COVID-19
QUESTIONS AND ANSWERS ARE UPDATED REGULARLY

Questions and Answers

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THE SITUATION IN CANADA

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

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

The Government of Canada has created the infrastructure needed to deal with public health threats posed by the virus. Working closely with provincial and territorial governments and international partners, it is well prepared to react in order to minimize the health, economic and social impacts of this rapidly evolving public health problem.

Canada's response is based on plans and guidance documents related to pandemic preparedness. The guiding principles are:

- **Collaboration** – all levels of government and stakeholders need to work in partnership to produce an effective and coordinated response.
- **Evidence-informed decision making** – decisions should be based on the best available evidence.
- **Proportionality** – the response to a pandemic should be appropriate to the level of threat.
- **Flexibility** – public health measures should be tailored to the situation and evolve as new information becomes available.
- **A precautionary approach** – timely and reasonable preventive action should be proportional to the threat and informed by evidence to the extent possible.
- **Use of established practices and systems** – well-practised strategies and processes can be rapidly scaled 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 Canada detect and respond to a pandemic outbreak. 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 the chief medical officers of health in the provinces and territories.
- The development of the Canadian Pandemic Influenza Preparedness: Planning Guidance for the Health Sector, a guide to preparing for and responding to a pandemic.
- The enhancement of diagnostic capacity in the National Microbiology Laboratory.
- The strengthening of working relationships with the World Health Organization and other international partners, such as the United States Centers for Disease Control and Prevention.

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

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

Q2. **When did the Public Health Agency of Canada become aware of COVID-19?**

The Public Health Agency of Canada (PHAC) became aware of an “undiagnosed pneumonia” in China on **December 31, 2019**, based on information collected overnight and reported through its Global Public Health Intelligence Network (GPHIN).

On **January 2, 2020,** the Chief Public Health Officer of Canada sent a written message about the situation to her colleagues in the provinces and territories across the country. PHAC’s National Microbiology Laboratory (NML) also sent an alert to a federal and provincial public health laboratory network on January 2, 2020.

In order to prepare laboratories, PHAC’s NML convened a meeting with the directors of provincial public health laboratories across Canada on **January 7, 2020,** to discuss preparing for a pandemic and to review guidance documents in light of the situation unfolding in Wuhan, China.

The initial discussion focused on preparedness for setting up federal, provincial and territorial screening capacity and the procedure for submitting samples to the NML if the virus were to enter Canada via travellers returning to the country.

PHAC officially activated the Health Portfolio Operation Centre in **mid-January** to ensure the effective planning and coordination of PHAC’s response efforts together with international, federal, provincial and territorial partners. The Federal/Provincial/Territorial Public Health Response Plan for Biological Events and the special federal/provincial/territorial advisory committee on COVID‑19 were created on **January 28, 2020,** to ensure a coordinated response across Canada.

On **January 26, 2020,** the NML received the first “presumptive positive” specimen from our partners at Public Health Ontario, taken from a returning traveller suspected of having COVID‑19. NML scientists tested the sample and confirmed the first case of COVID‑19 in Canada on **January 27, 2020**.

Typically, laboratories already have highly characterized samples of the virus they are trying to detect so they can be confident that their tests detect cases accurately. Although it is possible to quickly develop new tests based on the genome sequence of the virus, in this case, because the virus was new we did not yet have samples of SARS‑CoV‑2 when the first cases entered Canada. That is why the laboratory built up confidence in the results by using a multitude of tests on the first specimens, including tests designed in both Canada and Germany. We also

performed gene sequencing on the first specimens in order to obtain definite confirmation that the first cases were actually positive for COVID-19.

Once the first cases were confirmed, samples of the laboratory specimens were sent to Canada's provincial public health laboratories so they could also perform tests and obtain accurate results. During those early days the NML confirmed that all cases and results presumed to be positive underwent further testing at the NML. Shortly afterwards, working with the Vaccine and Infectious Disease Organization and Sunnybrook Hospital (where the first case was admitted), the SARS-CoV-2 virus was cultured using samples collected from patients in appropriate biocontainment facilities (containment level 3 laboratories) so that laboratories would have sufficient material to study the virus and, most importantly, to carry out quality assurance processes. Using this material and studying local cases, provincial laboratories did in-depth studies on the quality of their testing and then began to report confirmed cases directly, without needing further testing by the NML.

With the availability of tests to detect cases of COVID-19 and the expansion of testing capacity across the country, it was important that a national testing strategy be drawn up with provincial and territorial health authorities. This strategy continues to be fine-tuned today, not only as testing capacity increases, but also as the pandemic continues to evolve in response to Canada's public health efforts. This testing strategy goes beyond detecting new cases of COVID-19, aiming to identify and break chains of transmission as well as prevent transmission within and among high-risk settings and populations.

Q3. **Does Canada intend to base 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 in this respect. The 2006 Pandemic Influenza Plan was published after the SARS crisis and was adjusted to formulate our response to the previous H1N1 pandemic. We have continued to regularly update our plan since H1N1. One of the main lessons we learned from H1N1 is that our planning approach needs to be flexible and scalable.

We are carefully reviewing the updated WHO COVID-19 strategy in consultation with our partners. In the meantime, our public health efforts will continue to focus on reducing the spread of the virus by rapidly identifying cases, locating people who have been in close contact with those cases and using proven public health measures such as isolation and physical distancing.

We are continuously assessing the impact of our public health measures on the number of reported cases and adapting them as necessary, working with our provincial and territorial partners. Our response must be based on evidence as our scientific understanding of COVID-19 continues to grow.

Interim report on WHO's response to COVID-19 from January to April 2020

Q4. **What was Dr. Tam's role in drafting the joint review report? Does she represent the Government of Canada?**

- Dr. Tam is a member of the Independent Oversight and Advisory Committee for the WHO Health Emergencies Programme. The Committee advises the WHO Director-General and reports its findings through the WHO Executive Board at the World Health Assembly. Members serve as individuals and fulfil their responsibilities with full regard for the paramount importance of independence. The Committee made recommendations to strengthen the WHO Health Emergencies Programme in terms of human resources practices, the use of innovative technologies in response to outbreaks and application of the lessons learned from previous responses.

- Dr. Tam does not represent the Government of Canada in her role on the Committee.

- Her position is voluntary and is not remunerated by WHO.

Q5. Is Dr. Tam a member of other WHO committees on COVID-19?

- At this time, Dr. Tam is not a member of or advisor to any other WHO committees.

- Dr. Tam served as an advisor at the first two meetings of the *International Health Regulations* (IHR) Emergency Committee on the outbreak of novel coronavirus 2019-nCoV. The members of IHR committees are drawn from the IHR Expert Roster established under Article 47, which includes experts in all relevant fields of expertise, and from the members of WHO Expert Advisory Panels. The members and advisors are selected according to the expertise required for a specific meeting. As the situation surrounding the COVID-19 pandemic has evolved significantly since January, the Director-General made adjustments to the Committee members and advisors, and Dr. Tam is no longer an advisor to the Committee.

- Her position is voluntary and is not remunerated by WHO.

Q6. The report recommends that member States review funding for the WHO Health Emergencies Programme. What contributions does Canada make to WHO? Will Canada increase its contributions?

- Canada makes both assessed and voluntary contributions to WHO every year.

- The required amount of assessed contributions is approved by member States at the World Health Assembly and has remained relatively stable over the past few years. Canada made an assessed contribution of $17.5 million in 2020, in full and on time.

- The bulk of Canada's voluntary contributions to WHO is paid by Global Affairs Canada (GAC). Over the past ten years, Canada has contributed an average of over $70 million per year in assessed and voluntary contributions to support WHO's work.

Q7. Has Canada provided financing to WHO for the response to COVID-19?

- Canada has supported and will continue to support WHO leadership in the fight against the current COVID-19 outbreak.

- Canada has contributed $15.5 million to WHO since February 11, plus $1.5 million to the Pan American Health Organization—the WHO regional office for the Americas —in order to help vulnerable countries prepare for and respond to COVID-19.

- On April 5, 2020, Canada announced that it would contribute $159.5 million to support international efforts to fight the COVID-19 pandemic. That amount includes other contributions to WHO.

Q8. The authors of the interim report make recommendations to WHO to improve its response in various areas. Is Canada confident that WHO has the capacity to lead the global response to COVID-19? Does Canada agree with the recommendations?

- Canada is satisfied that WHO is using an evidence-based approach in response to the pandemic and that it makes sure the technical advice it provides is based on the best available scientific knowledge and evidence.

- Canada is grateful for the leadership and coordination role assumed by WHO in the fight against COVID-19, in particular its oversight of the *International Health Regulations*, its leadership in global research efforts to find new vaccines and effective treatments, its work with all stakeholders to address shortages of essential medical supplies and personal protective equipment, and its support to the most vulnerable countries for their preparedness and response efforts.

- Canada places great importance on the important work of the Independent Oversight and Advisory Committee, which plays an invaluable role in independently reviewing the performance of the WHO Health Emergencies Programme. The Committee's recommendations serve as a solid, objective, evidence-based foundation for continuing post-crisis discussions on how to improve the global response to health emergencies.

- The Committee's recommendations match many of the measures put forward by member States in the COVID-19 resolution adopted at the World Health Assembly (WHA) this week, responding to the requests for an independent assessment of the response to COVID-19. The assessment will focus on both member States and the

WHO Secretariat, and will be initiated at an appropriate time to assess the performance of the response and identify lessons for the future. Canada has clearly stated for weeks that it supports a comprehensive post-crisis review of the global response and is pleased to have co-sponsored this WHA resolution.

INFORMING CANADIANS

Q9. **What are Canada's forecasts for COVID-19?**

For the most recent information, go to Canada.ca/coronavirus. You can also follow Dr. Teresa Tam, Chief Public Health Officer of Canada, on Twitter (@CPHO_Canada).

A new toll-free telephone number (1-833-784-4397) has been set up to answer Canadians' questions about the 2019 novel coronavirus. The hours of operation are from 7 a.m. to midnight.

Canadians who are travelling abroad are encouraged to check the health advisories for travellers at travel.gc.ca.

Q10. **Why is the Government of Canada running an ad campaign on COVID-19?**

The Government of Canada is rolling out a major national public education campaign on COVID‑19 that will provide Canadians with credible information on the behaviours that protect individuals and overall public health. The campaign will include advertising, marketing on social media, information resource development, partnership building, and awareness-raising activities targeting at-risk populations. This work will complement the Public Health Agency of Canada's current communications and awareness activities, including the COVID‑19 website, which features a virtual assistant to help Canadians find the information they need, a toll-free information line, a self-assessment tool, digital ads, social media posts and regular media updates.

Educating the public is a key element of our response to COVID‑19, as it helps:

- improve awareness and understanding of symptoms and treatments
- provide information on preventive measures such as self-isolation
- dispel misinformation and address public concerns

Ads should be broadcast on a number of ethnic radio stations and appear in a selection of ethnic newspapers by the end of 2020. However, since some print outlets are closed and we have to look for alternatives, we are not able to provide a list of media outlets or a specific time line.

Virtual Health Tools

On Sunday, May 3, 2020, the Prime Minister announced an investment of $240.5 million to develop and launch virtual health tools to support Canadians.

Q11. How exactly will the money be spent?

The investment will promote the development and reach of the following:

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

- The **Wellness Together Canada** portal, which helps Canadians access standalone tools and find credible information on mental health and substance use issues. It also connects Canadians to peer support workers, social workers, psychologists and other professionals for confidential chat sessions or phone calls, in addition to providing online counselling sessions.

- **Our artificial intelligence capabilities**, which will help us gain new perspectives and knowledge about the emergence, spread and health risks of COVID-19. Health Canada and the Public Health Agency of Canada have contracted BlueDot to improve and expand our current expertise in this field.

The Government of Canada is also working with the provinces and territories and with Canada Health Infoway to promote the use of virtual health services. As a result, Canadians will be able to continue meeting their regular health needs safely and securely by telephone, text message or videoconference, in addition to in-person appointments.

Q12. Can you provide a breakdown of how the money will be spent?

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

Most of the investment ($200 million) will be used to give Canadians easier access to the health services they need through virtual tools and approaches. 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 health systems in Canada.

The remainder of the investment ($40.5 million) will support a growing set of digital solutions and tools, including the Wellness Together Canada portal and the Canada COVID-19 app.

Q13. Does the funding announcement also include a contact tracing application? If so, how will the Government of Canada make sure that Canadians' data is protected?

The thorough contact tracing carried out 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 outbreaks, the Government of Canada's national volunteer recruitment campaign included a call to assist provincial and territorial authorities with case tracking and contact tracing for COVID-19.

Our government is aware that many contact tracing tools are being developed to help automate

the process, including mobile apps, and we are closely monitoring those developments. All such apps must protect the privacy and security of users. Privacy concerns will remain at the core of all Government of Canada initiatives.

Q14. Vulnerable populations are being affected by COVID-19 in Canada. Will this funding address their specific needs?

Health Canada is exploring ways to help various populations implement virtual health services. Community partners could potentially use virtual technologies, notably, secure messaging and videoconferencing, in a way that meets the particular needs of vulnerable populations. However, there is a need for major discussions with provincial and territorial partners about the implementation of such tools.

The Canada COVID-19 app

Q15. How can I access the Canada COVID-19 app?

The free mobile app is available on smart phones and modern Apple iOS and Android tablets, and can also be accessed as a web app from any modern laptop or desktop computer.

Q16. How does the app work?

The app is user-friendly 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, like physical (or social) distancing, hand washing, food safety, pets and other common issues, as well as links to trustworthy and up-to-date sources of information on public health.

The Canada COVID-19 app will help Canadians access the information they need, either by email or via an application or online service. We are also introducing other tools to further improve Canadians' ability to easily obtain reliable, up-to-date information on COVID-19.

Q17. How does this app compare to other resources already in place in some provinces?

This app builds 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 the province of British Columbia and developed by Thrive Health.

Users in provinces and territories who access the mobile app through the national platform will be directed to a module specific to their provinces or territories.

Q18. What results has the self-assessment tool achieved?

Canadians who use this tool are able to obtain the information and advice they need, which results in fewer calls to 811 and telehealth lines, as well as fewer in-person visits to health care providers like family doctors, walk-in clinics and urgent care centres.

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

EXPERT ADVICE AND RESEARCH

Q19. **Do we have an emergency scientific advisory group, similar to the United Kingdom's Scientific Advisory Group for Emergencies, which advises the ministers and Cabinet on the coronavirus? If not, do we get all our scientific advice from the Public Health Agency of Canada?**

In January, the federal, provincial and territorial governments agreed to create a Special Advisory Committee (SAC) on COVID-19 to advise deputy ministers of health across Canada on coordination, public health policies and technical content related to the COVID-19 pandemic. The SAC comprises representatives of various federal departments and agencies, and also includes members from the Pan-Canadian Public Health Network Council and the Council of Chief Medical Officers of Health of Canada.

The committee is supported by three expert groups involving senior federal-provincial-territorial officers and public health experts: a Technical Advisory Committee, a Logistics Advisory Committee and the Public Health Communications Group.

The Minister of Health has held almost daily telephone meetings with her provincial and territorial counterparts since January, as has the Deputy Minister of Health Canada, in order to get a handle on the situation in each jurisdiction and accelerate cooperation to meet common needs.

In March, as part of the over $1 billion COVID-19 Response Fund, the Prime Minister announced an investment of $275 million to support research on the coronavirus and the development of medical countermeasures to combat COVID-19, including treatments and potential vaccines.

