps to better manage the changing risk environment and is investing in strategic assets such as medical countermeasures and mini-clinics to increase the Agency's ability to respond to surge capacity demands during health emergencies. In addition, provincial and territorial partners and other stakeholders have been encouraged to increase their awareness of the NESS's capabilities.

Q331. **Can you explain why the number of National Emergency Strategic Stockpile warehouses has been reduced, and whether this has resulted in a reduction in the quantity of personal protective equipment (PPE) stored by the federal government?**

Canada's National Emergency Strategic Stockpile (NESS) contains supplies that the provinces and territories can request in emergencies, such as infectious disease outbreaks, natural disasters and other public health events, when their own resources are insufficient. The purpose of the NESS is to provide back-up supplies for the provinces and territories; the stockpile is not intended to replace supplies held or procured by the provinces and territories. The provinces and territories are responsible for coordinating and maintaining their own procurement capabilities.

Over the past decade, we have reduced some of the supplies stored in NESS. For example, blankets used to be stockpiled, but they can now be accessed from other sources. As a result, the NESS no longer needs to store as many blankets. As the NESS has been modernized, it has focused on storing strategic medical supplies that are not generally held

by the provinces and territories, such as drugs and vaccines that require controlled environmental conditions.

As a result of an independent evaluation of federal warehouse network, there are now six warehouses operating across Canada instead of nine. They provide a more efficient distribution system without sacrificing response capability. For example, Canada's transportation infrastructure has improved since the NESS was created. This makes it easier to maintain the same 24-hour delivery target with fewer warehouses.

NESS supplies are periodically reviewed and supplies are purchased on a regular basis. In January, the Public Health Agency of Canada (PHAC) began monitoring the coronavirus outbreak in China, assessing its NESS inventory and procuring supplies to respond to a potential outbreak in Canada.

Q332. **In the early 2000s, the NESS had 165 fully equipped mobile hospitals. It also had 33,000 beds (hospital beds / cots) and during the events of September 11, 2001, 19,000 of these beds were deployed in Nova Scotia and Newfoundland and Labrador. What happened to those stocks?**

The National Emergency Strategic Stockpile (NESS) was established during the Cold War to provide medical supplies and social services in response to public health emergencies, particularly nuclear disasters. Mobile field hospitals were a relic of that era and did not meet Canada's current standards of care. Since 2013, the inventory from these field hospitals has been either reallocated for continued use in existing mini-clinics, set aside for future emergencies, destroyed/recycled, or donated for historical reasons in accordance with the Treasury Board policy on Disposal of Surplus Moveable Crown Assets.

Items stored include, but are not limited to, cots and blankets, which continue to be used upon request to support provincial/territorial responses to health emergencies. The NESS has stored a complete field hospital as an item.

Q333. **In the early 2000s, there were 10 regional warehouses, now there are five. Why was the decision made to rationalize the number of sites?**

Until 2011, the NESS consisted of 11 warehouses in nine locations. The decision to modernize and optimize the number of stockpile warehouses was made in 2013. These steps were taken to reflect changes in the NESS's new operating environment. These changes included the partners' (federal, provincial and territorial and non-governmental organizations) improved capacity and improved transportation infrastructure, which reduced the time required to deliver goods across Canada. An independent evaluation of NESS's federal warehouse network found that using six warehouses instead of nine across Canada would ensure more efficient distribution without sacrificing response capability.

In 2019, all NESS assets were consolidated into eight warehouses in six locations. In March 2020, an additional warehouse was leased in Ottawa, based on the volume of supplies donated to and purchased by the NESS as part of the federal government's COVID-19 response.

Q334. **Rationalization of the NESS stockpile has placed more emphasis on pharmaceuticals than on medical equipment. Can you confirm this and explain why?**

That's right. The NESS's role is to provide surge capacity to support provincial and territorial emergency responses. The NESS acquires assets based on the evolving threats and risks associated with emergency preparedness and response. The NESS focuses on its role as the primary provider of medical equipment that the provinces and territories do not usually stockpile. It also has a stockpile of antivirals to support the provinces' and territories' surge capacity in the event of an influenza pandemic.

Provincial and territorial governments are primarily responsible for procuring materials and equipment for health care services. Due to the unprecedented PPE shortages attributable to COVID-19, the Government of Canada has taken steps to:

- Order additional equipment as part of mass procurement efforts with the provinces and territories;
- Establish new logistical arrangements to enable the delivery of supplies;
- Ensure that certain supplies are produced in Canada.

VACCINE AND TREATMENT

Q335. **Is there a vaccine that protects humans against coronaviruses? If no vaccines are currently approved, are any vaccines being developed or tested?**

Currently, no vaccines that protect humans against coronaviruses have been approved.

The World Health Organization (WHO), in conjunction with the Coalition for Epidemic Preparedness Innovations, is coordinating an international collaboration to advance research and development of COVID-19 vaccines.

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 Canada's research community, will participate in global research efforts.

Q336. **Canada is spending millions of dollars to fund vaccine research. If a Canadian group succeeds in developing a vaccine, will Canadians be the first to receive the vaccine? Is this an explicit condition of all Canadian funding?**

The Government of Canada recognizes that access to the right COVID-19 tools and technologies, such as vaccines, will be critical to our response. Canada has joined other G20 countries in committing to strengthen coordination to develop, manufacture and distribute vaccines quickly while meeting the goals of effectiveness, safety, equity, accessibility and affordability.

The federal government is investing more than $1 billion in medical research to support many organizations working to develop vaccine candidates. Globally, universities, small and medium-sized enterprises and large multinational pharmaceutical organizations are developing more than 100 vaccine candidates, including 10 in Canada, which are in various stages of development. With the Government's support for vaccine development, Canada will be in a better position to access a vaccine quickly when it is ready.

The Government of Canada, through the Canadian Institutes of Health Research (CIHR) and the Natural Sciences and Engineering Research Council (NSERC), provides support in the form of grants to independent researchers working in external laboratories. CIHR and NSERC do not own the research findings that they fund and do not control commercialization of the research, because the researchers receiving the funds and their organizations are responsible for the research findings. Therefore, researchers and their institutions would be the initial owners of the intellectual property rights.

Providing the vaccine to Canadians first was not a condition of CIHR and NSERC funding. Conditions apply mainly to the free sharing of research findings and data relating to the COVID-19 pandemic, for example in peer-reviewed journals and among researchers. All terms and conditions of CIHR funding are posted on the CIHR website.

One of the conditions of NSERC funding was that applicants had to demonstrate that the proposed research provided benefits for Canada. Applicants were required to demonstrate these benefits based on the characteristics of each project they proposed. In the context of the COVID-19 grants, researchers were informed that discoveries would be freely accessible and proactively communicated to government authorities who could use them appropriately to produce timely results for Canada.

The Human Health Therapeutics Research Centre at the National Research Council Canada (NRC) also conducts vaccine research. When this work is performed in conjunction with external partners, our collaboration and technology transfer agreements promote benefits for Canadians. Should NRC-supported activities produce a vaccine candidate or new analytical tests, specific distribution plans will be developed in consultation with the Public Health Agency of Canada, if applicable.

Q337. **Would Canada impose limits on vaccine exports to ensure that products made in Canada are available to Canadians?**

To date, Canada has not imposed new export restrictions in response to COVID-19 and has worked to facilitate trade by introducing temporary duty and tax exemptions to encourage the importation of supplies that are critical to public health authorities, health care centres (e.g. hospitals, testing sites) and first response organizations require to deal with the COVID-19 crisis.

Canada is leading the work of like-minded countries and multilateral institutions to keep supply chains open so that people in Canada and around the world can have access to the drugs, medical supplies and other products they need, especially at such a critical time, as outlined in the joint ministerial statement and the G20 Trade and Investment Ministerial Statement.

To ensure a stable supply of medical supplies and equipment for Canadians, Canada is:

- taking steps to increase national supply by funding the University of Saskatchewan's Vaccine and Infectious Disease Organization-International Vaccine Centre (VIDOInterVac);
- helping the National Research Council upgrade its Human Health Therapeutics Research Centre to develop, test and scale up promising vaccine candidates to industrial production-ready status;
- providing Medicago with support through the Strategic Innovation Fund. This company has identified a viable plant-based vaccine candidate currently in pre-clinical trials, and will use the funding to move quickly to the clinical trial phase and then quickly scale up production to respond to the pandemic;
- purchasing equipment from other countries and, only if necessary, implementing targeted, proportionate, transparent and temporary import and export measures.

Q338. **Has Canada committed to donating 10% of its stockpile to the WHO? What steps is Canada taking to ensure that vaccines will be available where they are most needed?**

In addition to promoting domestic initiatives, Canada also makes major contributions to international vaccine development initiatives. Canada is funding the Coalition for Epidemic Preparedness Innovations (CEPI), which is working closely with the World Health Organization to develop a COVID-19 vaccine. As such, Canada is committed to supporting global efforts to develop and manufacture COVID-19 vaccines that will be equitably distributed globally.

One of CEPI's missions is to provide equitable access to vaccines for all affected populations during pandemics. In the context of the COVID-19 pandemic, this means that COVID-19 vaccines developed through CEPI-funded initiatives will first be made available to populations when and where they are most needed to stop an epidemic, regardless of geography or ability to pay.

The Government of Canada is a signatory to the Pandemic Influenza Preparedness Framework. Under this framework, vaccine or antiviral manufacturers must commit to at least two of six options in exchange for biological materials needed to develop and test vaccines or antivirals. One of these six options is to donate at least 10% of real-time pandemic vaccine production to the WHO.

Q339. **Has Canada already entered into a contract for the purchase of a pandemic vaccine with a supplier that can produce large quantities of vaccine in a timely manner?**

There are currently no COVID-19 vaccines. Therefore, Canada cannot establish a procurement market for the supply of a COVID-19 vaccine. Through investments of more than $1 billion in medical research, the federal government supports multiple organizations working to develop vaccine candidates. There are currently more than 100 vaccine candidates worldwide, including

10 in Canada, in various stages of development by academics, small and medium-sized enterprises, and large multinational pharmaceutical companies. It remains to be seen which vaccine candidates will be successful. Through its support for vaccine development, the government will be well positioned to quickly access a vaccine once it becomes available.

Canada has entered into a 10-year contract with GlaxoSmithKline for the distribution of a domestically produced pandemic influenza vaccine to respond to a declared influenza pandemic, but the contract and production facilities in question are limited to the production of egg-based influenza vaccines.

Q340. **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) and Middle Eastern Respiratory Syndrome (MERS-CoV). The challenge in developing a vaccine that protects against coronaviruses is that infection with human coronaviruses does not provide sustained immunity, meaning that a person can be re-infected after recovering from an initial infection.

While developing a vaccine that provides long-term immunity remains problematic, it may be possible to develop a vaccine that can provide short-term protection (similar to a pandemic influenza vaccine) to respond to a novel coronavirus outbreak.

It could take years for researchers to develop a vaccine against a particular coronavirus.

For example, there is currently no approved vaccine or specific treatment for the Middle East Respiratory Syndrome Coronavirus (MERS-CoV), a specific coronavirus first identified in 2012. We know that work is being done elsewhere to better understand how to prevent MERS-CoV infections and to develop a vaccine against this virus. This includes vaccine development efforts coordinated by the WHO and the Coalition for Epidemic Preparedness (CEPI).

Q341. **Could the PVC13 pneumonia vaccine be used to treat COVID-19?**

There are currently no vaccines or other health products approved specifically for the prevention or treatment of COVID-19, because it is a relatively new virus.

With respect to vaccines or other promising health products for treating COVID-19 including secondary infections associated with the disease, clinical trials are the best way to proceed, because they allow the health care community to routinely collect data on the effectiveness of treatments and the risks that may be associated with them. To date, Health Canada has not received any clinical trial applications for administering pneumonia vaccines as treatment for COVID-19 infections.

Health Canada is working closely with many potential COVID-19 clinical trial sponsors to promote access for Canadians. To facilitate faster access to therapeutic products needed to treat or prevent COVID-19, Health Canada will expedite the regulatory process for any COVID-19 health product, including the review of applications and approval of clinical trial applications, while continuing to ensure the safety of trial participants. In addition to the work performed by professional associations, clinical trials are coordinated across the health care sector in Canada and around the world.

Q342. **How are infected people treated?**

At this time, there are no medications or drugs available to treat people with a novel coronavirus infection. Researchers are examining the effectiveness of existing antiviral treatments.

The World Health Organization has provided health professionals with guidance, including recommendations for early-onset treatment, symptom management and prevention of complications.