The Chief Science Advisor of Canada (CSA) has assembled a multidisciplinary science expert panel to advise her on the latest scientific developments relevant to COVID-19. The group has sub-committees on health systems and modelling approaches. This information will assist the CSA in providing relevant, cross-disciplinary, independent advice to the Prime Minister and government. The expert group comprises distinguished Canadian scientists and meets on a regular basis to discuss available scientific data and evidence from disease modelling, risk perception, diagnostic and clinical research. The first meeting was held in March.

As the Prime Minister announced 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 here in Canada. Those measures include:

The creation of the COVID-19 Immunity Task Force, which 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 set priorities and coordinate a series of country-wide blood test sampling that will tell us how widely the virus has spread in Canada and provide reliable estimates of potential immunity and vulnerabilities in Canadian populations.

Q20. What is CanCOVID?

Canada's Chief Science Advisor worked with departmental science advisers, 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 research collaborations on COVID-19.

Q21. Could you explain the importance of Dr. Francesco Marchetti's response to the revision of OECD test guideline 488?

The revisions to OECD guideline 488 are based on the update to the recommended protocols for germ cell mutagenicity tests. The original guideline included some protocols that were found to be ineffective in detecting germ cell mutagenicity and that, if used to test agents for regulatory submission, could have led to erroneous findings. Germ cell mutations are associated with a variety of hereditary diseases, and the appropriate classification of chemicals as germ cell mutagens is important under the Globally Harmonized System of Classification and Labelling of Chemicals. The revised guideline provides recommendations that should generate more robust data on the potential for chemicals to induce mutations in germ cells. It also provides a common sampling time period for the simultaneous assessment of mutagenicity in somatic tissues and germ cells, which significantly reduces the number of animals required for testing.

Health Canada led the OECD expert group tasked with revising the germ cell section of TG 488. Those revisions were ratified after lengthy discussions among several member countries. The consensus was reached largely on the basis of two publications by the germ cell working group of the Genetic Toxicology Technical Committee of the Health and Environmental Sciences Institute, chaired by Health Canada.

FUNDING

Q22. How much has the Public Health Agency of Canada received for COVID-19? How much of that amount has been used to fund COVID-19 tests throughout the country? What proportion was used for public health surveillance? How much was 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 earmarked:

a) $25.7 million for COVID-19 testing (this funding supports 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 budget, since it is done locally by the provinces and territories.

Q23. What will the $240.5 million dedicated to mental health tools during the COVID-19 pandemic consist of?

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

This funding will help further the development and extent of:

- The Canada-COVID-19 mobile app, which provides Canadians with access to a symptom-tracking tool, credible sources of information 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 addiction. This portal also connects Canadians with peer helpers, social workers, psychologists and other professionals who offer confidential chat sessions, phone calls and online counselling.

- Enhanced analytical capacity to better understand the emergence, spread and public health risks of COVID-19: Health Canada and the Public Health Agency of Canada have contracts with BlueDot Inc. to improve and develop existing expertise in this area.

The Government of Canada is also working with provinces, territories and organizations such as Canada Health Infoway to support initiatives to develop virtual health services that can help meet Canadians' usual health needs safely and securely by telephone, text messaging or videoconferencing, as well as 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 in terms of technology and virtual care infrastructure.

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

Health Canada is exploring ways to serve diverse populations as it rolls out virtual health services. Community partners could potentially use virtual technologies, notably, secure messaging and videoconferencing, to address the particular needs of vulnerable populations. However, the implementation of these tools requires extensive discussion with provincial and territorial partners.

Q24. How much money has the government allocated to mental health services?

The Government of Canada is investing $5 billion over 10 years to improve Canadians' access to mental health services. This targeted investment is provided directly to the provinces and territories to help them extend access to community-based mental health and addiction services for children and young people, integrated services for people with complex needs, and the dissemination of proven models of community-based mental health care and culturally appropriate interventions linked to primary health services. This is in addition to federal health funding provided through the Canada Health Transfer, valued at $41.9 billion in 2020‑2021, which supports provincial and territorial health systems.

On May 3, 2020, the Prime Minister announced an investment of $240.5 million to increase access to virtual services and digital tools to support the health and well-being of Canadians. The Government of Canada recognizes that Canadians need access to credible tools and resources that provide reliable health information, screening tools and support. The funding is allocated as follows:

- $25 million has been allocated to Wellness Together Canada. A $16 million contract has been signed for Wellness Together Canada, a portal on mental health and addiction that provides Canadians with free professional resources, tools and support services to help them improve their well-being and resilience, as well as deal with their mental health and addiction issues.
- $15 million has been allocated to support the growing family of digital products, including the Canada COVID-19 app, which helps people track their symptoms, receive the latest updates and access reliable resources.
- $200 million has been allocated to expanding virtual care services across Canada in partnership with the provinces, territories and other federal partners such as Canada Health Infoway. Discussions are under way with the provinces and territories on how best to allocate these resources to meet the needs of Canadians.

Q25. **Is the $16 million Wellness Together Canada contract the total amount committed to date, with an additional leeway of $9 million?**

Health Canada has signed a $16 million contract with the Wellness Together Canada consortium; $2 million for development of the portal and continuous quality improvement, and $14 million for direct services (e.g. text, voice, chat). The remaining $9 million is in reserve to meet emerging needs and make any necessary improvements to the portal (e.g. services for health care providers, frontline responders and essential service workers).

Q26. **Can you confirm what the Public Health Agency will do with the $50 million allocated to public health information work on COVID-19?**

The Government of Canada has been working hard since the start of the COVID-19 pandemic to provide Canadians with the information they need to protect themselves, their families, their communities and their businesses.

On March 11, 2020, the Government of Canada announced $50 million to support communications and public awareness efforts to ensure that Canadians have timely access to the reliable, evidence-based information they need.

The national public awareness campaign includes advertising, social marketing, documentary resources, partnership building and outreach activities for at-risk populations. This work will complement the Public Health Agency of Canada's existing communications and awareness activities, including:

- the Government of Canada's canada.ca/coronavirus website, where the latest information on COVID-19 is posted
- the free information line (1-833-784-4397)
- ongoing social media campaigns to share information and updates with Canadians, as well as general awareness and prevention messages
- digital advertising that provides infection prevention and travel advice and encourages readers to visit canada.ca/coronavirus

- regular updates in the media
- display and distribution of documents to travellers at airports and borders
- public health messages broadcast in a coordinated manner with provincial and territorial partners and intermediaries

$30 million of the overall public awareness campaign budget is spent on advertising. To date, this includes three 30-minute national television spots, two 30-second national radio spots, print ads in daily, weekly, Indigenous- and foreign-language newspapers, and digital ads posted on a wide range of platforms. Almost all the ads are placed in Canadian media.

These ad activities involve the communication of information to Canadians in several languages. In addition to English and French, the first radio announcement was broadcast in Farsi, Italian and Mandarin. Those languages were chosen because there was an urgent need to disseminate information to communities with links to countries that had posted travel health advisories at the time of production.

In April, print ads appeared in newspapers in Tagalog, Punjabi, Spanish, Arabic, Tamil, Urdu, Korean, Hindi, Inuktitut and Cree. The choice of languages was based on the main foreign languages spoken in Canada in addition to English and French, according to Statistics Canada. We have also taken account of the availability and reach of the media.

It is not possible to provide a breakdown of advertising expenditures at this time because the Government of Canada's Agency of Record works with publishers to get ads distributed, then bills the government. We will continue to work with the Agency of Record to determine what ad space is available on various channels and platforms for the next steps in public awareness. Below are links to the television and radio spots in English:
First series of televised ads (broadcast between March 24 and April 12)
https://youtu.be/sscyXpYQ6Dk
https://youtu.be/k7ns6t9NzXs

First series of radio spots (broadcast between March 18 and April 12)
https://www.canada.ca/en/public-health/services/diseases/2019-novel-coronavirus-infection/awareness-resources/covid-19-radio-public-service-announcement.html

Second series of televised spots (broadcast between April 18 and May 3)
https://www.canada.ca/en/public-health/services/video/covid-19-stay-home.html

Q27. **Are Spotify ads aimed at raising awareness 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 in a position to provide information on expenses.

Q28. **How much will be dedicated to digital ads on Google and Facebook?**

Digital advertising on platforms such as Google and Facebook is an important tool for reaching Canadians. The Agency of Record is still in the planning stage and the campaign is still under

way. PHAC is unable to provide the total amount spent at this time, as we are still waiting for final invoices for digital advertising purchases.

Q29. When will the "newspaper" component of the Public Health Agency of Canada's advertising campaign be rolled out? Why has the government taken so long to place ads and purchase advertising in newspapers?

The situation in Canada is evolving rapidly and we are learning more about COVID-19 every day. Canadians must have easy access to resources that will help them get the information they need about COVID-19.

PHAC has launched an extensive public awareness campaign to ensure that Canadians have access to the most up-to-date information on COVID-19. This plan includes the use of both digital and printed platforms. The first phase of the campaign included a national printed material purchase, and our ad appeared in approximately 950 daily, weekly, Indigenous and ethnic newspapers across Canada in late March and throughout April 2020. Due to the rapid evolution of the COVID-19 response, the Agency of Record's media planning has taken longer than expected. The Agency of Record continues to plan the next steps as the situation in Canada evolves.

Q30. Which of the organizations funded by the $30 million COVID advertising campaign were not Canadian outlets? How much money has been 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; exceptions have been made, however, for some 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 purchase, as the campaign is ongoing and the final invoices have not yet come in.

Q31. What is the cost of the contract between the government (PSPC) and Cossette? How much is Cossette receiving for this work?

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 on request and paid for based on the work performed (task authorizations), in accordance with the contract payment terms, 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

Q32. How can I access the Wellness Together Canada portal?

The portal can be found on the canada.ca/coronavirus website, and in the Canada COVID-19 app, with other Health Canada virtual COVID-19 tools.

Q33. Does the Government intend to make other digital COVID-19 tools and resources available to Canadians?

The portal is part of a set 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 the Canada COVID-19 app have already been launched.

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

Q34. New funding has been announced for virtual services and digital tools to support the health and well-being of Canadians. Will some of this money go to private companies that already have virtual health care platforms, or is the government planning to spend it all on the existing Wellness Together Canada platform?

The Government of Canada recognizes that Canadians need access to virtual services and digital tools and resources to support their health and well-being, including easily accessible information, mental health supports, alerts and screening tools. That is why, last Sunday, the Prime Minister announced an investment of $240.5 million to help Canada's health systems expedite access to virtual services and digital tools and resources to support the health and well-being of Canadians.

Of the $240.5 million announced on Sunday, $40.5 million is dedicated to providing Canadians with easy access to the information and resources they need through a growing set of digital solutions and tools, including Wellness Together Canada, an online portal that provides Canadians with free resources, tools and professional support services to help them improve their well-being and resilience, as well as their mental health and drug and alcohol use. This investment will also support a growing family of digital products that includes the Canada COVID-19 app, which helps people track their symptoms, receive the latest updates and access reliable resources.

However, most of the funding, $200 million, will be used to improve access to necessary health services by helping the provinces and territories rapidly deploy virtual tools and approaches.

Health Canada is already working with the provinces and territories, as well as health system experts and organizations such as the Canada Health Infoway, to determine where additional

support is most needed in terms of virtual care technology and infrastructure. These discussions will lead to a better understanding of how best to support health systems as virtual care is rolled out, and will be essential in determining the next steps in the coming weeks and months.

Q35. How does the portal work?

The portal will provide Canadians with much-needed mental health and substance use support in the context of the current COVID-19 pandemic. It will offer them different levels of support based on their needs, ranging from information and self-assessment tools to the opportunity to speak to peer support workers and other professionals. The conversations may include a limited number of telephone sessions.

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

Q36. Is the information I share on this portal protected?

Crisis support links and a number of resources can be accessed directly through the portal without registering. You can register for additional support and resources. The resources and services included in the portal are provided by licensed professionals. All information you provide will remain strictly confidential.

Q37. How many Canadians are expected to be able to use the Wellness Together Canada app? 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. Canadians can also access the services of more than 6,000 Homewood Health and Kids Help Phone employees through the portal.
Following the SARS outbreak it was found that more than 40% of 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, approximately 11 million Canadians are expected to experience high levels of stress at home and at work, and nearly 2 million will show signs of traumatic stress. That is why access to the portal will be closely monitored so that the services can be adapted to Canadians' needs.

Q38. How many psychologists, social workers, peer helpers and "other professionals" have been secured to date, and how many are the government hoping to secure? How many of these employees are available on a full-time basis?

The tools on Wellness Together Canada will offer Canadians different levels of support depending on their needs, ranging from information and self-assessment tools to the opportunity to chat with peer helpers and other mental health professionals. Homewood Health and Kids

Help Phone are making more than 6,000 employees available to provide psychosocial support services to Canadians via text message and telephone.
Although the exact composition of the care providers is not available at this time, they represent a range of health professions, including social work and psychology, and have a variety of backgrounds in counselling psychology, clinical social work, rehabilitation, crisis management, child psychology and neuropsychology, sexuality, adolescent problems, marital and family therapy and addiction. Almost all of these service providers are licensed mental health and addiction professionals.

Q39. I understand that Homewood / Kids Help Phone staff handle the calls, but do the agents do an initial screening to direct people to the right services and, if so, how many new people have been hired, or is it a matter of redeployment?

Federal public service employees do not provide health services through the portal. This service connects people in need with specialized consultants and trained counsellors. The Wellness Together Canada portal provides access to immediate SMS support and a wide range of psycho-educational resources for both young people and adults to deal with common mental health and addiction issues. People also have the option of creating an account and completing a self-assessment that will help them decide what other resources would be appropriate for them. If they are unsure which resources to use, they can also contact a counsellor by telephone or text message to help them navigate the portal resources and find what is right for them. This includes access to self-managed therapy, peer support and supervised therapy, as well as individual counselling via telephone or text message.

Q40. Will the federal government pay the psychologists listed on the mental well-being portal consulted by Canadians?

The Wellness Together Canada portal is part of a set of virtual products that are supported or funded by Health Canada to provide Canadians with information and support during the COVID-19 pandemic. Funding for the portal is paid 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. Health Canada pays for those services out of the same funds that pay for the portal.

Q41. Will the Government of Canada invest more in mental health and suicide prevention?

Due to school closures and reduced access to community resources, Kids Help Phone is dealing with increased demand for its confidential, 24/7 crisis support services available online, by telephone and via text messaging. In response, the Government of Canada has provided Kids Help Phone with $7.5 million to help it meet the increased demand and provide young people with the mental health support they need during this difficult time.
This additional funding will make it possible to offer electronic mental health services in English and French to children and young people across Canada who are dealing with the social and financial effects of the COVID-19 pandemic. This will help vulnerable Canadian children and young people find the help they need when they need it most.

Q42. Does this portal take account of the specific needs of First Nations?

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

Q43. Can people with no Internet access use the portal?

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

Q44. Do you have preliminary statistics on the use of the Wellness Together Canada portal? Can you also give us a breakdown by province?

150,000 Canadians have accessed the portal to date (as of May 8). Below is the breakdown by province:

Eastern Canada	7.04%
Québec	12.75%
Ontario	51.87%
Western Canada	28.00%
Nunavut/Yukon/NWT	0.33%

Q45. Now that the Wellness Together Canada portal is up and running, is it being used more than expected? Do projections still indicate that 11 million Canadians are feeling stressed?

We know that Canadians are feeling stressed and concerned because of the pandemic, and we anticipate that an increasing number of Canadians will begin using the service in the coming weeks. Since the portal's launch three weeks ago, its use has grown every day. For example, from April 22 to May 6, the number of Canadians who accessed the portal increased by 87%.

Q46. What is the status of the Pan-Canadian Suicide Prevention Service?