The novel coronavirus causes mild to severe symptoms depending on the individual. Therefore, if you have travelled abroad, it is important that you monitor your health when you return to Canada. During your trip, 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 fever, cough or difficulty breathing, contact your health care professional or local public health authority to inform them about your symptoms. They will provide advice on what you should do.

Q343. **Is Health Canada investigating these reports, and are there any current guidelines for the use of vitamin C as a defence or treatment against coronavirus?**

Since the outbreak of COVID-19, Health Canada has taken action to help Canadians access the health products they need to treat or prevent COVID-19. Currently, there are no drugs specifically approved to treat COVID-19 because it is still a relatively new virus. Every effort is being made to investigate potential new treatments, including drugs that may have been approved to treat diseases other than COVID-19. With respect to promising COVID-19 drugs, the best way to access treatment is through clinical trials, which allow the health care community to systematically collect information on the effectiveness of treatments and the associated risks.

Health Canada recently approved a clinical trial application to study the use of intravenous vitamin C in patients with COVID-19 to help improve the functioning of certain affected organs in severe cases of COVID-19, and to monitor its progress.

To promote faster access to therapeutic products needed to treat or prevent COVID-19, Health Canada will expedite its regulatory process for any health product related to COVID-19, including the review of submissions and approval of clinical trial applications. In addition to the work done by professional associations, clinical trials are coordinated across the health care sector in Canada and around the world. The landscape is changing quickly, and the health care sector is striving to adapt to changing needs.

Q344. **Are there any safety issues related to using ibuprofen to treat COVID-19?**

There is currently no scientific evidence linking ibuprofen or other non-steroidal anti-inflammatory drugs (NSAIDs) to worsening of COVID-19 symptoms.

If you have COVID-19 symptoms, talk to your health care provider about the most appropriate health products to relieve fever or pain. If you are currently taking ibuprofen, especially for a chronic condition, continue to take it.

Q345. **Can hydroxychloroquine and azithromycin be used to treat any coronavirus patient? Will they be effective in all people?**

Hydroxychloroquine is an antiparasitic drug 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 evidence that these drugs may be effective in some patients. However, these are preliminary findings from a few small-scale studies. There are also significant safety risks associated with both drugs, including QT interval prolongation, which is a serious heart rhythm condition. A health care professional may choose to use these drugs off label, depending on the patient's situation, including the severity of the patient's illness, if the potential benefits outweigh the known risks of the drugs.

In Canada, a physician's decision to prescribe a particular drug to a patient, whether for an approved indication or an off-label indication, is a standard medical practice. Although Health Canada regulates drugs, health professionals are responsible for considering evidence published in medical journals, reports and peer-reviewed studies when prescribing a drug.

Q346. **Does Health Canada have an official position on hydroxychloroquine and chloroquine for the treatment of COVID-19?**

Health Canada recognizes that Canadians with COVID-19 must have access to safe and effective drugs and treatments. Hydroxychloroquine and chloroquine are available on the Canadian market for the treatment of other diseases, but they have not been approved for the treatment of COVID-19.

International reports have suggested that hydroxychloroquine and chloroquine are promising drugs for the treatment of COVID-19, but this has yet to be confirmed. The best way to provide promising COVID-19 drugs to Canadians is through clinical trials. Clinical trials allow the health care community to systematically collect information about the effectiveness of treatments and the associated risks. Therefore, Health Canada encourages manufacturers to work with researchers to make these drugs available to patients with COVID-19 in clinical trials.

As of April 8, 2020, Health Canada has approved two clinical trials for the use of hydroxychloroquine for the treatment of COVID-19. Health Canada has also approved nine other clinical trials using other potential therapies. A list of clinical trials approved for the prevention or treatment of COVID-19 and associated complications is available in Health Canada's Clinical Trials Database. This database can be searched by entering "COVID" in the "Medical condition" box.

Q347. **What is Health Canada doing about products that claim to prevent, treat or cure COVID-19?**

There are currently no COVID-19 vaccines or natural health products, including traditional Chinese medicines, approved for the prevention or treatment of COVID-19.

Selling unauthorized health products or making false or misleading claims about the treatment, prevention or cure of COVID-19 is illegal in Canada. The Department takes this issue very seriously and will take steps to stop this activity. To date, Health Canada has not approved any products to treat or cure COVID-19. Health products that have been approved for sale by Health Canada will bear an eight-digit Drug Identification Number (DIN), Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM). The Department is taking steps to address complaints about products not approved for sale in Canada that contain false or misleading claims about the treatment, prevention or cure of COVID-19.

The Department encourages anyone who has information about the potentially non-compliant sale or advertising of any health product that claims to treat, prevent or cure COVID-19 to report it using our online complaint form.

When Health Canada identifies or is informed of a potential non-compliance with the *Food and Drugs Act* or *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 seizure of products and advertising material. The primary objective of the Department's approach to compliance and enforcement is to manage risks to Canadians by using the most appropriate level of intervention, in accordance with Health Canada's *Compliance and Enforcement Policy for Health Products*.

Q348. **What steps will Health Canada take if health products are non-compliant because they claim that they 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 that companies are distributing free samples of unauthorized products or of approved products that make false and misleading claims, Health Canada will ask the parties involved to immediately stop distributing these free samples and will take all necessary steps to enforce compliance, which may include seizing the products.

As previously mentioned, Health Canada has not approved any product for the treatment or cure of COVID-19, including any traditional Chinese medicines. The sale of unauthorized health products or making false or misleading claims about COVID-19 and the prevention, treatment or cure of COVID-19 is illegal in Canada.

The distribution of free samples of approved products making false and misleading claims or any other form of advertising making such claims is illegal. The Department takes this issue seriously and will not hesitate to use all the tools at its disposal to stop such activities.

Currently, Health Canada is assessing this advertising issue and will take all necessary steps to enforce the Act if it finds that advertising does not comply with the Act or Regulations.

The Department encourages anyone who has information about the potentially non-compliant sale or advertising of any health product that claims to treat, prevent or cure COVID-19 to report it using the online complaint form.

Q349. **Are there any natural health products, including traditional Chinese medicines, Ayurvedic remedies and homeopathic products, that can be used to treat or protect against this virus?**

No natural health products have been approved to treat or protect against COVID-19. This includes traditional Chinese medicines, Ayurvedic remedies and homeopathic products.