In its 2019 budget, the government announced that it would invest $25 million over five years, and $5 million annually thereafter, to implement and maintain a fully operational pan-Canadian suicide prevention service. It will provide people across Canada with 24/7 access to knowledgeable, bilingual crisis support staff, using the technology of their choice (telephone, text message or chat).

In July 2019, the Public Health Agency of Canada issued a call for funding applications to

organizations that could set up a pan-Canadian suicide prevention service. That process ended on October 31, 2019, and a decision is expected shortly.

Q47. 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, housing, etc., for people who use drugs. It is committed to ensuring that the provinces and territories have the tools needed to address the combined effects that the opioid overdose crisis and the COVID-19 pandemic are having 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 verbally prescribe controlled substances, pharmacists to more easily extend or renew prescriptions and transfer prescriptions to other pharmacies, and drugs to be delivered to or picked up by another person.

  This will ensure that people with substance use disorders who are receiving opioid agonist therapy will continue to have access to their medications while maintaining the recommended physical distancing.

- On April 6, 2020, Health Canada granted class exemptions to allow the provinces and territories to set up new public health sites to respond to urgent public health needs (also known as temporary overdose prevention sites) within existing supervised consumption sites, shelters and other locations to help people avoid overdoses while staying physically distant and self-isolating.

  The Department will also allow community health service providers to ensure that existing supervised consumption sites can quickly adapt their operations to meet public health recommendations with regard to COVID-19. That can be done without the need to notify Health Canada or request additional authorization. Changes to operations could include, but are not limited to, new measures regarding how people move around the premises and changes in hours of operation or number of cubicles.

Q48. What are the current statistics on the number of Canada COVID-19 app downloads and the number of clicks on the mental health portal? How many Canadians were 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, some 70,000 Canadians had visited the mental health portal.

Q49. What services could be provided to help bereaved Canadians, starting when?

Now more than ever, Canadians must have the tools and resources they need for their health and well-being. The Government's recent investment of $240.5 million in mental health resources will help Canadians access reliable health information and provide easier access to health services through virtual approaches and tools.

This funding will support the continuing development and reach of the Wellness Together Canada portal, giving Canadians easy access to interactive tools and credible information on mental health and substance use. It connects Canadians with peer support workers, social workers, psychologists and other professionals for confidential chat sessions, telephone calls and online counselling that can help Canadians deal with the grief they may be experiencing following the loss of a loved one.

The consortium responsible for the Wellness Together Canada portal offers support to individuals for all kinds of psychological and emotional problems. Its responses are goal- and solution-oriented. Service providers include a wide range of health professionals, such as social workers and psychologists, from a variety of backgrounds. The consortium also provides access to many articles and resources, including educational bereavement resources provided by its partners.

Health Canada is working with the consortium to increase access to bereavement support services through the portal. The consortium hopes to be able to create new partnerships with other responders who provide specialized bereavement support and resources.

Health Canada is currently funding a project ($2 million over two years) with Canadian Virtual Hospice (CVH) to expand its current web-based offering and develop new resources and services to meet the needs of under-served communities, including Canada's Francophone community, the LGBTQ2 community and families caring for a dying child.

During this challenging period, Health Canada will continue to work with the provinces, territories and other responders to help meet Canadians' health needs.

Q50. **What other resources are available to Canadians?**

The COVID-19 pandemic is a new and unexpected phenomenon that can be very disruptive. People feel they are no longer in control of their own destinies. It is normal for individuals and communities to feel sadness, stress, confusion, fear and worry.

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

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

There are many resources for people in crisis, including:

Kids Help Phone - 1-800-668-6868 or text the word CONNECT to 686868 (a 24/7 resource for young Canadians aged 5-29 who are seeking confidential and anonymous care from professional psychological counsellors).

Hope for Wellness Helpline - Call the toll-free help line at 1-855-242-3310 or use the online chat service (a resource available to all Indigenous people in Canada who need immediate help in a crisis situation).

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

GUIDELINES

Long-term care facilities

Q51. **Why are you recommending that personal support workers and essential visitors and volunteers wear personal protective equipment when there is a shortage of such equipment?**

Personal support workers are an integral part of the health care system. They provide direct care to patients. Every person entering 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 by buying in bulk with the provinces and territories, boosting our national production capacity and researching alternatives and ways of extending product life.

Q52. **Why do you tell 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 due to underlying health problems and age.

Proximity means that seniors in long-term care facilities and assisted living homes are at even greater risk of virus transmission and infection. When workers move from one facility to another, they increase the risk of spreading the infection, which translates to a higher risk of seniors contracting the virus. We need to protect our seniors in these difficult times.

The guidelines recommend identifying employees who work in more than one location and ensuring that efforts are made to prevent it where possible.

Q53. **How will residents' needs be met if there are further restrictions on the availability of personal support workers?**

The administration of long-term care is the responsibility of provincial and territorial governments. They have taken many steps to continue providing quality care to residents throughout this crisis, such as flexible staffing policies and approaches, as well as collaboration with outside providers for short-term care support.

The Government of Canada is working with the 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 with case tracking duties and support the cutting-edge health care system. There is a list of volunteers for provincial and territorial governments to draw upon as needed.

For more information please visit: https://emploisfp-psjobs.cfp-psc.gc.ca/psrs-srfp/applicant/page1800?toggleLanguage=en&poster=1437722

Q54. What measures has the government taken to help the working poor?

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 will help Canadian workers, both employees and self-employed individuals, who have had to stop working and have lost their income as a result of COVID-19. 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 set up an online portal where workers can get the information they need and apply for this new benefit.

Q55. What measures has the Government of Canada taken to protect seniors' financial security?

The Government of Canada is taking steps to ensure that the Canada Pension Plan and Old Age Security benefits that our seniors rely on continue to be paid promptly, and that all 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. It is based on age and place of residence, and is in no way related to employment history or investment income. Seniors continue to receive this benefit each month.

The income-based Guaranteed Income Supplement is paid to all low-income seniors. Old Age Security recipients who experience a drop in income due to the pandemic may be eligible for this supplement.

Several new measures are being implemented to provide additional protection for the financial security of our seniors. The government has been paying moderate- and low-income Canadians, including seniors, a special one-time Goods and Services Tax (GST) credit as of April 9, 2020. This amount will be about $400 for low-income single adults and about $600 for low-income couples.

The minimum amount to be withdrawn from Registered Retirement Income Funds (RRIFs) has 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 balances owing or instalments before interest or penalties are charged.

Q56. What measures has the Government of Canada taken to protect seniors' pension plans?

New measures were announced in the 2019 budget to increase the viability of workplace pension plans if companies become insolvent.

Measures are now in effect to make insolvency proceedings more equitable, transparent and accessible to workers and pension recipients.

Stricter expectations and better monitoring have also been implemented with regard to corporate behaviour:

- companies incorporated under federal statutes can now explicitly take retirees' and workers' interests into account when acting in the company's interest
- publicly traded, federally incorporated companies will be required to disclose their policies pertaining to workers and retirees, as well as executive compensation, or explain why they have no such policies

Lastly, measures protect Canadians' hard-earned benefits by specifying that, even if a federal plan is wound up, it must still pay out pension benefits just as it did when it was active.

Q57. What is the government doing 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 consequences that elder abuse has on the victims and their families.

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

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

Q58. What measures has the government taken to protect seniors from COVID-19-related fraud and scams?

The Government of Canada is taking action 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 through other departmental communication channels.

In the longer term, the government will draw up a national definition of "elder abuse," invest funds to improve data collection and law enforcement, and incorporate new *Criminal Code* penalties pertaining to elder abuse.

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 aid in the fight against elder abuse.

Q59. **Why did PHAC take so long to release its long-term care guidelines?**

One of our priorities is to protect residents and staff in long-term care facilities; for this reason, PHAC is working with provincial and territorial governments on all aspects of the response to the COVID-19 pandemic affecting this segment of the population. PHAC consulted with the administrations in charge as well as other experts across the country to put together the information for protecting residents and staff members in the document entitled Infection prevention and control for COVID-19: Interim guidance for long term care homes. Scientific knowledge about how COVID-19 is transmitted is evolving rapidly; the document is a summary of the latest findings on the transmission of COVID-19.

It illustrates the meticulous, evidence-based work required to provide the highest possible level of protection for residents and staff in long-term care facilities across Canada.

Q60. **How many deaths have occurred in long-term care facilities?**

As of May 8, it is estimated that 81% of the 4,569 deaths attributable to COVID-19 in Canada can be linked to long-term care facilities. The figures for deaths in long-term care facilities are taken from reports from the public health authorities in the various provinces and territories.

It should be noted that those figures reflect public reporting by the provinces and territories.

Q61. **Does the Public Health Agency of Canada compile data pertaining to COVID-19 outbreaks in long-term care facilities?**

PHAC is monitoring the impact of COVID-19 on our most vulnerable populations, including residents of long-term care homes. Data are collected through daily communications among federal, provincial and territorial epidemiologists who are working together to collect and share information. Case data are collected from the provinces and territories through a reporting form that includes a field to indicate residence in a long-term care facility. We supplement this information with publicly available data sources. Local public health authorities report the data pertaining to outbreaks in long-term care facilities to their provincial or territorial public health counterparts who compile the information, report it publicly and implement control measures.

We are currently putting together a standardized data set for long-term care facilities. PHAC also publishes information pertaining to possible virus exposure in places like long-term care facilities on its website.

Q62. Which provinces/territories have adopted the long-term care facility guidelines?

The Infection prevention and control for COVID-19: Interim guidance for long term care homes document advises long-term care facility operators to identify staff members who work in more than one location (e.g. in other long-term care facilities or care facilities), and make efforts to avoid that type of situation wherever practicable, thereby limiting cross-infection among facilities, and provide information for investigations if/when outbreaks occur. The phrase "wherever practicable" was included to ensure that no residents are unintentionally harmed as a result of inadequate staffing caused by a shortage of human resources in the facilities. To further mitigate the risk of harm, these guidelines also recommend that all staff and visitors wear masks upon entering a long-term care facility in order to prevent asymptomatic or pre-symptomatic transmission of COVID-19. Staff must be carefully monitored and tested for symptoms at least twice a day. If staff members develop fever or symptoms, they must be relieved of duty immediately and tested for COVID-19. Among the additional protective measures in these guidelines, it is recommended that staff who are ill or exposed to COVID-19 cases should not enter a long-term care facility for at least 14 days from last exposure, unless local public health authority policies differ.

These guidelines have been drawn up for Canadian long-term care facilities and their employees. Long-term residential care is governed by provincial and territorial legislation, and these guidelines should be read in conjunction with relevant provincial, territorial and local statutes, regulations and policies. Please contact the provinces and territories for information about the adoption of these guidelines.

More advice for people with disabilities in Canada

Q63. What factors could make people with disabilities more vulnerable to COVID-19?

There are factors that may increase the risk of people with disabilities contracting COVID-19 or developing severe symptoms. Beside age and any chronic, underlying conditions, other risk factors include:

- the nature of the disability (for example, difficulty washing hands or a visual impairment that requires them to touch objects for support or information)
- proximity to others due to living in group homes
- interacting with multiple caregivers and support persons, which increases the risk of exposure
- difficulty accessing public communications about COVID-19, as well as intervention services and programs
- receiving treatment within the health care system for a different health problem
- loss of community services and support (employment, treatment, schools), which may cause some people with disabilities to regress

Q64. What specific steps 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 follow the measures listed below.

- The following measures are the best way to prevent the spread of COVID-19:
  - Stay home, away from others, when you are sick
  - Wash your hands often
  - Cough into a tissue or sleeve
  - Practise physical distancing
  - Clean and disinfect all surfaces and objects
  - Protect those most at risk of contracting the virus

Q65. What should caregivers do to meet the needs of people with disabilities?

Caregivers should consider adapting the way things are done for people with disabilities and their caregivers, to ensure ongoing access to their services.
People with disabilities must be entitled to be accompanied at all times by essential personal support workers, who may be paid employees, friends or family members.

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

For people with hearing or visual impairments and those with cognitive or intellectual disabilities, personal protective equipment such as a face shield is a good alternative to a mask, provided their personal support workers do not have COVID-19.

Q66. What should testing centres do to meet the needs of people with disabilities?

It is important that people with disabilities have access to services at designated COVID-19 testing centres. In particular, testing centres should ensure accessibility (ramps, accessible parking) and accommodations for people who suffer from anxiety or who have cognitive or intellectual disabilities. This could also include allowing people to skip lines, providing a private room, taking account of noise and light sensitivity, or providing alternatives to swabbing in cars.

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

Testing centres should ensure that test results are communicated directly to the people with disabilities or to their support networks. Communication should be available in several languages and in a functionally and culturally appropriate manner.

ISOLATION, QUARANTINE (VOLUNTARY ISOLATION) AND PHYSICAL DISTANCING

Q67. **Will a certain percentage of the population have to be tested before we can ease physical distancing restrictions?**

We continue to test on a massive scale; Canada has one of the highest testing rates in the world. We understand that testing is crucial for identifying new cases so that the chains of transmission can be identified and broken. We are currently running 20,000 tests per day, which is nearly double the number we were running earlier this month. That number will continue to grow.
We do not have a precise target for the number of tests that need to be conducted each day in order to ease physical distancing measures. The number will vary across jurisdictions. However, increasing the number of tests is helping with early detection of new cases and their contacts, allowing us to prevent or reduce the spread of COVID-19.

Canada has maintained a positivity rate of approximately 6-7%, which is within the effective detection range to accurately target the circulation of the disease. We want as accurate a picture as possible of what is happening in our communities. This shows that we have a very sensitive testing system. We will continue to expand our laboratory capacity to ensure that this continues.
Our main goal is to test individuals who are symptomatic and those in high-risk settings such as long-term care facilities and correctional facilities, as well as health care workers and outbreak control support staff in every setting.
Our priorities remain: access to reagents for testing, assessment of rapid, non-laboratory tests and access to authorized test kits so the provinces and territories are adequately equipped to accelerate testing as required.

Q68. **Can asymptomatic people go outside for a walk, provided they practise physical distancing?**

You can go out for a walk if:

- you have not been diagnosed with COVID-19
- you have no symptoms of COVID-19
- you have not travelled outside Canada in the past 14 days

If you go for a walk, do not gather with others, and practise physical (social) distancing by staying at least two metres from others at all times.

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

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

BORDER MEASURES

The ArriveCAN mobile app

Q69. **How do I get the ArriveCAN app?**

The mobile app is available on Google Play and from the Apple App Store.
It can be downloaded and installed free of charge on these devices:

- iPhone running iOS 12 or newer
- Android phone or tablet running OS 6 or newer

ArriveCAN is also available by signing in online via any laptop or desktop computer browser.

Q70. How does the app work?

Very simple to use, the ArriveCAN app is designed to record travellers' essential contact, travel and location information to ensure they are self-isolating. The app also allows them to submit answers (yes/no) to questions about symptoms and their self-isolation plans.

Q71. Does the government intend to make additional COVID-19 digital tools and resources available to Canadians?

The Government of Canada is working with the provinces and territories to bring additional digital platforms online in response to the COVID-19 pandemic; the idea is to assist in education, information, mental health and substance use support efforts, send alerts and make testing easier.

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

- information and recommendations on the risks they are exposed to
- symptom monitoring tools
- links to reliable and up-to-date sources of public health information
- COVID-19 information 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 online on any laptop or desktop computer.

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

Q72. 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, border services officers and quarantine officers by minimizing physical contact.

Q73. What is the difference between the app and the online form?