Q350. **Are Avigan or favipiravir approved in Canada? Is Canada taking steps to approve them?**

Favipiravir is sold under the brand name Avigan. This antiviral has been approved in Japan and China for the treatment of influenza. No products containing favipiravir are currently approved in Canada.

Since the beginning of the COVID-19 pandemic, Health Canada has taken steps to ensure that Canadians have access to the health products they need to treat or prevent COVID-19. To provide faster access to a COVID-19 vaccine or treatment, Health Canada will expedite its regulatory process for all COVID-19 health products, including the review of submissions and approval of clinical trial applications.

Health Canada has initiated discussions with companies that manufacture promising COVID-19 products, including the company that manufactures favipiravir. However, Health Canada has not yet received any submissions for products containing favipiravir. It is ultimately up to the manufacturer to decide whether to seek authorization to market their product in Canada.

With respect to promising COVID-19 drugs, such as favipiravir, Health Canada encourages sponsors to collaborate with researchers and offer such drugs to patients in clinical trials. This would enable patients to provide informed consent and the health care community would know whether the treatments were effective and what the associated risks were.

Q351. **Will Health Canada or the Public Health Agency of Canada publish clinical guidelines if it is proven in other countries or jurisdictions that antivirals such as favipiravir or other drugs provide an effective treatment for COVID-19?**

Currently, there is insufficient evidence to recommend a specific treatment for COVID-19 in patients diagnosed with COVID-19 who are not participating in clinical trials. Clinical trials are underway to test various experimental antivirals posted at https://clinicaltrials.gov/ or on the Chinese registry of clinical trials (http://www.chictr.org.cn/abouten.aspx). The development of clinical guidelines is underway with the Association for Medical Microbiology and Infectious Disease Canada and the Canadian Critical Care Society.

Drugs that are not available in Canada can be accessed through clinical trials or the Special Access Program. In the event that there are sufficient data indicating that a drug provides an effective treatment of COVID-19 to make a submission to Health Canada and the submission is approved, directions for use would be included in the product monograph. Other organizations could also develop guidelines for off-label use of other products that have been shown to be effective.

Q352. **What other regulatory flexibilities is Health Canada considering 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 whether there are other flexibilities that Health Canada should consider for their submission in response to the COVID-19 pandemic.

Clinical Trials

Q353. **Are clinical trials underway to determine the efficacy of hydroxychloroquine and azithromycin?**

Yes. Health Canada has authorized clinical trials on the use of hydroxychloroquine to treat COVID-19 in Canada. Health Canada is also monitoring the progress of other clinical trials underway around the world.

Any company or health care professional involved in treating patients with COVID-19 who would like to conduct a clinical trial on 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 and associated complications is available in Health Canada's Clinical Trials Database**.** This database can be searched by entering "COVID" in the "Medical condition" field.

Q354. **Are hydroxychloroquine or chloroquine being used in Canadian hospitals for trials or treatment?**

Two Canadian-approved clinical trials are being conducted in several locations across the country.

Since both hydroxychloroquine and chloroquine have been approved in Canada for the treatment of other diseases, physicians may prescribe these drugs off label. The use of off-label drugs is within the scope of medical practice and is regulated by the provinces.

Q355. **Does Health Canada sometimes approve human challenge trials? Is this WHO document one of the reference tools that Health Canada uses to develop its human challenge trial regulations? Or are updated WHO regulations available?**

No COVID-19 vaccine trials are yet underway in Canada, and Health Canada has not received any requests for challenge studies. The list of clinical trials approved by Health Canada for COVID-19 is available online.

Pursuant to the *Food and Drug Regulations*, a clinical trial must be conducted in accordance with good clinical practices, the approval of a research ethics board, informed consent and thorough safety monitoring to protect participants. If it is carefully controlled, a challenge study may be conducted to assess the effectiveness of a vaccine. Health Canada's approach would

generally be consistent with international best practices, such as guidelines issued by the World Health Organization and other major regulatory bodies.

Q356. **COVID-19 plasma therapy has not yet been approved. Can you give us details on how it works?**

Health Canada worked closely with clinical trial sponsors and blood suppliers, Canadian Blood Services and Héma-Québec to provide regulatory and scientific advice to support the development of this blood plasma testing protocol. Health Canada 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. The time it usually takes to approve clinical trials depends on the information submitted in support of the trial. It can take up to 30 days. The time it takes to review priorities varies, but this review is expected to be completed within one or two weeks. The purpose of the Health Canada review is to protect the health of study participants or the health of others, to ensure that the trial is in the best interests of the study participants, and to determine whether the study objectives will be met.

Q357. **What are the criteria for plasma donation for men who have had sex with men (MSM) in the last three months? Will they be allowed to donate plasma, or does the status quo apply?**

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 approval. The purpose of the Health Canada review is to determine whether the trial could endanger the health of study participants or the health of others, whether the trial is in the interest of the study participants, and whether the study objectives will be met. In addition to the undergoing a Health Canada review, 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 responsibility of the CTA sponsor to identify the protocols for conducting the trial in the application. For trials involving plasma or blood products, this would include donor selection criteria.

To date, Health Canada has approved one convalescent plasma clinical trial for the treatment of COVID-19. This multi-centre trial is designed to determine the safety and efficacy of convalescent plasma collected from donors who have recovered from COVID-19 infection to reduce the risk of intubation or death in adults admitted to hospital for COVID-19 respiratory disease. 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 existing Health Canada protocols, including the current donor exclusion for men who have had sex with another man in the past three months.

Q358. **Is Canada participating in the WHO-led Solidarity II project?**

As part of the World Health Organization (WHO) R&D Blueprint and response efforts to combat COVID19, the WHO has launched a multinational clinical trial to investigate potential COVID-19 treatments.

To date, signatories 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 following the same study protocol at multiple sites in order to obtain statistically reliable results from a sufficient number of patients.

The principal investigator in Canada is Dr. Srinivas Murthy of British Columbia. Currently, 31 Canadian hospitals are in various stages of implementing 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 be included are: 1) lopinavir/ritonavir combination currently marketed to treat HIV versus standard of care; and 2) hydroxychloroquine, currently marketed to treat malaria, to be added to the protocol at a later date.