Travellers can access the online form using their laptops, tablets or Internet-enabled phone browsers. Using the online form requires entering an alphanumeric code which the traveller obtains at the port of entry to Canada.

The ArriveCAN app can be downloaded directly to a mobile phone. Travellers can enter information without a code before arriving at the port of entry. The code provided at the port of entry is required only to submit the information after it has been initially entered on the app.

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

Q74. Will the app be used to track travellers' movements?

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

Q75. We know the provinces and territories are planning and developing mobile app to track cases. Is ArriveCAN a case monitoring app?

ArriveCAN is not a case monitoring app and does not overlap with any current digital or mobile solutions. Pursuant to the emergency orders issued under the *Quarantine Act*, all travellers arriving in Canada must provide the Government of Canada with essential contact information and a quarantine plan. The app is designed to collect essential information to support compliance with the mandatory 14-day quarantine or isolation measures.
The ArriveCAN app is a digital solution that makes it easy to collect essential information and also simplifies the way traveller responses are presented. The app also supports physical distancing efforts by limiting contact between travellers and border services staff, as the information can be submitted easily and securely from mobile devices. The mobile app can be downloaded at any time, including before travellers leave, so they can enter their information, making it easier and faster to enter Canada.

Q76. What type of information is entered in the app?

The information submitted through ArriveCAN and on the paper and online forms is mandatory under the *Quarantine Act*. It includes:

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

Q77. What is the difference between the ArriveCAN app and the Canada COVID-19 app?

The Canada COVID-19 app provides all Canadians with general information and resources about COVID-19. The ArriveCAN app is used only for travellers entering Canada who are

required to provide essential information allowing PHAC to ensure compliance with the regulations and emergency orders issued under the *Quarantine Act.*

Q78. 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 such information.

Q79. 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. monitoring and verifying compliance with mandatory isolation orders, and applying penalties if necessary
2. providing information to help travellers comply with mandatory isolation orders
3. conducting follow-up activities related to public health

Compliance and enforcement officers will be able to use the information to contact travellers during mandatory isolation to check that they are complying with the conditions and remaining in their places of isolation. It is not a surveillance or monitoring tool.

Upon entering Canada, travellers are informed of such control and verification measures, the possible consequences of non-compliance, and the penalties that could apply.

The Public Health Agency of Canada is working with the Royal Canadian Mounted Police and provincial law enforcement to ensure that travellers entering the country comply with mandatory isolation orders. These measures will be determined using a risk-based approach and will be based on the information provided by travellers at the border.

Q80. 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 a* ***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****.*

Q81. Why is more information required on the ArriveCAN app than on the paper and online forms?

With the app, you can enter all the information required 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 provided 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.

Even though some information is not asked on the paper or online form, each traveller entering the country is asked questions by border services officers about symptoms and the preparation of a self-isolation plan. The border services officers enter the answers themselves.

At the end of the process, the coronavirus information required on the mobile app and the paper and online forms will be the same. PHAC is currently working with the operations team to ensure that all travellers entering Canada communicate this information in a standardized way on all three media.

Q82. What is the ArriveCAN online form for travellers entering Canada?

Travellers entering Canada by air or land are required to provide basic information using a traveller contact information form which is available via the ArriveCAN mobile app, an online form or a paper form. Access to the online form is restricted and requires an alphanumeric code available at the airport. Please refer to the traveller form in English and its French equivalent.

Upon arriving in Canada, travellers are informed of monitoring and compliance verification measures, the possible consequences of non-compliance, and the enforcement measures and penalties they may be subject to. Individuals who violate the mandatory isolation or quarantine requirements may be subject to a range of enforcement measures under the *Quarantine Act*, including verbal and written warnings and arrest or detention.

The Government of Alberta provides enhanced screening measures at border crossings and ports of entry.

Q83. Why does the Government of Canada not do temperature checks at all ports of entry?

The Government of Canada continues to take the measures that have proven to be effective, based on the latest scientific data and assessments of the situation. Currently, border services officers do not do temperature checks at ports of entry. Past use of thermal imaging at Canadian ports of entry did not prove effective in detecting communicable diseases in travellers. For example, during the outbreak of Severe Acute Respiratory Syndrome (SARS) in 2003, thermal imaging did not detect cases of the disease among the 2.3 million travellers subject to rigorous screening.

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

Q84. If the Government of Canada believes that temperature checks are not a reliable way of reducing the spread of COVID-19 by people entering Canada, why is it allowing the Government of Alberta to implement this measure?

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

Q85. 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 isolation is necessary. Alberta's recent decision to conduct a temperature check at airports is an additional health control measure based on an assessment of the situation in that province.

Q86. Is there an overlap of screening and information-gathering efforts between the federal and provincial governments?

Entry screening is an important part of the Government of Canada's multi-pronged response to the COVID-19 pandemic and is designed to collect information from travellers and share information with them upon their arrival in Canada. The Government of Canada works with provincial and territorial governments at all ports of entry to avoid any overlap and ensure consistency in public health measures. Information collected on travellers entering Canada is shared with all the provinces and territories to assist them in their public health efforts.

The provinces and territories have issued their own orders, which are in line with the federal orders to a certain extent, but may have additional features. PHAC continues to discuss border approaches with the provinces and territories, as well as with the Special Advisory Committee comprising the Chief Medical Officers of Health.

Q87. How do the federal and provincial roles and responsibilities for passenger screening at airports differ?

With respect to the roles and responsibilities of the federal government, all arriving passengers are informed of their obligation under the *Quarantine Act* to self-isolate or quarantine for 14 days from the day they enter Canada. Under the *Quarantine Act*, travellers entering Canada must first be screened by a federal officer of the Canada Border Services Agency (CBSA) who will ask them questions about their health status and symptoms and, if necessary, inform them of their obligation to report to a federal screening or quarantine officer. Quarantine officers are on site at airports and can be consulted remotely from land borders.

Through the ArriveCAN app and fact sheets provided at airports and other ports of entry, travellers are made aware of their responsibilities under the *Quarantine Act* and the need to consult with their provincial or territorial public health authorities about further measures or restrictions that may apply to their situation.

The provinces and territories do not have direct regulatory or legislative control over travellers at international borders, as these are under federal jurisdiction. However, at their discretion they may introduce additional control measures in accordance with their own requirements.

Q88. Are enhanced provincial screening measures in place only at airports? Are there different control measures at other ports of entry?

The Government of Canada continues to work with the provinces and territories to prevent the spread of COVID-19 from our ports of entry.

As the current health situation continues to evolve, additional health control measures such as those implemented by other jurisdictions (e.g. temperature checks at Alberta ports of entry) may need to change. The Government of Alberta has designated the province's two major airports (Calgary and Edmonton) as priority locations for checking the temperature of travellers entering the province.

It is important for travellers to consult their provincial or territorial public health authorities for the latest information on enhanced screening measures in their areas.

The Government of Canada has created a list of resources for travellers entering and leaving Canada:

- Canada.ca/Coronavirus
- Online awareness resources
- ArriveCAN app
- Traveller information documents issued at all ports of entry
- COVID-19 application

Order 10 - Emergency Order – Mandatory Isolation

Q89. Section 220 of Subdivision K under Various Measures of the *Budget Implementation Act, 2019,* repeals two subsections of the *Quarantine Act.* It appears that the parts of the Act that were repealed required that authorization be obtained from Parliament before regulations were made under the Act. Why was this amendment made? Was it recommended by public health authorities? If so, when and why?

The *Budget Implementation Act, 2019,* introduced legislative changes to the *Quarantine Act*, simplifying the regulatory process by repealing the requirement for the Minister of Health to lay proposed regulations before both chambers before creating or updating regulations. The amendments allow the Minister to follow the normal Governor in Council process, including pre-publication and public consultation in the *Canada Gazette*. They are also consistent with the objectives of the *Fall Economic Statement 2018*.

These amendments to the *Quarantine Act* provide for a more consistent and standardized approach compared to other federal regulations. The process is now better suited to stakeholders' needs for flexible, agile and up-to-date regulations because it makes it easier to repeal outdated or ineffective regulations that may not adequately protect public health and safety or that may impede innovation and economic growth. The amendments have also simplified the regulatory process to meet the needs of the travel and transportation sectors.

New or updated regulations under the *Quarantine Act* will continue to comply with the Cabinet Directive on Regulation so they can be created and updated in a transparent and inclusive manner, always have a clear rationale based on public health and safety, and promote a fair and competitive economy.

Q90. What is the new federal emergency order under the *Quarantine Act* and why has the Government of Canada issued it?

On April 15, 2020, the Government of Canada issued a federal emergency order under the *Quarantine Act* that requires everyone entering Canada by air, land or sea to self-isolate for 14 days if they have symptoms of COVID-19 or to quarantine for 14 days if they have no symptoms unless otherwise exempt, in order to limit the introduction and spread of COVID-19.

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

These measures will help protect the health of those individuals, of the people living in their homes and of Canadians in general, including vulnerable people like adults aged 65 and older and those with known health problems who are at the greatest risk of serious disease from COVID-19.

Q91. How is this new order different from the first order imposing mandatory self-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 non-medical masks or face coverings when travelling to their places of isolation (if symptomatic) or quarantine (if asymptomatic).

Previously, only symptomatic individuals were prohibited from self-isolating in a place where a vulnerable person would be exposed.

This order extends the directive to asymptomatic people as well. Asymptomatic individuals cannot quarantine in a place where they would be in contact with vulnerable people like adults aged 65 and older or people of any age with weakened immune systems or underlying health conditions that make them susceptible to complications from COVID-19.

If an asymptomatic person cannot quarantine in an appropriate location, that person 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 starts showing signs or symptoms of COVID-19 or is exposed to someone who is subject to the order and who shows signs and symptoms of the disease after entering Canada.

Q92. How will travellers be informed of the protocol applicable to this type of situation when they enter Canada?

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

Travellers will receive a document informing them that they are subject to the order; the document outlines the requirements of the order and provides general public health advice, as well as a link to the Canada.ca/Coronavirus website for further information.

People entering Canada are also asked to consult their provincial or territorial public health authorities for information on other measures and restrictions about mandatory isolation or quarantine.

Q93. What does the order issued under the *Quarantine Act* require of travellers returning to Canada? For returning travellers, what is the difference between what they can do at home if they have symptoms and what they can do if they have none?

All travellers returning to Canada must answer relevant questions at the border and provide any required information or records in their possession. They are also required to wear non-medical masks or face coverings upon arrival and while in transit to their places of isolation or quarantine.

In addition, the order requires that any person entering Canada who is not exempt be placed in one of two categories: asymptomatic (without symptoms) or symptomatic (with symptoms).

Asymptomatic persons

Persons entering Canada who do not show signs or symptoms of COVID-19 are subject to the order and must **quarantine** for 14 days upon entering the country, since they could develop symptoms and infect others.

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

Asymptomatic persons arriving in Canada must:

- go directly to their places of quarantine without delay and stay there for 14 days
- quarantine in a location where they will not come into contact with vulnerable people like adults aged 65 and older and people of all ages with weakened immune systems or underlying health problems
- be able to spend their quarantine in a suitable place where they have access to basic necessities
- monitor their health for signs and symptoms of COVID-19 for the full 14 days
- remain in the place of quarantine at all times, except to receive medical attention
- arrange for delivery of basic necessities such as food or medicine
- avoid public transit
- avoid receiving visitors
- avoid going to school, the workplace or any other public place

- practise physical distancing at all times (i.e. maintain a distance of at least two metres from others)

Asymptomatic persons are asked to use private transportation, such as a personal vehicle, to get to their places of quarantine. If they use public transit instead, they must wear suitable non-medical masks or face coverings while travelling. They must make no stops and must practise physical distancing at all times.

Asymptomatic persons may be required to stay in a quarantine facility selected by the Chief Public Health Officer of Canada if they plan to quarantine at a location:

- 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 the stay)

It is important to note that travellers returning to Canada may be asymptomatic upon arrival, but may become ill later. Unfortunately, there have been cases where an asymptomatic person develops symptoms and deteriorates quite rapidly.

People who develop symptoms within 14 days must:

- self-isolate
- immediately call a health professional or the public health authority in their province or territory, then:
  - describe their symptoms and outline their travel history
  - follow the prescribed procedure

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

Anyone who develops signs or symptoms of the disease must follow the instructions for symptomatic persons.

Symptomatic persons

Persons entering Canada who show signs and symptoms of COVID-19, or who have reasonable grounds to believe that they have such signs or symptoms, are subject to the order and must remain in **isolation** for 14 days upon entry into the country because they risk contaminating others.

“Isolation" means the separation of persons who are infected with COVID-19, or who show signs and symptoms of the disease, from others so as to prevent the spread of the virus or contamination.

Symptomatic persons arriving in Canada must:

- use private transportation (i.e. a personal vehicle) to get to their places of isolation
- wear non-medical masks or face coverings while travelling to their places of isolation
- go directly to their places of isolation without delay and stay there for 14 days

- self-isolate in a location where they will not come into contact with vulnerable people like adults aged 65 and older and people of all ages with weakened immune systems or underlying health problems
- be able to spend this period in a suitable place where they will have access to basic necessities
- submit to the required medical examinations
- monitor the signs and symptoms of the disease and advise the public health authority if they require further medical attention
- remain in their places of isolation
- remain in the places of isolation at all times, except to receive medical attention
- arrange for delivery of basic necessities such as food or medicine
- avoid public transit
- avoid receiving visitors
- avoid going to school, the workplace, or any other public place
- practise physical distancing at all times (i.e. maintain a distance of at least two metres from others)

Symptomatic persons entering Canada may be required to stay in a quarantine facility selected by the Chief Public Health Officer of Canada if:

- they have to use a method of public transit to get to their places of isolation
- they are planning to self-isolate for 14 days in a location:
  - 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 the stay)

Q94. What is meant by "vulnerable person"?

People aged 65 and older, and those of all ages with weakened immune systems or underlying health problems that make them susceptible to developing complications linked to COVID-19. All these groups are exposed to an increased risk of becoming seriously ill.

Q95. What is the difference between isolation and quarantine?

Isolation means the separation of people infected with COVID-19 or showing signs and symptoms of COVID-19 so as to prevent the spread of infection or contamination.

Quarantine is the isolation of people entering Canada to prevent the possible spread of infection or contamination.

Q96. 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 set out in the order for isolation or quarantine in an appropriate place.

Conditions to be 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 could be newly exposed

because of the person's stay), where the person will have access to basic necessities and will not be in contact with vulnerable people. Travellers who are unable to meet one or more of these conditions will have to self-isolate for 14 days in a quarantine facility selected by the Chief Public Health Officer of Canada.

People entering Canada should also consult their provincial or territorial public health authorities for information on other measures and restrictions about mandatory isolation or quarantine.

Q97. How can I monitor the onset of COVID-19 signs and symptoms?

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

Consult the public health authority of the province or territory where you are located to get further information, including when to contact the public health authority.

Q98. When does the 14-day period begin? Is it from the day of entry into Canada or from the day the traveller arrives at the place where they will self-isolate or quarantine?

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

People should consult the their provincial or territorial public health authorities for information on other measures and restrictions, such as the issuance of a provincial emergency order requiring people to self-isolate for 14 days when entering their province from another part of Canada.

Q99. What is considered an appropriate non-medical mask or face covering?

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

An appropriate 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 fasteners or loops. Masks or face coverings should allow for easy breathing, keep the same shape after washing and tumble drying, and be changed as soon as possible if they are damp or dirty.

Q100. Who determines whether a traveller is wearing an appropriate non-medical mask or face covering when entering Canada?

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

If it is agreed that a traveller is wearing an inappropriate non-medical mask or face covering, the traveller will be asked to remove it pursuant to PHAC guidelines. The traveller will have to put on an appropriate non-medical mask or face covering.