Lianhua Qingwen capsules

Q359. **Are Lianhua Qingwen capsules approved for sale in Canada? If so, why?**

Lianhua Qingwen capsules have been approved by Health Canada with the following recommended use: “Traditionally used in Chinese medicine to help eliminate heat-toxin invasion of the lungs, including symptoms such as fever, aversion to cold, muscle pain, stuffy and runny nose, dry or sore throat, red tongue with a yellow, 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 evaluates the safety, effectiveness and quality of natural health products based on their ingredients and health claims. An eight-digit Natural Product Number (NPN) or Homeopathic Medicine 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 on Lianhua Qingwen (NPN 80033781) is available in Health Canada’s public Licensed Natural Health Products Database.

Q360. **Do Lianhua Qingwen capsules provide an effective cure for COVID-19 as claimed by the manufacturer?**

Currently, no health products used to treat or protect against COVID-19, including traditional Chinese medicines, have been approved by Health Canada.

In Canada, it is illegal to sell unlicensed health products or make false or misleading claims regarding the prevention, treatment or cure of COVID-19. The Department takes this issue very seriously and will take steps to stop this activity. To date, Health Canada has not approved any products used to treat, prevent or cure COVID-19. The Department is taking steps to respond to complaints about products not approved for sale in Canada that make false or misleading claims about the treatment, prevention or cure of COVID-19.

Health Canada is assessing this advertising issue and will take all necessary steps to enforce the Act if it finds that advertising does not comply with the Act or Regulations.

The Department encourages anyone who has information about the non-compliant sale or advertising of any health product that claims to treat, prevent or cure COVID-19 to report it using the online complaint form.

Q361. Is it true that ephedra is one of the ingredients used in Lianhua Qingwen capsules and that it is prohibited by Health Canada?

The medicinal ingredient ephedra (*Ephedra sinica*) is not prohibited by Health Canada. The Monograph: Ephedra provides detailed information about the requirements to ensure the safety of this ingredient in natural health products. All natural health products, including products containing ephedra, must be approved 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.

Q362. 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 case files and is taking steps to verify whether there have been any cases of non-compliance. Given that these are active and ongoing cases, the Department is not in a position to provide details on any compliance and enforcement actions it might consider.

When Health Canada identifies potential cases of non-compliance with the *Food and Drugs Act* or Regulations, or when the Department is informed of such cases, 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 seizure of products and advertising material.

The Department encourages anyone who has information about a potentially non-compliant advertisement claiming that a health product can treat, prevent or cure COVID-19 to report it by emailing us at drug-device-marketing@canada.ca or through the online complaint form.

Temporary Exemptions for Medical Treatments under the Controlled Drugs and Substances Act

Q363. Have the provinces and territories requested this exemption?

A few governments have asked Health Canada whether measures would be implemented to facilitate access to certain medical treatments during the pandemic. The Department responded quickly to address their concerns and avoid potential problems with access to medical treatment during the pandemic.

Q364. When will pharmacists and practitioners be able to engage in these new activities?

In response to the COVID-19 outbreak, Health Canada has granted a temporary exemption for certain new activities for pharmacists who are registered and licensed to practise under the laws of their province or territory and who are authorized to engage in activities involving controlled substances. They will be able to engage in these activities if the province/territory in which they practise and the regulatory body of which they are a member adopt these measures. Health Canada recommends that provincial and territorial regulators be contacted for more information.

Given the seriousness of the COVID-19 outbreak, Health Canada is working to take prompt action to help governments ensure continued access to drugs for Canadians.

Q365. What activities are pharmacists currently authorized to perform?

Pharmacists are medication experts and play an important role in monitoring patients and medications to ensure their safe and optimal use, while contributing to the delivery of evidence-based care. Pursuant to the regulations made under the *Controlled Drugs and Substances Act,* pharmacists are authorized to sell or provide a controlled substance to a person if they have received a prescription or written order from a practitioner.

Although these regulations do not allow pharmacists to prescribe drugs, other related activities included in the meaning of “sell” and “dispense” are permitted as long as the quantity dispensed does not exceed the quantity originally prescribed. These activities include, but are not limited to:

- **Adjusting the formulation:** adjusting the dosage form in which the drug was prescribed
    - e.g. change from pill to liquid form;
- **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 20 mg per day for 5 weeks to 10 mg per day for 10 weeks;
- **De-prescribing:** the planned and supervised process of reducing or stopping a medication;
- **Part-filling:** dispensing a quantity of a medication which is less than the total amount of the drug prescribed by the practitioner
    - for greater clarity, this includes part-fills requested by the 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.

In order to ensure better drug management and the health and safety of Canadians, Health Canada has provided pharmacists with an interpretive guide on activities related to the prescription of controlled substances under the *Narcotic Control Regulations*, the *Benzodiazepines and Other Targeted Substances Regulations* and Part G of the *Food and Drug Regulations*.

Q366. If a patient does not have a prescription, can a pharmacist now prescribe a new drug?

This exemption allows pharmacists to renew or extend a prescription in order to provide the patient with access to a drug. Pharmacists are not authorized to prescribe new medical treatment involving controlled substances (e.g. narcotics).

Q367. **Are other health care professionals covered by this exemption?**

Other health professionals, such as nurse practitioners, dentists and veterinarians, are covered by this exemption, which allows them to prescribe narcotic drugs orally (depending on the prescriber's scope of practice and provincial/territorial authorization).

Q368. **Is a permanent expansion of the activities that pharmacists can perform being considered?**

Pharmacists are medication experts and play an important role in monitoring patients and medications to ensure that they are used safely and optimally.

To ensure better drug management and to protect the health and safety of Canadians, in March 2019, Health Canada launched an official consultation to seek input on how to modernize the role of pharmacists in the health care system. The Department is currently reviewing all the comments it has received. It will still be possible to comment on any draft regulations in Part I of the Canada Gazette. Health Canada invites everyone to participate in the consultation.

Q369. **Are there specific measures in place to assist supervised consumption sites during the COVID-19 pandemic?**

Health Canada recognizes that local pandemic precautionary measures could have an impact on the operation 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 changes to their protocols and practices. Operators are encouraged to contact the Exemption Section of the Office of Controlled Substances by email (hc.exemption.sc@canada.ca).

VIRUS TRANSMISSION

Q370. **How is COVID-19 transmitted?**

Current evidence suggests that COVID-19 is most often transmitted by an infected person:

- from respiratory droplets emitted 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, after which unwashed hands come into contact with the mouth, nose or eyes.