Q101. **How many Public Health Agency of Canada quarantine officers are present "in person" at ports of entry?**

Currently, there are PHAC representatives, including quarantine officers, at the four airports designated to receive international flights. The number of quarantine, screening and information officers on site varies depending on the airport and time of day.

PHAC officers include screening officers and information officers, who also work as quarantine officers. Screening officers do preliminary screening and symptom identification, assess whether travellers have a suitable place to self-isolate or quarantine, and provide quarantine or isolation information materials and masks. Information officers provide information and answer questions from the travelling public, including information on the signs and symptoms of the disease, and current public health measures (e.g. hand washing and cough hygiene).

Q102. **Are they only present in person at airports or are they also at land ports of entry?**

PHAC is increasing the presence of designated representatives, including quarantine officers, at ports of entry across Canada. Over the next seven weeks, PHAC officers will be deployed to 36 high-volume ports of entry that receive 90% of travellers and comprise major land borders.

Q103. **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, provided that the person is a consenting adult or a parent or a minor in a parental relationship.

Q104. **Do I have to comply with the order if my province or territory has its own legal quarantine or isolation requirements?**

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

The provinces and territories may implement their own legal quarantine and isolation requirements. People entering Canada will be required to comply with the federal government order and any measures or restrictions applied by their province or territory, insofar as they do not contradict or supersede those set out in the order (i.e. they would have to be more stringent than the requirements or the order).

People should consult their provincial or territorial public health authorities for any additional measures or restrictions.

Q105. **What type of masks or face coverings will be provided at the borders? If all travellers entering Canada are required to wear masks, what impact will that have on the supplies available for health care workers?**

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

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

Even if you wear a non-medical mask or face covering, strict hygiene and public health measures—including frequent hand washing and physical distancing—must be maintained to reduce the risk of virus transmission. It is also important to know that it has not been proven 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 extra measure that people can take to protect others, including those without symptoms.

Q106. **Will the new requirements (travellers having to confirm where they will self-isolate or quarantine; receiving a non-medical mask or face covering) create backups at airports?**

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 is to be expected that the processing of travellers at the border will initially increase wait times, the additional measures will subsequently 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 separation by maintaining a distance of two metres between travellers. All travellers have a responsibility to contribute to the safety of Canadians.

Travellers who have no symptoms (asymptomatic)

Q107. **Why do travellers with no signs or symptoms of COVID-19 have to quarantine? Is it mandatory?**

Yes. Under the order, travellers with no signs or symptoms must quarantine. They must quarantine without delay and monitor for signs and symptoms of COVID-19 until the end of the 14-day period, which begins on the day they enter Canada.

Given the rapid spread of COVID-19 around the world and widespread transmission in an increasing number of countries, people who have travelled outside of Canada are considered to be at risk of exposure to COVID-19. There are also many examples of people who were asymptomatic when they entered Canada but have become ill afterwards, and new public health science tells us that asymptomatic and pre-symptomatic people could spread COVID-19. It is therefore extremely important for their own health and the health of others that travellers entering Canada quarantine themselves and monitor for the onset of symptoms.

Strict additional measures are needed to reduce the risk of spread by people who do not have symptoms. The Government of Canada has issued an order requiring any asymptomatic person entering Canada by air, land or sea (and who is not exempt) to quarantine for 14 days in order to limit the introduction and spread of COVID-19.

Q108. **Why is it that some people with no symptoms can quarantine at home or at a place of their choice, while others have to go to a quarantine facility?**

Asymptomatic travellers entering Canada will be asked to go directly and without delay to their places of quarantine and stay there for 14 days. If they are unable to quarantine as the order stipulates, they will be sent to a quarantine facility at the discretion of the quarantine officer.

Conditions to be 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 could be newly exposed because of the person's stay), where the person will have access to basic necessities and will not be in contact with vulnerable people. Travellers who are unable to meet one or more of these conditions will have to self-isolate for 14 days in a quarantine facility selected by the Chief Public Health Officer of Canada.

Q109. **If I do not have symptoms, can I quarantine at home if vulnerable people live with me?**

No. Asymptomatic travellers cannot quarantine at home if they live with one or more vulnerable people who are at higher risk of becoming seriously ill, as new scientific evidence suggests that both asymptomatic and pre-symptomatic people could spread COVID-19.

Q110. **Why does my quarantine period start all over again if I am exposed to COVID-19 by another person covered by the order?**

Under the new order, the 14-day quarantine period recommences if the person begins to show signs and symptoms of COVID-19 or is exposed to a person 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 expose others who are in quarantine with them and are also covered by this order. Since symptoms can appear up to 14 days after exposure, stricter measures are needed to reduce the risk of spread.

Q111. **Can travellers with no symptoms take public transit (including taxis) or rent a vehicle (at the airport) to get to their homes or places of quarantine?**

Yes, travellers who do not have symptoms can take public transit or rent cars to get to their places of quarantine. However, they must wear appropriate non-medical masks or face coverings while in transit and go directly to their places of quarantine without delay.

While in transit, people must follow the recommendations of the quarantine and screening officers to prevent spread of infection to others. For example, follow the physical distancing

guideline—maintain a distance of two metres from others—ensure good hand hygiene and practise respiratory etiquette.

According to the order, public transit includes an aircraft, bus, train, taxi, subway or ride-sharing service.

People returning home for mandatory quarantine should also consult their provincial or territorial public health authorities about additional measures or travel restrictions in their region.

Q112. **Can travellers without symptoms who are going to return home in a private vehicle ask someone to pick them up, or do they have to be the only occupants of the vehicle? If someone drives them, does that person then have to quarantine for 14 days?**

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

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

In both cases, pay at the pump if you buy gas. If you want to eat, use a drive-thru service. If you have to stop, use rest areas or other places where you can park and rest 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.

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

Q113. **Why do I have to wear a non-medical mask or face covering when taking public transit to my place of quarantine if I have no symptoms of COVID-19?**

New scientific evidence suggests that asymptomatic and pre-symptomatic people may spread COVID-19, which could explain the emergence of a number of secondary cases. Stricter measures are therefore needed to reduce the risk of spread by people without symptoms.

Wearing a non-medical mask or face covering is an extra measure 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 it is not possible to physically distance in public, e.g. on public transit.

Q114. **Are travellers without symptoms allowed to take connecting flights?**

Yes, people with no symptoms can take connecting flights to their destinations to quarantine, provided they wear appropriate non-medical masks or face coverings during the journey.

Quarantine or screening officers will instruct travellers to take extra precautions while travelling to their places of quarantine to prevent the spread of infection to others. For example, follow the

physical distancing guideline—maintain a distance of two metres from others—ensure good hand hygiene and practise respiratory etiquette.

People returning home for mandatory quarantine should also consult their provincial or territorial public health authorities about additional measures or travel restrictions in their region.

Q115. **What happens if a Canadian traveller who has no symptoms misses a connecting flight and has to spend the night in a city before taking a connecting flight the next day? Can that traveller stay in a hotel or with friends or family?**

As directed by the quarantine or screening officer, travellers who enter Canada without symptoms may be allowed to stay in a hotel for one night before boarding their connecting flights the next day. They must wear appropriate non-medical masks or face coverings when in a public place and travel directly to their hotels without making any unnecessary stops along the way.

During their stay at the hotel, travellers returning from abroad should stay in their rooms to avoid contact with others, respect the physical distancing guideline (i.e. maintain a distance of two metres from others), ensure good hand hygiene and practise respiratory etiquette. To get meals, travellers must use a drive-thru or room service, provided the meal is left outside the hotel room door.

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

Q116. **If people arrive in Canada on a charter flight without landing at one of the four designated international airports, can they use private vehicles to travel to their final destinations in another province to self-isolate?**

Yes. People can continue to travel, including in private vehicles, to self-isolate in another province.

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

If you buy gas, pay at the pump. If you want to eat, use a drive-thru service. If you have to stop, use rest areas or other places where you can park and rest in your vehicle, and avoid contact with others.

Once you get 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.

Q117. **What about people returning to Canada by land? Can they spend the night in a hotel during their drive home?**

As directed by the quarantine officer or screening officer, asymptomatic people may be allowed to spend the night in a hotel if necessary, but they must go directly to their hotel without making any unnecessary stops along the way. An appropriate non-medical mask or face covering must be worn at all times in public places.

While at the hotel, travellers returning from abroad should stay in their rooms to avoid contact with others, respect the physical distancing guideline (i.e. maintain a distance of two metres from others), ensure good hand hygiene and practise respiratory etiquette. For meals, travellers must use room service, provided that the meal is left outside the hotel room door.

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

Q118. **RVs have been spotted in store parking lots near the border. Are they allowed to stop so the travellers can shop on their way home?**

Asymptomatic people travelling in recreational vehicles will generally be instructed that they can spend the night in their recreational vehicles. The recreational vehicles will essentially become their quarantine sites.

If they have to stop for the night, they must take precautions to prevent the spread of infection to others. They must remain in their recreational vehicles and avoid contact with others, i.e. maintain a distance of two metres from others, ensure good hand hygiene and practise respiratory etiquette. They cannot go to stores to shop.

Q119. **Can travellers stop to refuel, use a bathroom or buy essential items on their way home to self-isolate?**

It is important for travellers entering Canada to avoid all contact with others. According to the instructions provided upon entry into Canada, you must proceed directly to your place of quarantine without delay and wear an appropriate non-medical mask or face covering while in transit.

If you have to stop, take precautions to prevent the spread of infection to others. Avoid all contact with others (maintain a distance of two metres from others), ensure good hand hygiene and practise respiratory etiquette at all times.

If you buy gas, pay at the pump. If you want to eat, use a drive-thru service. If you have to stop, use rest areas or other places where you can park and rest in your vehicle.

Once you get 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.

Q120. **What happens if an asymptomatic traveller has nowhere to quarantine for 14 days?**

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

- that is deemed appropriate (e.g. it should not be a shelter or other location 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 Canadian port of entry and the quarantine facility will be provided by the Government of Canada.

Symptomatic travellers

Q121. **Why can some people with symptoms isolate at home, while others have to go to a quarantine facility or hospital?**

Travellers entering Canada who report that they have COVID-19 or signs and symptoms of COVID-19, or 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 to isolate, they will be sent to a quarantine facility or a hospital, at the quarantine officer's discretion.

Factors to consider include the severity of symptoms or disease and whether the travellers have a suitable place to isolate in where they have access to basic necessities and will not be in contact with vulnerable people. Symptomatic travellers must also have private transportation to their homes or places of isolation.

For example, if they have to make a travel connection, if the distance to their homes or places of isolation is too far for PHAC-organized medical transportation, or if they live with at least one vulnerable person, travellers will be required to spend the 14 days in isolation in a quarantine facility selected by the Chief Public Health Officer of Canada.

Q122. **What is the definition of "symptomatic"?**

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

Q123. **Can symptomatic travellers returning home to isolate by private transportation be driven by another person, or must they be the only ones in the vehicle?**

Symptomatic travellers must have private transportation to their homes or places of isolation. They cannot ask someone to come 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 homes or places of isolation.

If the distance to their home or place of isolation is too far for PHAC-organized medical transportation, or if they live with one or more vulnerable people, travellers will be required to

spend the 14 days in isolation in a quarantine facility selected by the Chief Public Health Officer of Canada.

Q124. **If I am symptomatic, can I stop at a hotel when travelling home by car?**

No. It is important to avoid all contact with others. You must travel directly to the location where you will spend your mandatory 14-day isolation. That means you must:

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

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

Q125. **Can I stop at a store to buy essential items on my way to isolation?**

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

Once you get 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.

Q126. **What happens if symptomatic travellers are unable to travel to a location where they can 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 travellers have a travel connection or if the distance to their home is too far for PHAC-organized medical transportation, they will be required to spend the 14 days in isolation in a quarantine facility selected by the Chief Public Health Officer of Canada.

Quarantine facilities, such as hotels designated by the Government of Canada, will be used to house symptomatic individuals who are unable to quarantine in a location:

- that is deemed appropriate (e.g. it should not be a shelter or other location 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 Canadian port of entry and the quarantine facility will be provided by the Government of Canada.

Compliance with and enforcement of the Act

Q127. **Who will ascertain 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 monitoring and compliance purposes.

If there is a concern that a traveller may not be complying with the requirements of the Interim Order, peace officers may be called in to contact the traveller and confirm 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 ascertain that travellers returning to Canada comply with the Interim Order.

Q128. **What happens if someone does not comply with the Order?**

Failure to comply with the Order is an offence under the *Quarantine Act*. People who violate the requirements of mandatory isolation or mandatory quarantine may be subject to a range of coercive measures 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 ascertain compliance with the Order.

Maximum penalties include a fine of up to $750,000 or imprisonment of six months or less. Peace officers will use their discretion to determine the most appropriate action in each situation. In addition, anyone who wilfully or recklessly contravenes the Act or the regulations and exposes another person to an imminent danger of death or serious injury is liable to a fine of up to $1,000,000 and/or imprisonment of three years or less.

Amendments to the *Contraventions Act* now allow for greater flexibility in enforcing *Quarantine Act* offences. Law enforcement agencies, including the RCMP and local and provincial police forces, can issue tickets to individuals who are subject to fines ranging from $275 to $1,000, depending on the severity of their non-compliance with the *Quarantine Act* and the Order.

PHAC will work with its federal and provincial partners to encourage, monitor and ascertain compliance with the Order.

Q129. **How is the Public Health Agency of Canada working with its federal and provincial partners to ascertain compliance with the Order?**

PHAC is working with the RCMP and provincial law enforcement agencies to check that returning travellers comply with the mandatory isolation order, using a risk-based approach based on information provided by travellers at the border.

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

Subsequent to regulatory amendments made under the *Contraventions Act*, police authorities, including the RCMP and local or provincial police forces, can now issue fines to individuals who do not comply with orders under the *Quarantine Act*, such as those requiring individuals to isolate after international travel.

Q130. How many Canadians have been sanctioned under the *Quarantine Act*? Of that number, how many were fined? How many have been sentenced to prison?

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

Based on the information we have received from the police to date:

- No sanctions have been imposed under the *Quarantine Act* or under amendments to the *Contraventions Act* since the isolation Orders (issued March 25 and April 14, 2020) came into effect. Three Canadians have received verbal or written warnings from peace officers.
- One $1,000 fine has been issued in accordance with the amendments to the *Contraventions Act*.
- No appearance notices, summonses, recommendations for prosecution or jail sentences have been issued under the *Quarantine Act*.

Essential workers

Q131. Are essential workers exempt from the Order?

Quarantine obligations do not apply to certain individuals who regularly cross the border to ensure the continued flow of essential goods and services, or to those who receive or provide other essential services from or to Canadians, provided they do not have any COVID-19 symptoms at the time they enter Canada.

Canada Border Services Agency agents will assess whether individuals crossing the border may be exempted from the Order.

Those exempted from mandatory quarantine are still required to meet the intent of the Order in minimizing the spread of COVID-19 in Canada, including wearing non-medical masks or appropriate face coverings upon entry into Canada, during transit and while in public places. They will receive a document at the border advising them to monitor their health for COVID-19 symptoms and to be aware of and follow public health advice and instructions in the regions where they are travelling to or located. The document will also include a link to the Canada.ca/coronavirus website where they can obtain more information.

Q132. Why are some essential workers not allowed to work with people aged 65 or older until after their 14-day quarantine?

Adults aged 65 years and older are one of the groups most likely to become seriously ill from COVID-19. Recent circumstances have highlighted the fact that residents of long-term care

facilities are vulnerable to infections due to their shared living spaces and health care providers, external visitors and transfers from other care facilities.

People entering Canada whose work requires them to provide direct care to people aged 65 or older must undergo a mandatory 14-day quarantine to reduce the risk of spreading COVID-19.

Q133. How will employers of temporary foreign workers ensure compliance with the Order?

Employers have an important role to play in helping prevent exposure and spread of COVID-19. Employers must not prevent workers from meeting their obligations under the *Quarantine Act*. Employers are 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 that worker from the 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 to local authorities any violation of the *Quarantine Act* by a worker who is in quarantine or isolation. This includes workers who do not comply with the mandatory quarantine or isolation period.

Q134. I am a temporary foreign worker and I do not have a place to quarantine for 14 days in Canada. What do I need to do?

Employers must provide housing for asymptomatic workers to quarantine in that is separate from those not in quarantine. It may be necessary to find alternate accommodations (e.g. a hotel) if this condition cannot be met. Appropriate quarantine facilities must provide an environment that ensures access to basic necessities (e.g. food, water, heat) while preventing exposure to vulnerable populations.

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

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

Q135. 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 of entry for foreign nationals seeking to come to Canada temporarily from the United States to make a refugee claim, with some exceptions. Refugee claims submitted by people covered by those exceptions will be processed.

Q136. In response to the pandemic, the Government of Canada has introduced 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 reopening the border to refugee claimants?

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

Individuals who are ineligible to apply for refugee protection under the Safe Third Country Agreement (STCA) will be returned to the United States, a designated safe third country, and those who are prohibited from entering Canada to make a claim for refugee protection will have to return to the United States. While international travel has decreased as a result of the pandemic, this change in policy on refugee claimants could result in 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.

When applicants are unable to self-isolate or quarantine adequately, the federal government will work to find a suitable place where they can quarantine. Discussions are ongoing between PHAC, IRCC and CBSA to establish an effective border procedure.

Q137. What are the exceptions under the Safe Third Country Agreement?

The exceptions under the STCA are based on principles that account for the importance of family unity, the best interests of children and the public interest.

There are four types of exceptions:

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

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

Q138. What are the exceptions to the prohibition of 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 refugee claim will still be redirected to the United States, a designated safe third country, with the exception of:

- unaccompanied minors
- U.S. citizens and stateless persons who ordinarily reside in the United States

NOTE: Parents and guardians of U.S. citizens under the age of 18 were covered by an exception under Order 9; however, that was not consistent with the STCA, so the exception was removed in Order 11.

Q139. **Can a refugee claim be made at an airport?**

The prohibition against making a refugee claim at an airport and any non-land port of entry remains in place unless the claimant is an unaccompanied minor, a U.S. citizen or a stateless person who ordinarily resides in the United States.

Quarantine facilities

Q140. **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 arriving in Canada who are unable to self-isolate or quarantine in a manner that meets the conditions of the federal Interim Order (e.g. if they are living with a vulnerable person or have no private transportation if symptomatic). Transportation between the port of entry and the quarantine facility will be provided by the Government of Canada.

These measures will help protect the elderly and medically vulnerable, who are the most likely to become seriously ill as a result of COVID-19.

PHAC is working with its partners to provide travellers who will be isolated in a designated quarantine facility with necessities, including food and medical care or equipment.

Q141. **If travellers return to Canada and have to be quarantined at a quarantine facility, will they be required to reimburse the costs of their stay?**

The 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 will also be provided free of charge.
During their stay at the quarantine facility, travellers are provided with three meals a day and other essential items under a contract with the Canadian Red Cross. All items will be delivered to their rooms. A toll-free telephone number (Canadian Red Cross) is also available for them to indicate any essential items they need.

Q142. **How will my medical needs be met if I have to stay in a quarantine facility?**

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

Q143. **How many people are in quarantine in federal facilities?**

Under the *Quarantine Act*, the Chief Public Health Officer of Canada has designated 13 quarantine sites in 9 cities across the country. As of May 12, we have sent 181 returning travellers to these sites: Vancouver 42, Calgary **5**, Toronto 83, Montréal 50, Halifax **0** and Fredericton **1**.

MODELLING AND MONITORING

Q144. **What is predictive modelling?**

Predictive modelling uses mathematical equations to estimate the number of cases that might occur in the coming weeks or months. Many of the variables included in the calculation are based on what we know about the affected population, the disease, the virus and its spread. We can then adjust the calculations to show how public health measures would reduce transmission and assess how effectively these measures can control the epidemic.

Q145. What are the objectives of modelling?

The objectives are to:

- predict the number of COVID-19 cases possible in the coming weeks and months
- assess the best methods for controlling 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 get COVID-19.

Q146. Which factors are used for modelling data? What knowledge is used to make these forecasts?

There are two main categories of models:

- Forecasting models: Forecasting models are based on what we know about how the pandemic has evolved in Canada and other parts of the world over the past few days and weeks, and 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 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 (SARS-CoV-2) and its spread, derived from studies conducted by researchers around the world. From this knowledge, a mathematical representation (model) is derived on the potential spread of COVID-19 in the Canadian population, based on the public health measures taken to control the disease. These models are valuable planning tools and are adjusted as data on the actual spread of the pandemic becomes more accurate. The resulting forecasts will change over time.

Q147. What public health measures taken by communities are used to model potential effects on the pandemic?

We are currently attempting to gauge the impact of the following key public health measures through modelling:

- Social or physical distancing: measures such as telecommuting and closing schools, universities and gathering/meeting places in order to reduce the possibility of virus transmission from one person to another
- Case detection and isolation: identifying infected people through testing and public health monitoring and isolating them (at home or in hospital) so they cannot transmit the infection to others

- Contact tracing and quarantine: tracing people who have been in contact with a person who has COVID-19 and making sure they remain in isolation for 14 days (or longer if they develop symptoms), so they do not transmit the virus to others

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

Q148. **How reliable is the data?**

Our knowledge of COVID-19 is constantly evolving on an international scale. The epidemic in Canada also continues to evolve, with new case data being reported daily. Modelling predictions will be updated and adjusted as the science evolves and as new data on cases in Canada become available. The models will also be updated to reflect changes in public health measures used to control the epidemic.

This iterative approach applied 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 Canadians take every day will continue to affect forecasts and actual data.

Q149. **Why offer two different models? Isn't one enough? What is the difference between the two models and what are their limitations?**

Forecasts 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 to date in Canada and other countries.

Dynamic models give us a long-term view of the possible evolution of the epidemic and help us plan public health measures to minimize its impact on the Canadian population.

Q150. **Does the Public Health Agency of Canada have up-to-date data or future modelling or projections on the indirect health effects of COVID-19 physical distancing measures (such as the number of patients who had surgeries, routine screenings or other appointments or procedures postponed)?**

PHAC is exploring multiple options with various partners to determine the most efficient way(s) to collect data. Since the pandemic is unprecedented, the effects of COVID-19 on injuries, violence and mental health are not fully understood. The data we expect to collect will be used to learn about the effects of COVID-19 and could frame our modelling for future pandemics.

PHAC is also working with the Canadian Institute for Health Information (CIHI). CIHI collects and publishes data from hospitals, regional health authorities, long-term care facilities and governments (among others) over a longer period of time. It provides retrospective data that are cleansed and standardized to allow for reliable comparisons and help health care systems learn from each other. Over the coming weeks and months, as information becomes available, CIHI will attempt to assess the impact of COVID-19 on health care systems and the types of care in Canada.

One of the reports that CIHI hopes to release in the coming weeks will help estimate scheduled surgeries that have been cancelled because of COVID-19, using historical data. It will provide information on the number and type of hospitalizations and day surgeries scheduled for patients between February 1 and April 30, 2019. This historical data can be used to estimate the impact of surgery cancellations due to COVID-19.

We know that it provides essential modelling information to health policy-makers by setting up potential scenarios. Although modelling is not predictive, it helps guide health care system planning. CIHI actively supports a certain number of provinces and territories in developing and validating specific modelling. Timely and informed decisions have been made with this support, based on the most recent available information that, in turn, has contributed to awareness efforts aimed at mitigating the impact of COVID-19.

Q151. **Does the Public Health Agency of Canada have up-to-date data or future models on injuries or deaths resulting from domestic violence, abuse or the exacerbation of mental health problems while people are staying at home?**

With respect to domestic violence, we recommend contacting the police or women's shelters, which may be better suited to talk about the number of reports they receive. It is extremely difficult to determine such instances from our information about emergency services and short-term care because our data pertain to health services and needs, but not necessarily their causes. CIHI may be told that a broken arm had to be treated, for example, but would have no way of knowing how it was broken.

Please contact CIHI's media relations office to find out more about its work.

Q152. **Do forecasts differ among the provinces and territories that have released their modelling data? If so, why?**

We use comparable methods to predict the number of cases that may occur over the coming weeks and model the effects of different public health measures, but our predictions and models deal with Canada as a whole, while those of the provinces and territories cover only what occurs locally. Since the provincial models are based on data about local cases, their forecasts are different and focus on the changing situation at the provincial level.

Q153. **Which outside experts have been brought in to help with this work?**

PHAC has set up an external advisory group to support its COVID-19 prediction and modelling efforts. The advisory group consists of 37 infectious disease modelling and epidemiology experts from provincial and territorial public health agencies across Canada. It meets twice a week.

PHAC is participating in the World Health Organization's modelling group in order to draw lessons from studies conducted all over the world and compare their findings with those of our own studies.

Q154. **When will the modelling studies conducted outside of PHAC be released?**

The modelling studies carried out outside of PHAC have been released and widely distributed. PHAC is committed to scientific excellence and will provide the details of those studies in reputable scientific publications. The publication process is already under way, and PHAC will make them widely available as soon as possible.

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

Q155. **Will these models show whether we are meeting our objectives?**

The models give an indication of what will happen based on the different public health measures that are adopted, and the efficiency of those measures will be revealed in surveillance data. We are continuously assessing the impact of our public health measures on the number of reported cases as part of surveillance. If necessary, we will revise these measures together with our provincial and territorial partners. We must bear in mind that the effects of public health measures are not reflected in surveillance data until about two weeks later. That is the time it takes from when a person becomes infected to when the case is reported to PHAC as a confirmed case.

Q156. **Why is there a delay in determining the mortality rate, and are there plans to step up the release of data so as to reflect the current pandemic?**

PHAC is working with provincial and territorial public health authorities to provide Canadians with the best and most accurate up-to-date information, including the number of COVID-19 cases and deaths. Every effort is being made to release the data in a timely manner but, as with any disease tracking and given the heavy toll COVID-19 is taking on provincial and territorial staff, there is some delay in the release of information to PHAC, in particular with respect to deaths. The Centre for Immunization and Respiratory Infectious Diseases (CIRID) program area is working on a data strategy with additional indicators, including more recent death-related data, in order to complete what is found in current COVID-19 case report forms and beyond.

Q157. **What is the median age of people who have died from COVID-19 in Canada?**

As of April 22, 2020, (noon EDT) the median age of people who have died from COVID-19 is 84. The median age is based on an analysis of 764 COVID-19 case report forms indicating a death and for which age information is complete.

Q158. **In the daily epidemiology report, only about one-third of COVID-19 cases include information about hospitalization. Why is that? Have some provinces failed to provide hospitalization data? If so, which provinces and why?**

Every effort is being made to obtain information in a timely manner, but there are inherent delays in collecting information in a surveillance system that extends from a local to a national scale. PHAC is working closely with provincial and territorial public health authorities to provide the most accurate information possible to Canadians. As we said earlier, detailed case-related data have been received from the provinces and territories for about 65% of reported cases. The data on these cases are preliminary and may lack information for features of interest or may be coded "unknown." In most cases, when hospitalization information is not available on a case report form it is because the hospitalization status was coded as "unknown."

Q159. **Is the total number of COVID-19-related deaths in Canada higher than the reported number, and will modelling based on overall death statistics be needed after the pandemic is over to understand the true extent of deaths?**

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

As in all countries, this measurement varies over time during the course of an epidemic. The estimate is usually lower at the start of the epidemic because people generally die later during the course of the disease. Other emerging factors can influence this estimate at any time, such as recent outbreaks among vulnerable populations in long-term care facilities and other factors affecting data reporting. We are expecting CFR accuracy to increase during the course of the epidemic.

Our knowledge of COVID‑19 continues to increase every day. Modelling forecasts will be updated and adjusted as the science evolves and as new data on cases in Canada become available.

Data modelling – April 28, 2020

Q160. **What are the modelling figures at the present time? How do they compare to those that were first published?**

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

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

Based on predictions, the number of COVID-19-related deaths should have been between 500 and 700 on April 16. The actual cumulative number of deaths reported on April 16 was 1,048. The modelling was then revised to correct the underestimation of deaths in previous model.

Q161. **What are we to surmise about the value of this modelling exercise when we look at the huge gap between the best-case and worst-case scenarios?**

The purpose of the modelling is to help predict the potential number of COVID-19 cases that may occur over the coming weeks or months and determine the best ways of controlling the epidemic in Canada. The models provide information on what may occur in various scenarios so we can prepare for the worst and steer public health action toward the best possible outcome. All these forecasts help us decide which public health measures to use and how to prepare the health care system for the projected number of patients with COVID-19.

Q162. **Two weeks ago you incorrectly estimated the expected number of deaths. Why should we believe your figures are accurate now?**

PHAC projects the number of deaths on a statistical range based on a case fatality rate of 2.2%, which is the ratio between the number of deaths and the number of cases. This is the ratio used by the World Health Organization.

Models, understandably, have inherent limitations. The estimated case fatality rate is usually low at the start of an epidemic because the number of confirmed cases in the denominator rises much faster than the number of deaths in the numerator.

We did not factor in emerging trends such as recent outbreaks in vulnerable populations at long-term care facilities. Modelling predictions are also very sensitive to changes in the measures being taken (e.g. the extent to which people obey physical distancing directives).

Q163. **Have you fine-tuned your method to make predictions more accurate?**

Models cannot predict what will happen, but they can help us understand what *might* happen. The dynamic modelling approach means that models are continuously updated as information comes in on the transmission of the virus causing COVID-19. The method we use for weekly predictions will depend on what is consistent with the course of the epidemic, based on the number of reported cases and deaths over the previous weeks.

Short-term predictions of the cumulative number of cases have proven effective. A different method is used for short-term predictions of the number of deaths. In the first press release, death predictions were based on a fixed value of the calculated case fatality rate, which did not account for rate fluctuations over time. The case fatality rate was particularly affected by the large number of deaths in long-term care facilities. We believe the new method will produce more accurate predictions.

Q164. **What new data or variables have been added, if any? Which variables are you actually using (age, gender, underlying health conditions)?**

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

The method we use to make these predictions is based on the course of the epidemic, i.e. the cases and deaths reported in the previous weeks. Using this dynamic modelling approach, we can attempt to predict the total possible number of cases during the entire epidemic based on the levels of control outlined in various scenarios.

These total figures are then used to assess how many Canadians may be affected to a slight or severe extent and how many may die, based on global estimates of the levels of severity among different age groups, taking into account the age profile of the Canadian population. University partners are developing models to assess the number of cases and health needs by province taking into account local data on underlying health conditions, age and gender.

Q165. **What dates is the projection modelling based on?**

PHAC periodically updates its modelling work, which includes national projections of the total number of cases. The forecast presented on April 9 was produced on April 6 and was for a 10-day period until April 16. Similarly, the projection presented on April 28 was produced on April 24 for a 10-day period until May 5.

The modelling of projections based on data collected up to April 18 provided a projected range over a 10-day period of 39,950 to 47,235 cumulative reported cases and 2,330 to 4,017 cumulative deaths as at April 28.