In general, coronaviruses form a large family of viruses, some of which cause disease in humans, while others circulate in animals, including camels, cats and bats.

Q371. **Can COVID-19 be transmitted even when a person is asymptomatic?**

Now that more countries have recorded many cases and analyzed modes of transmission, recent studies show that infected people can transmit the virus before they even have any symptoms. This is known as *pre-symptomatic transmission*.

Data also show that some infected people can transmit the virus without ever having any symptoms. This phenomenon is called *asymptomatic transmission*. Currently, we do not know the extent to which pre-symptomatic and asymptomatic transmission play a role in the progression of the pandemic, but we do know that this type of transmission occurs in people who come into close contact or are in cramped quarters with other people.

The main drivers of the COVID-19 pandemic are people with obvious symptoms, because coughing and respiratory droplets are the main ways that the virus spreads. However, because asymptomatic transmission has now been proven to exist, it is important that everyone, even people who do not feel sick, follow practices proven to prevent transmission.

The following are proven methods to prevent transmission of COVID-19:

- Stay home as much as possible;
- Practise physical distancing;
- Wash your hands;
- Protect the most vulnerable people from infection and limit their exposure to others;
- Cough into a handkerchief or into your sleeve.

Q372. **What should you do if you have been exposed to a confirmed case of COVID-19?**

If you **have no symptoms**, but you think you have been exposed to a source of COVID-19, the Public Health Agency of Canada asks you to take the following steps for the next 14 days:

- Monitor your health to detect the appearance of **fever**, **cough** and **breathing difficulties**;
- Avoid places where you cannot easily move away from others if you get sick.

To further protect those around you, wash your hands often and cover your mouth and nose with your arm when you cough or sneeze.
If you **have COVID-19 symptoms**, isolate yourself from others as soon as possible. Immediately contact a health care professional or public health authorities at 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 tell you what steps you should take.

Q373. **What are the statistics on asymptomatic cases in Canada?**

The Public Health Agency of Canada (PHAC) and provincial and territorial public health authorities work 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 COVID-19 case report form. According to the 22, 217 infection reporting forms received as at April 22 at 11:00 a.m. EDT, PHAC is aware of

220 cases that were classified as asymptomatic, representing 2.7% of cases with known symptom status (n=7,879). It should be noted that in 65% of cases reported to PHAC, it was not known whether the cases presented with symptoms.

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, the data on these cases on the reporting form are preliminary and some values for characteristics of interest may be missing. The provinces and territories may not routinely update detailed data. Although a patient's condition may change as the disease progresses, PHAC does not receive regular updates on the patient's status.

Q374. **Are Canadians at risk of contracting COVID-19 if they touch a potentially contaminated surface?**

As a general rule, coronaviruses do not survive on surfaces that have been contaminated.

The best way to prevent COVID-19 and other respiratory diseases is to:

- avoid touching your eyes, nose and mouth with your hands;
- consistently follow good hand hygiene practices, which include washing your hands often 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;
- practise good respiratory etiquette, such as covering your mouth and nose with your arm or sleeve when coughing or sneezing, disposing of used tissues as soon as possible, and after you cough or sneeze, washing your hands immediately with soap and alcohol-based hand sanitizer when soap and water are not available;
- frequently clean and disinfect surfaces that people commonly touch, such as toilets, bedside tables, doorknobs, telephones and television remotes, with regular household cleaners or diluted bleach (one part bleach to nine parts water).

Q375. **Are Canadians at risk of contracting COVID-19 from products shipped from Canada or abroad?**

It is not yet known how long the COVID-19 virus survives on objects and surfaces, but early indications suggest that it could vary from a few hours to a few days depending on a variety of factors, including:

- temperature;
- type of surface;
- ambient humidity.

Products shipped from Canada or abroad could also be contaminated. However, because it usually takes several days or weeks to deliver packages, and they are transported at room temperature, the risk of spread is **low**. There is no evidence that coronaviruses could enter Canada simply by being present on packages or parcels.

To protect yourself from COVID-19, be sure to do the following when handling products that have been shipped from Canada or abroad:

- follow good hygiene practices;
- clean and disinfect surfaces regularly;
- do not touch your eyes, nose or mouth.

Q376. **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 no reports of foodborne transmission of COVID-19 at this time. The virus is not likely to infect people through food.

Scientists and food safety officials 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 Canadian Food Inspection Agency (CFIA) becomes aware of a food safety risk, appropriate steps will be taken to ensure the safety of Canada's food supply.

Animals

Q377. **Is it possible to get the virus from an animal in Canada?**

At present, the spread of COVID-19 results from person-to-person transmission. There is no evidence that pets and other animals may play a role in the transmission of the disease to humans. Scientists are still trying to understand if and how the disease affects animals.

Q378. **Can pets and other domestic animals get the virus?**

It is possible that certain types of animals could be infected with the coronavirus that causes the disease, but we do not yet know if they would get sick.

As a precautionary measure, if you have COVID-19 symptoms or are self-isolating due to contact with a case of COVID-19, you should follow the same recommendations that apply to people when you deal with animals:

- 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, ask another member of the household to care for your pets.
    - If this is not possible, always wash your hands before and after touching animals, their food and supplies, and follow good respiratory hygiene practices when coughing or sneezing.
- Limit contact between your pets and people and animals outside your household until you are no longer sick.

These measures are basic practices to prevent the transmission of diseases between humans and animals and are recommended as a precautionary measure. If you have concerns, consult a veterinarian or public health professional who can help you find answers to your questions.

More information about animals and COVID-19 is available on the Canadian Food Inspection Agency (CFIA) website.

Q379. **Am I at risk of contracting COVID-19 if I have been in 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 by the Canadian Food Inspection Agency. Currently, there is no requirement in Canada that restricts the import of animals because of the COVID-19 pandemic, since there is no evidence that pets or other domestic animals can spread this virus. However, until more information is available, we encourage importers, rescue organizations and adoptive families to limit or postpone the importation of animals from affected areas.

Any animal imported from an affected area must be closely monitored for signs of disease. If an animal becomes ill, contact your veterinarian and inform him of the situation. Contact him by phone first to ensure that he is aware of the circumstances.
Animals imported from other countries can carry a variety of diseases that do not exist in Canada and can spread between animals and between animals and humans. Therefore, it is always a good idea to have a veterinarian examine a recently imported animal so that he can advise you on the care and vaccinations needed to keep the animal healthy and protect the health of your family members.
Take the following precautions to prevent the transmission of disease from animals to humans:

- Always wash your hands after touching an animal, its food or supplies and after picking up its waste or cleaning its bedding;
- Do not kiss animals, do not share food with them, and do not let them lick your face;
- Make sure to regularly clean and disinfect the areas where the animals live.

More information on animals and COVID-19 is available at the following sites:

- https://www.oie.int/fileadmin/Home/eng/Our_scientific_expertise/docs/pdf/COV-19/COVID19_21Feb.pdf

- https://www.who.int/emergencies/diseases/novel-coronavirus-2019/advice-for-public/myth-busters?

Q380. **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 of our population in order to understand its transmission dynamics. Children have been shown to be major drivers in the transmission of other respiratory diseases (e.g. influenza). Therefore, it is worthwhile examining whether there is evidence that SARS-CoV-2 is more or less prevalent among children than among other age groups.

Q381. **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 control of COVID-19, including a recent quick review of the evidence on transmission in children. PHAC will provide the detailed results of the literature review of reputable scientific publications and websites. The publishing process for these publications is already underway.

Q382. **Is the information being revised or is the Government working with partners?**

These quick reviews are conducted by individuals 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 COVID-19 response.

PREVENTION AND RISKS

Q383. **How can I protect myself against this virus?**

Here are some tips to stay healthy and prevent the spread of infection:

- wash your hands frequently with warm water and soap for at least 20 seconds;
- use alcohol-based hand sanitizer or a Health Canada-approved alcohol-free hand sanitizer only if soap and water are not available;
- avoid touching your eyes, nose or mouth with unwashed hands.
- avoid contact with sick people, especially if they have a fever, cough or difficulty breathing;
- Cover your mouth and nose with your arm when you cough or sneeze to reduce the risk of spreading germs;
- if you get sick, stay home to avoid infecting other people.

Q384. **Should people in Canada wear masks to protect themselves from this virus?**

The following are proven methods to prevent transmission of COVID-19:

- Stay home as much as possible;
- Practise physical distancing;
- Wash your hands;
- Protect those most vulnerable from infection and limit their exposure to others;
- Cough into a tissue or your sleeve.

Health care workers need medical masks, including surgical masks, procedural masks and respiratory masks such as N95s. It is extremely important that we reserve the supply of medical

masks for health care workers, as they are urgently needed for medical procedures and to care for individuals who have COVID-19.

There is no evidence that a non-medical mask or face shield (i.e. manufactured to completely cover the nose and mouth and fit snugly over the face, held in place by ties behind the ears or cords behind the head and neck) in the community protects the person wearing it. However, wearing a non-medical mask or face shield is one more step you can take to protect those around you.

Wearing a non-medical mask is another way to cover your mouth and nose to prevent your respiratory droplets from contaminating others or landing on surfaces. Like covering your mouth with a tissue or your sleeve when coughing, a cloth mask or face shield can reduce the risk of exposing others to your respiratory droplets.

For short periods of time when it is not possible to practise physical distancing in public (e.g. at the grocery store or in confined spaces such as public transit vehicles), wearing a non-medical mask is a way to protect those around you.

Young children under two years of age and people who have respiratory problems, are unconscious, or are unable to remove a mask on their own should not wear non-medical masks or other face coverings.

Q385. **Why were the recommendations regarding mask use changed? What prompted these new recommendations?**

Canadian public health guidance for COVID-19 has changed with the emergence of new evidence and a fuller understanding of the new virus. We are continually reviewing the latest scientific evidence as it becomes available and work with our partners across Canada and around the world to learn more about the virus. From the onset of the COVID-19 outbreak, it was recommended that symptomatic people who were known to have COVID-19 wear masks when they were within two metres of other people or if they left their homes for essential reasons (i.e. to seek treatment). Masks were not recommended for widespread use by healthy people in the community.

Thinking about the use of masks has evolved with the emergence of evidence that the virus can be transmitted by infected people before symptoms appear (pre-symptomatic transmission). There is also evidence that some infected people who never develop symptoms can also transmit the virus (asymptomatic transmission). The extent to which pre-symptomatic and asymptomatic transmission plays a role in the spread of the COVID-19 pandemic is not known at this time, but it is known to occur in individuals who are in close contact or in confined spaces with other people. This evidence led to the Council of Chief Medical Officers of Health's recommendation that individuals could wear non-medical masks and face shields as an additional layer of protection in environments where physical distancing might not be possible.

Frontline COVID-19 health care workers need medical masks, including surgical masks, masks for medical procedures and respirators such as N95 masks, and it is extremely important that these masks be reserved for them. Although it has not been proven that wearing a non-medical mask or face shield 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 to cover your mouth and nose to prevent respiratory droplets from contaminating others or landing on surfaces. A cloth mask or face shield can reduce the risk of others coming into contact with your respiratory droplets. Also, following our recommendation to cover your mouth with a tissue when coughing or coughing into your sleeve can reduce this 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 you're sick;
practising physical distancing;
washing your hands;
protecting the most vulnerable people from infection and limit their exposure to others;
covering your mouth with a non-medical mask, or cough into a tissue or your sleeve.

Q386. Did Health Canada observe an increase in the number of calls from people reporting health problems 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 control centres across Canada have collaborated to analyze the number of calls to poison control centres related to exposure to cleaning products. The data were collected by the poison control centres, shared with Health Canada and compiled to provide an overview of the situation across Canada.

The analysis compared the number of reported exposures in 2019 and 2020. Data for January 2019 were not included because information from one of the poison control centres was not available. Also, data for April 2020 are not yet available.

When comparing reports made in February and March 2019 to data from the same months in 2020, poison control centres saw a 58% increase in the number of cases of exposure from 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 a variety of factors, including the following:

- People, including children, are spending more time at home;
- The quantity of cleaning products available in households has increased as a result of increased purchases in response to the pandemic;
- More products are available due to enhanced cleaning and disinfection in the 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 on its website.

Q387. Can vaping / smoking / drug use damage the lungs and make a person more vulnerable to COVID-19?

No direct evidence has been published on vaping or drug use and their association with COVID-19 outcomes.

Studies that have examined the association between smoking and the severity of COVID-19 disease have indicated that smokers may be more susceptible than non-smokers.