Q166. **Dr. Tam has repeatedly stated that the course of the pandemic is not the same in different parts of Canada or among all demographic groups. Are you drawing up demographic models or providing models that cover specific vulnerable populations, such as individuals living in long-term care facilities or those who are homeless?**

PHAC uses a range of modelling methods to assess and understand how COVID-19 may spread in Canada over the coming weeks and months. From the data the provinces and territories have provided on their reported cases, we know that the patterns of transmission and the populations affected differ across jurisdictions.

We have no specific model of transmission in long-term care facilities. However, although we have been making predictions based on models for all of Canada, we are also developing models that take into account the range of differences between provinces and territories, municipalities and vulnerable populations.

Such models, which may factor in local demographic variations, show the complexity of epidemics in each province and are more useful for planning purposes at the provincial and local levels.

PHAC is committed to scientific excellence and will provide the details of its modelling results in reputable scientific publications. The process for such publications is already under way. PHAC will widely distribute those results as soon as possible after they have been published.

Q167. **Do you collect data based on race and ethnic origin, including Indigenous populations? Would this not make your modelling more accurate?**

There is no indication that race or ethnic origin is a risk factor for COVID-19. Some circumstances or environments that make it difficult to comply with public health measures like physical distancing do affect the risk of virus spread.

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

Q168. **The modelling data for British Columbia and Ontario show that they have already reached a peak in community outbreaks and that the numbers appear to be decreasing. Is that the case for Canada in general? As provinces note a decrease in the number of cases and start to ease restrictions, how will this affect the modelling data?**

Surveillance data suggest that, in general, the public health measures implemented in Canada have a significant impact and are slowing the epidemic. The level of control of the epidemic varies greatly across jurisdictions. We are closely monitoring the situation.

The epidemic in Canada is continuing to evolve, and model-based projections continue to be updated and revised as new figures become available. The models are also updated to reflect any changes in public health measures used to control the epidemic.

Modelling allows us to assess the possible impact of public health measures over time, adjust calculations to reflect how public health measures decrease transmission and assess the extent to which these measures may control the epidemic. The modelling data presented take into account changes made to public health measures (time, type and location). The modelling data also provide information on when schools, workplaces and other sites can be reopened and when restrictions must once again be increased, if necessary.

It is important to remember that we cannot let our guard down, and we must be realistic and realize that the epidemic will last for some time. If public health measures are eased too soon, the epidemic will likely intensify very quickly.

Q169. **Have you taken into account the reopening of some provinces and territories, several of which have begun unveiling their plans? Are there any possible impacts on and from other regions that are affected to a greater extent?**

Surveillance data suggests that, in general, the public health measures implemented in Canada have a significant impact and are slowing the epidemic. The level of control of the epidemic varies greatly across jurisdictions. We are closely monitoring the situation.

The epidemic in Canada continues to evolve, and model-based projections continue to be updated and revised as new figures become available. The models are also updated to reflect any changes in public health measures used to control the epidemic. PHAC is working with academic partners to explore the possible effects of lifting public health measures.

Modelling allows us to assess the possible impact of public health measures over time, adjust calculations to reflect how public health measures decrease transmission and assess the extent to which these measures may control the epidemic. The modelling data presented take into account changes made to public health measures (time, type and location) and examine when schools, workplaces and other sites can be reopened and when restrictions must once again be reinforced, if necessary.

It is important to remember that we must not let our guard down, and we must be realistic and realize that we are still in the early stages of the epidemic. If public health measures are eased too soon, the epidemic will likely return in full force very quickly.

Q170. **How can governments talk about reopening the economy when the figures show 3,277 to 3,883 deaths by May 5 if current measures are not maintained?**

Although PHAC makes model-based projections for all of Canada, it is known that the epidemic differs across various parts of the country. Each region will have a different timeline for easing current public health measures.

PHAC is working with federal, provincial and territorial governments, as well as universities, to investigate the future possible spread of COVID-19 in Canada and estimate the number of cases, hospitalizations and deaths that may occur in the weeks and months to come under the various public health response scenarios.

We continue to monitor the impact of our public health measures by reviewing and analyzing surveillance data on cases and outbreaks. We are also adapting our surveillance systems as needed, working with our provincial and territorial partners.

Q171. **The lack of recent quality data has been presented as a problem in developing the modelling. Did you encounter any problems during the last cycle? Does the information you are presenting show any vulnerabilities due to a lack of data?**

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

Q172. **What improvements are being made to ensure that you obtain recent quality data for the modelling? Will there be better data for the next update, and when do you think it will be?**

Dynamic models are being constantly updated as new information on the transmission of the COVID-19 virus becomes available. The projected number of cases and deaths is constantly being updated using prediction methods such as analyses of the cases and deaths reported in previous weeks.

Short-term projections for cumulative cases have proven to be effective. A different method is used for short-term predictions of the number of deaths. In the first version, death projections were based on a fixed value for the calculated case fatality rate, which did not account for rate fluctuations over time. The case fatality rate was particularly affected by the large number of deaths in long-term care facilities. We believe that the new method will be more accurate.

Q173. **A significant decrease in emergency room visits for non-COVID-19-related illnesses has been reported across Canada. Do you have figures on the number of Canadians who are at risk of dying because they are afraid to go to the hospital and be infected by the virus?**

It is currently impossible to estimate or model the reasons for the changes in emergency room visits; that information is therefore not included in our modelling data. The provinces and territories may have more detailed information on the situation in their respective jurisdictions.

We understand that many Canadians may have concerns about going to a doctor's office or hospital in light of the current pandemic. However, we would like to point out that it is very important for Canadians to continue to take care of their health and consult health professionals if they do not feel well.

Q174. **Do you report higher numbers than you expect just to frighten people and make them obey the restrictions in their daily lives?**

Modelling cannot predict what will happen. But it can help us understand what *might* happen. The purpose of sharing the models is not to provide distorted or inaccurate images to frighten Canadians and make them comply with public health measures. The intent behind the modelling is to help people understand and envision the potential number of COVID-19 cases that could develop in the coming weeks or months and assess the effect that public health measures have had on reducing the impact of the pandemic. PHAC's work demonstrates 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 designed to break chains of transmission within communities. It is important to remember that we cannot let our guard down, and we must be realistic and realize that the fight against the epidemic is still in progress. If public health measures are eased too soon, the epidemic will likely return in full force very quickly.

Q175. **Does the season (temperature) affect your forecasting?**

At present, the available data do not suggest that the expected summer temperatures for Canada will affect the transmission of the virus. Short-term projections do not take into account the season (temperature).

Q176. **Has Health Canada advised the provinces to review previous records of patients who were admitted to hospital with pneumonia before the first case of COVID-19 was reported?**

To our knowledge, only one province has done so to date, and no previous cases have been detected retrospectively.

Understanding the virus that causes COVID‑19, its origin and its subsequent evolution are important issues being studied. Retrospective tests on samples of serious respiratory infections taken before the first cases were reported in Wuhan, China, will provide valuable evidence as scientists learn more about the virus. However, current public health measures are focused on testing for active cases in order to break the chains of transmission and inform important public health decisions to protect the health of Canadians.

Q177. **What is PHAC's response to Amir Attaran's criticism of Canada's COVID-19 modelling?**

Modelling provides information about what might happen in various scenarios so that we can prepare for the worst and adjust public health measures to produce the best possible outcome. The possible scenarios featured in the Government of Canada's models are a synopsis of modelling studies, including those carried out by PHAC and other epidemiologists and modellers in Canada and around the world. The following three possible scenarios were featured: "no control effort," where an uncontrolled outbreak occurs and infects a very large proportion of Canadians; "weaker controls," where the epidemic is not controlled by public health measures but is prolonged and has a reduced peak due to public health measures; and "stronger epidemic control," where the epidemic is controlled through a combination of public health measures. These scenarios are used for planning and are not forecasts. Studies conducted outside PHAC have already been published and are widely available, whereas those conducted by PHAC will be published 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 estimate the range of cases, hospitalizations and deaths that could occur in the coming weeks and months under various public health response scenarios. Predictive modelling of COVID‑19 requires us to make assumptions based on incomplete data and evolving science. These assumptions are changing as new information about the virus and more data about the epidemic in Canada become available. We are continuously improving the models so that we can provide Canadians with the best possible information on the potential scenarios.

The work cited by Mr. Attaran is consistent with our own studies and those of other groups. Without public health measures, 70% or more of Canadians could become infected. If public health measures are put in place but relaxed suddenly or too quickly, the epidemic will simply resume. Although public health measures may not be enough to end the epidemic, they can still somewhat reduce the percentage of Canadians who need to become infected and immunized to create “herd immunity” as a way of stopping the epidemic.

Additional work conducted by PHAC and other modellers was consistent with observations from other countries in suggesting that strong public health efforts could lead to low rates of infection (1-10%) among Canadians. Such efforts would include sustained public health measures to prevent retransmission, to detect and isolate cases in Canada, and to trace and quarantine people who had been in contact with those cases.

Q178. **Mr. Attaran also accused PHAC of censoring the data provided to scientists. If this is the case, why did PHAC censor this data before releasing it?**

PHAC set up an external advisory group to support our efforts to model and forecast the COVID‑19 epidemic. This advisory group comprises more than 40 experts in infectious disease modelling and epidemiology from provincial and territorial public health authorities and universities across Canada. The group meets twice a week. PHAC is also committed to making sure the research and scientific information it produces is made available to the public in a timely manner and in compliance with the Government of Canada’s Directive on Open Government, together with a daily epidemiological report and tables containing preliminary data on confirmed cases. In some cases, PHAC may not be able to transfer some data because they belong to a third party or there are compelling reasons to restrict their disclosure, such as protection of privacy. Our knowledge of COVID‑19 continues to evolve on an international scale. The epidemic in Canada also continues to evolve, with new case data becoming available daily. Modelling forecasts will be updated and adjusted as the science evolves and as new data on Canadian cases become available.

FLUWATCHERS

Q179. **What did the FluWatchers program do before COVID-19? Can you also provide some figures, such as the number of Canadians who volunteered to take part in the FluWatch program in 2018 and 2019?**

FluWatchers began in fall 2015 and is part of FluWatch, Canada’s national flu surveillance program. The program uses syndromic surveillance to monitor flu-like illnesses in Canada.

Traditional flu surveillance programs such as laboratory and hospital surveillance only cover people who seek medical care or test positive for the flu, missing a high number of potential flu cases as a result. That is why PHAC launched FluWatchers in order to track cases of flu-like illnesses in people who did not seek medical care or undergo flu testing. This program gives Canada a more accurate portrait of Canadian flu cases over a typical flu season. The FluWatchers program also provides other valuable surveillance indicators, such as the number of symptomatic people who saw a doctor and the number of people who were tested and their results.

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

Q180. **When did the FluWatchers program begin to track COVID-19, and why?**

PHAC has been monitoring data from FluWatchers since the beginning of the pandemic in Canada, watching for signs of an unusual increase in the number of Canadians with coughs and fever. Minor changes were made to the questionnaire in late March 2020 to include questions about COVID-19. PHAC uses FluWatchers to track COVID-19 for the same reasons the program is used to track the flu. Most people are unlikely to seek medical care or undergo testing, which means that a large part of the population would not be covered under the traditional surveillance methods currently in use. The FluWatchers program also provides an idea of the number of symptomatic people who saw a doctor and the number of people who were tested and their results. We hope this program will give Canada a better idea of the COVID-19 cases in the country, as it does for the flu.

Q181. **How do you differentiate between COVID-19 and the flu in the answers you are currently receiving?**

Syndromic surveillance programs such as FluWatchers are used to detect signals. When the program reports something, it prompts us to review our other surveillance data to validate the signal we are witnessing. We are able to validate the results obtained from FluWatchers against data from our other flu surveillance programs. For example, according to our current laboratory surveillance data, there are very few flu viruses or other seasonal respiratory viruses circulating in Canada right now. Other flu indicators such as hospitalizations and outbreak surveillance are also showing very low influenza activity. We can apply this knowledge to the data reported by the FluWatchers program. If the flu were in high circulation, we would suspect that it was probably responsible for the answers collected by FluWatchers. But, since the flu and other respiratory viruses are currently in very low circulation and the flu season is ending, we can assume that the answers reported by FluWatchers could be attributable to COVID-19.

Q182. **Can you tell us how many Canadians took part in COVID-19 tracking through the FluWatchers program? Were there any trends among your responses?**

On April 3, 2020, PHAC started promoting the FluWatchers program more strongly on social media in order to recruit other participants. Since then, our weekly participation rate has risen from 3,200 to 8,700 participants per week. The higher the number of participants making reports, the more accurate the data.

The percentage of participants who report having a cough and fever is low. For example, during the week of March 29, 2020, 0.5% of 6,200 participants (32 participants) reported having a cough and fever. For the week of April 5, 0.3% of 8,700 participants (24 participants) reported having a cough and fever. The low rates of cough and fever may be the result of physical distancing measures, and we hope these rates remain low in the coming weeks.

ROLE OF THE GLOBAL PUBLIC HEALTH INTELLIGENCE NETWORK IN SURVEILLANCE

Q183. **During virus outbreaks, what data do the Global Public Health Intelligence Network (GPHIN) collect and use for alerts, and in which languages are the data disseminated?**

PHAC's Global Public Health Intelligence Network (GPHIN) is an early-warning and situational awareness system for potential chemical, biological, radiological and nuclear threats worldwide—including outbreaks of infectious diseases.

GPHIN users include non-governmental organizations and government authorities worldwide that conduct public health surveillance. GPHIN is a significant contributor to the World Health Organization's Epidemic Intelligence from Open Sources initiative.

Some 7,000 articles are entered into the GPHIN system every day. The web-based application in the GPHIN system continuously scans and acquires new sources of information from around the world in nine languages (Arabic, Farsi, English, French, Portuguese, Russian, Spanish, and simplified and traditional Chinese).

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

In addition, GPHIN analysts have programmed specific Google Alerts and monitor other news 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 the data are in the GPHIN system, they are processed, validated and assessed.

Q184. **How are GPHIN's threat assessments and analyses compiled?**

GPHIN does not produce threat assessments. 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.

More than 7,000 articles are entered into the GPHIN system every day. Once data are entered into the GPHIN system, they are processed, validated and assessed, after which they are included in reports, including the Situational Awareness Daily Report published every morning.

Q185. **When were the first data collected on the coronavirus outbreak, and from where?**

On December 31, 2019, at 5:16 a.m. EST, an article entitled "China probes mystery pneumonia outbreak amid SARS fears" was released by Agence France Presse and uploaded into the GPHIN system at 5:42 a.m. EST.

Q186. When did GPHIN first send out an alert about the coronavirus outbreak, and to whom was it sent?

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

Q187. Have Chinese officials already briefed Canadian officials on COVID-19? If so, when were they briefed and what was said?

Canada and China have been exchanging information on a regular basis since the outbreak occurred in early 2020. This has led to discussions among health officials in both countries and many exchanges among health and foreign affairs officials involving our respective embassies in Ottawa and Beijing. Exchanges have also taken place during multilateral processes such as the G20.

Minister Champagne discussed issues relating to COVID‑19 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

At the beginning of the year, as part of his regular communication with the Chinese Embassy, Paul Thoppil, Assistant Deputy Minister, Asia-Pacific at Global Affairs Canada, also had several meetings with the Chinese ambassador, Cong Peiwu, on issues related to the progression of the outbreak. From January on, other Global Affairs Canada officials in Ottawa and at the Canadian Embassy in Beijing, including Ambassador Dominic Barton, also took part in several conversations about COVID‑19 with Chinese officials. Early conversations focused on sharing

information about the progression of the outbreak and the evacuation of Canadian citizens from Wuhan, and were 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 been particularly focused on China's provision of medical supplies to Canada and global lockdown measures.