Q388. **In the United States, people under 44 years of age account for a large percentage of hospitalizations. What percentage of hospitalizations is attributable to younger Canadians?**

In Canada, people under 40 years of age account for 31% of cases. Compared to other age groups, people under 40 years of age suffer from less serious illnesses, because this age group accounts for only 9% of hospitalizations and 4% of intensive care admissions. (These figures are subject to change as new cases are identified and the situation evolves.)

Q389. **What is your message to young people (specifically those who smoke / vape / use drugs) who believe they are immune to COVID-19?**

Everyone is susceptible to this virus – you are not immune. Vaping can increase your exposure to chemicals that can harm your health (for example, cause lung damage). It is also important to remember that devices used for vaping or taking drugs should never be shared with others. Maintaining a healthy lifestyle is particularly important today.

Q390. **Until February 22, 2020, PHAC still considered the public health risks associated with COVID-19 in Canada to be "low." When did this health risk assessment change? What are the current public health risks associated with coronavirus in Canada?**

The public health risk assessment provided in the Health Portfolio Situation Reports was based on the risks posed by COVID-19 to the Canadian population at that time. As at February 22, 2020, the risks to the Canadian population were low because 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 then low for the general population, but moderate for the elderly and those with underlying medical conditions.

When it was confirmed that there was community transmission of COVID-19 in Canada, the health risk was determined to be high. The current public health risk assessment for coronavirus in Canada, effective March 16, showed that the risk to the general population was high.

5G TECHNOLOGY and COVID-19

Q391. **What is the role of the Government of Canada with respect to 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, review 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 are consistent with the current scientific consensus to prevent potential adverse health effects.

Innovation, Science and Economic Development Canada (ISED) is responsible for deploying 5G wireless technology. To help protect Canadians, ISED has adopted the limits set out in the Health Canada document entitled Security Code 6 for wireless devices and infrastructure.

Safety Code 6 has always maintained an exposure limit below the threshold for adverse health effects. The Government of Canada continues to monitor the best available evidence and will take appropriate action if new scientific evidence becomes available.

Q392. **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 thereof) from 3 kHz to 300 GHz. This range includes frequencies used by existing communication equipment, as well as those that can be used by equipment using 5G technology (i.e. above 6 GHz).

Q393. **How does Safety Code 6 protect the health of Canadians?**

The recommended exposure limits in Safety Code 6 are designed to protect Canadians from all scientifically established adverse health effects from exposure to radiofrequency electromagnetic fields. These effects are tissue heating (like heating the skin) 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, they would not experience adverse health effects.

Q394. **Is radiofrequency exposure from cell towers and antennas safe?**

Yes, radiofrequency exposure from cell towers and antennas is safe. There is no scientific basis for recent claims that 5G networks are linked to the COVID-19 outbreak. The World Health Organization and the International Commission on Non-Ionizing Radiation Protection have also recently communicated this message on their websites. ISED manages the use of the radio frequency spectrum and requires all antenna systems to comply with the limits of Safety Code 6 to protect the public from overexposure. More information about antenna towers is available at www.ic.gc.ca/towers.

Q395. **How does Canada compare with other countries in regulating radiofrequency emissions?**

The exposure limits in Safety Code 6 are consistent with 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 set out in Safety Code 6.

The exposure limits in Safety Code 6, and Health Canada's findings, 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.

EMPLOYEE SAFETY

Q396. **What is Health Canada doing to ensure that federal employees take appropriate precautions?**

Health Canada's Public Service Occupational Health Program (PSOHP) provides occupational health services and health advisory services to various departments.

In accordance with standard protocols for such situations, the PSOHP has issued a general Occupational Health Advisory to departments and agencies that provides advice on the novel coronavirus and recommended precautions for employees, such as frequent hand washing, proper cough and sneeze etiquette, and self-monitoring for symptoms.

The advice and information are based on science and the level of risk determined by the Public Health Agency of Canada and the World Health Organization.

In addition, given the variety of federal workplaces, the PSOHP has developed additional guidance for specific workplaces. The first priority was advice for airport employees who interact with travellers. This included advice on the personal protective equipment to be used when searching baggage or escorting a traveller who is ill. Health Canada's occupational health nurses also assisted our departmental partners by organizing information sessions for staff 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 the occupational health information they need.

Health Canada's occupational health experts will continue to work closely with departments to ensure the health and safety of federal public service employees.

Q397. **What protocols did Health Canada follow after receiving confirmation that an employee had been diagnosed with COVID-19?**

A Health Canada employee working at Tunney's Pasture tested positive for COVID-19. The employee is self-isolating and following local public health authority guidelines.

The Department followed established protocols.

- The area where the employee works, including common areas, has been properly cleaned in accordance with Public Services and Procurement Canada standards. The area was cleaned in conjunction with Statistics Canada, because the two departments share a common workspace.

In addition, local public health authorities reached out to the employee to identify any relevant contacts. This involved contacting some colleagues, who were advised to self-isolate by local public health authorities.

The Government of Canada requires employees to work from home whenever and wherever possible, while taking into account the operational requirements of each department. Departments and other federal organizations are actively using this flexible work option. We are constantly reassessing the situation and striving to balance our duty to Canadians with the health and safety of all public servants.

The government is developing a mechanism to centralize information on confirmed cases within the public service. The Treasury Board Secretariat works closely with Health Canada and the Public Health Agency of Canada to provide departments and agencies with workplace information and advice so that they can manage their workforces accordingly.

Q398. **Can you confirm that a number of employees working at the National Microbiology Laboratory of Canada in Winnipeg have tested positive for COVID-19?**

Two employees working at Canada's National Microbiology Laboratory (NML) in Winnipeg tested positive for COVID-19. The employees are self-isolating and following local public health authority guidelines. Contact tracing is being carried out by local public health authorities, who will implement all necessary follow-up procedures to prevent the virus from spreading.

In accordance with standard laboratory protocols, procedures for cleaning and disinfecting work areas and common areas were followed. Our employees continue to practise effective public health measures, including social distancing, hand washing and respiratory etiquette.

It is not surprising that we are seeing cases among our workforce as COVID-19 circulates in our community. We are prepared for such circumstances through business continuity plans that ensure that essential NML operations continue when employees are ill or absent. The Government of Canada's policy during the COVID-19 pandemic allows federal employees to work from home if they can perform their duties remotely. We wish our employees a speedy recovery and are thinking of them and their families during this difficult time.