Q188. **What is the GPHIN Renewal Project? Why was the renewal carried out in phases?**

The GPHIN Renewal Project aimed to create an enhanced web platform in compliance with Government of Canada information technology policies to provide greater automation in the collection, collation and analysis of open source information.

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

This was a collaborative initiative between PHAC and the National Research Council of Canada.

The GPHIN Renewal Project achieved the following objectives:

- The platform complies with information technology policies, guidelines and standards, and the Government of Canada has the capacity to introduce further enhancements and innovations to the system.
- GPHIN can tap into the variety, volume and velocity of available data–including data from social media and a greater number of websites–and provide a visual representation of events in time and space, using its integrated analytical and assessment capability and automated article summarization.
- The system's artificial intelligence is able to learn and improve the accuracy of its relevance score.

Adopting a phased approach enabled PHAC to develop, create, implement and test functionality. A post-deployment review of version 1 identified quality and functionality problems, which were then solved in version 2, resulting in further system enhancements.

Q189. **Were there complaints about the GPHIN search system after the NRC system version 1 update? What about the fact that the search results were sometimes missing and had to be entered manually?**

After the initial launch of the updated system in August 2016, analysts noticed that the search function was slower. In the summer of 2017, the NRC called in an industry expert to analyze the issues and recommend changes. The changes were made in mid-2018, and assessment measures showed clear improvements.

Q190. Did Shared Services Canada order GPHIN to transfer external government servers to a private system in order to integrate them with the Government of Canada's system?

A request for information issued by Public Services and Procurement Canada to gauge the interest of private sector companies in upgrading the GPHIN platform remained unanswered. The platform was upgraded within the established scope and budget in cooperation with the NRC.

Q191. Have analysts ever been told to stop reporting on COVID-19?

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

Q192. Is there a ban on sharing information with subscribers?

Sharing information with subscribers is not prohibited. GPHIN continues to regularly provide information to its users. GPHIN also provides them with special reports on COVID-19 in response to needs expressed by organizations such as the World Health Organization.

Q193. What public notice/news bulletin/press release did PHAC first issue about COVID-19? Can you provide a link?

The first travel health advisory was released on **January 7, 2020**.

Q194. How have screening and testing guidelines been adapted as COVID-19 has evolved? Please provide a timeline of such guidelines starting in early January 2020.

With regard to border screenings, enhanced measures were introduced on **January 22, 2020,** to identify and screen individuals travelling from Wuhan, China, and arriving at airports with direct flights from China (Vancouver, Toronto and Montréal). Information (e.g. brochures, messages posted on screens) was also made available at major airports on **January 22, 2020,** to inform travellers entering Canada of their obligation to notify a Canada Border Services Agency (CBSA) officer if they were experiencing symptoms such as fever, cough or difficulty breathing, and to show travellers where they could find more information from the Government of Canada about the novel coronavirus. This information was adjusted as screening measures were enhanced. PHAC increased the presence of quarantine officers and public health officers in major airports to help CBSA border officers screen sick travellers and provide information to healthy ones.
As the virus spread around the world, those measures were applied to seven other airports and, on **March 6, 2020**, to all land, rail and ferry points of entry. Screening measures were expanded to identify symptomatic persons travelling from regions affected by a COVID‑19 outbreak, particularly China's Hubei province, Iran and Italy.

On **March 13, 2020,** the Government of Canada issued an official global travel advisory to avoid non-essential travel outside of Canada. All travellers entering Canada, no matter where they came from, were screened for COVID‑19 symptoms and asked to voluntarily self-isolate for 14 days upon entering Canada, whether or not they had symptoms.

The Government of Canada began limiting international flights to four international airports (Montréal, Toronto, Calgary and Vancouver) and, since **March 18, 2020,** the *Aeronautics Act* has obliged air carriers to conduct basic health examinations of all air travellers boarding flights to Canada in accordance with the directives issued by PHAC. If a traveller exhibits symptoms of COVID‑19, the air carrier is obliged to deny boarding to that individual for 14 days.

On **March 18, 2020,** the Government of Canada issued an Emergency Order to temporarily close the country's international borders, prohibiting entry into Canada by foreign nationals from any country other than the United States. On **March 20, 2020,** a similar temporary Emergency Order was issued to prohibit entry into Canada from the United States; it came into effect on **March 21, 2020**.

On **March 25, 2020,** the Government of Canada issued an Emergency Order requiring travellers entering Canada to self-isolate (if they had symptoms of COVID‑19) or quarantine (if they had no symptoms).

On **March 26, 2020,** the Government of Canada replaced the existing Emergency Orders, prohibiting entry into Canada by all foreign nationals, with some exceptions such as aircraft crew members, diplomats and people providing essential services.

On **April 15, 2020,** the Government of Canada issued a new Emergency Order requiring all travellers entering Canada to self-isolate (if they had symptoms of COVID‑19) or quarantine (if they had no symptoms) upon entering Canada and to wear non-medical masks or face coverings while in transit to isolation or quarantine. No travellers subject to the order were allowed to self-isolate or quarantine in a location where they would be in contact with vulnerable individuals, such as adults aged 65 and up or people with pre-existing conditions, or where they would not be able to access basic necessities such as food and medication.

New measures came into effect on **April 20, 2020,** requiring all air travellers to wear non-medical masks or face coverings over their mouths and noses during the flight.

On **April 22, 2020,** the temporary Emergency Order prohibiting foreign nationals from entering Canada via the United States was extended for 30 days.

Q195. ***How do experts in Canada communicate with one another? Does the Public Health Agency of Canada use external experts, or are there Canadian health experts working in the Agency? Does Canada rely on the expertise of WHO?***

The Government of Canada has created the infrastructure needed to respond to the public health threats posed by the virus; it is well prepared to act to minimize the health, economic and social impacts of this rapidly evolving public health problem together with the provincial and territorial governments and international partners.

PHAC employees are in regular contact with key national and international partners. In the case of COVID‑19, by using existing mechanisms such as the federal, provincial and territorial public health tables and by working with appropriate stakeholders, the Government of Canada has put together important guidance documents to help Canada set up public health measures in all jurisdictions in order to flatten the curve.

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

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

The 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 the country would be well prepared to detect and respond to a pandemic outbreak. Our key international partners include the World Health Organization (WHO) and its regional office, the Pan American Health Organization. Canada continues to support WHO in its efforts to assist countries in their fight against the virus, and has implemented public health measures in line with its guidance.

Canada has engaged with international partner countries in a variety of ways since the emergence of the novel coronavirus, some of which are ahead of us in terms of the epidemiological curve. This international engagement has also allowed us to learn from the experiences, expertise and best practices of others and to inform our national response. Existing engagement mechanisms such as the Global Health Security Initiative, the G7 and the G20 have facilitated such information sharing. Canada also has a long history of cooperation with other *ad hoc* multilateral groups such as Asia-Pacific Economic Cooperation, the Organization of American States and others, both at the ministerial and public servant levels, as well as with international NGOs like Doctors without Borders.

Q196. **What information or modelling were PHAC and Dr. Tam working with in early March, when the message to Canadians was that the risk was still low? How has the risk assessment progressed to a high level for all Canadians?**

In March 2020, public health risk assessments evolved to reflect the risk of COVID-19 to Canadians in Canada at that time. The risk to the Canadian population went from low (as there was no evidence that COVID-19 was circulating in the Canadian population) to low for the general population but moderate for seniors and people with underlying medical conditions, and then to high for the general population due to the community-wide spread of COVID-19 within the Canadian population.

Q197. **Can you describe 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 influenza)?**

GPHIN analysts work collaboratively on national and global surveillance. While the analysts focus on regions and countries corresponding to their language aptitudes, they all share responsibilities for national surveillance. This practice has been in effect for many years.

Q198. **What is GPHIN's annual budget?**

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

Q199. **How does GPHIN's selection or analysis of data differ from the approaches used by ProMED, HealthMap and commercial suppliers such as Blue Dot?**

GPHIN has two essential components:

- A professional, multidisciplinary team of scientific analysts who review information in nine languages and conduct rapid risk assessments to detect public health threats
- An information management tool that uses machine learning and natural language processing to facilitate the analysts' work

GPHIN requires that eligible users register free of charge; this includes non-governmental organizations and government authorities that oversee public health.

ProMED uses information provided by volunteer "reporters" and subscribers and through staff searches on the Internet, various official and unofficial websites and in the media. Moderators assess these reports for reasonableness, edit them as needed, and often add comments or context before posting. ProMED is one of the many sources of GPHIN data.

HealthMap's content is gathered from freely available information (including ProMED) and is processed automatically by machine learning algorithms. Unlike GPHIN, the published information is not subject to human review, which could affect the system's performance.

BlueDot is a private company that requires registration (paid subscription) to access its data. The application brings together information from official sources and mass media, including WHO and ProMED-mail.

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

Q200. **Does the Government of Canada use BlueDot's AI to track individuals who have been in contact with COVID-19?**

The Public Health Agency of Canada and Health Canada have contracts with BlueDot. None of those contracts relate to the use of AI to track individuals.

Q201. **I have confirmed with Public Health Ontario and the Institut national de santé publique du Québec that they are not collecting data on race/ethnicity in relation to COVID-19. My understanding is that the Public Health Agency of Canada does not collect this type of data either. Can you confirm this?**

It is true that the COVID-19 case report form does not include any questions on race or ethnicity, but it does include a section for the purpose of identifying and classifying cases as Indigenous (First Nations, Métis, Inuit).That section is filled in only when the person affected indicates that they belong to one of the three categories of Indigenous people. The data in that section is often incomplete or missing.

Q202. **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 about age and known risk factors, such as having a pre-existing health condition or being a resident of a long-term care facility. These data are analyzed regularly and included in an epidemiological summary.

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

Q203. **What is Health Canada's role in the Ontario Health Data Platform? Will it become the standard in all provinces? Does Health Canada approve this plan, which is designed to slow the spread of COVID-19?**

Understanding a patient's medical history is essential to providing safe and appropriate care. That is why the exchange of health information among health care providers, protected by strict confidentiality and data security requirements, can produce better results through better informed, coordinated and integrated care. A system that meets patients' needs 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 protection of personal health information.

Q204. **Are there any Canadian studies on COVID-19 and wastewater analysis?**

At this time, the Public Health Agency of Canada is not aware of any Canadian studies collecting wastewater samples for the detection and identification of COVID‑19.

It is too early to consider doing this type of analysis; more research is needed as to its usefulness. The Public Health Agency of Canada is staying abreast of the science in this area.

As part of the Canadian 2019 Novel Coronavirus (COVID-19) Rapid Research Funding Opportunity Results, 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 evolution of COVID-19 (https://www.canada.ca/en/institutes-health-research/news/2020/03/government-of-canada-funds-49-additional-covid-19-research-projects-details-of-the-funded-projects.html). However, it is not yet known whether wastewater samples will be part of this work.

Q205. ***Why was the emerging infections surveillance platform project initiated and what is its scope?***

The emergency infections surveillance platform was designed to improve internal processes for managing and assessing data on emerging infectious diseases. The pilot project, launched in 2016, 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 were implemented.

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

- A data innovation centre fully dedicated to meeting PHAC's data needs using digital tools for 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 that intelligence
- The implementation, together 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 rapid public health response
- International cooperation under the Global Health Security Initiative (GHSI) for real-time communication of public health risk assessments, detection methods and data collection approaches

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

NML INTERVENTION AGAINST THE OUTBREAK

Q206. **Why did National Microbiology Laboratory 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 the Public Health Agency of Canada responded to the request in 2019 by sending samples for scientific research. The National Microbiology Laboratory (NML) exchanges samples with other public health laboratories 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 offers 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 PHAC scientists in the emergence of the novel coronavirus has no basis in fact.

Q207. **Do the Government of Canada and PHAC support the investigation of the possibility that a breach or accident associated with the Wuhan laboratory may be linked in some way 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 PHAC scientists in the emergence of the novel coronavirus has any basis in fact. Our response to COVID-19 will continue to be science-based.

TESTING AND CASE CONFIRMATION

Q208. **When did the NML develop its own test? Does the NML conduct the tests by automation or manually?**

The NML has established a test (trial) based on published, peer-reviewed targets approved by the World Health Organization (Corman *et al*., 2020). It was first tested at the NML on **January 26, 2020.** The tests that are now commonly used are based on the Corman tests.

In the early stages, several other tests designed or modified by the NML were considered and used. Some of those tests were used for the initial screening of samples for the virus, and others were used to confirm the initial results. Those tests were modified from the existing coronavirus tests available at the NML, and all were designed based on the novel coronavirus genome sequence communicated by China in January. It is described in an article (see "diagnostic tests") that includes the dates of the first patient (i.e. first use of the tests).

The use of this first, broader set of tests was then refined down to those based on the Corman test, both to streamline the screening process and to support the expansion of screening to other sites. A validated and simplified screening approach allows individual laboratories to report confirmed results without the need for additional testing at a reference laboratory like the NML.

The NML uses both manual and automated testing protocols, depending on the volume of samples received.

Q209. **Can you confirm whether the NML "validates" Class 1 medical devices and what it means when a product is "validated"?**

PSAC's NML does not validate Class 1 medical devices.

The role of the NML is to undertake scientific studies on diagnostic tests and supplies in order to assist provincial laboratories in making decisions to adopt those tests for use in clinical settings. The studies are conducted in cooperation with provincial laboratories and clinical researchers in order to determine the effectiveness of a test under real-world conditions. Diagnostic test performance results are shared with manufacturing companies, all provincial laboratories and Health Canada to provide additional evidence of diagnostic test accuracy.

Q210. **How is Canada currently detecting COVID-19 in patients?**

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

The NML is recognized worldwide for its scientific excellence.

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

The NML provides laboratory reference services to all provinces and territories. These testing 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.

Q211. **What is the Public Health Agency of Canada's testing capacity?**

We continue to test on a massive scale; Canada has one of the highest testing rates in the world. We understand that testing is crucial for discovering new cases so that the chains of transmission can be identified and broken. We are currently conducting more than 20,000 tests per day, almost double what we were doing in April, and that number continues to grow.

We do not have precise figures for the number of tests that need to be conducted each day in order to ease physical distancing measures, and the figures vary from one jurisdiction to another. The goal 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. Provinces continue to increase their testing capacity as needed. On some days, in some provinces, the capacity exceeds the number of people who want to be tested.

Canada has maintained a positivity rate of approximately 6-7%, which is within the effective detection range to accurately target the circulation of the disease. We want as accurate a picture as possible of what is happening in our communities. This shows that we have a relatively sensitive testing system. We will continue to expand our laboratory capacity to ensure that this continues.

The main objective is to test symptomatic individuals to detect cases and quickly follow up on contacts. Another key objective is to intensify testing in high-risk situations, especially long-term care facilities, health care facilities and correctional facilities, with a view to supporting outbreak control in all settings.

Our priorities remain: access to reagents for testing, assessment of rapid, non-laboratory tests and access to authorized test kits so the provinces and territories are adequately equipped to accelerate testing as required.

Q212. **What more could be done to speed up the process? When does the federal government expect to reach the 500,000 tests per week threshold?**

As of May 12, the average number of tests conducted in Canada was between 26,000 and 28,000 per day, and that number continues to grow.

Canada has maintained a positivity rate of 5-7%, which is within the limits necessary to accurately detect disease circulation.

The number of 60,000 tests per day was based on the current capacity of provincial public health laboratories. There is no specific number of daily tests that would allow us to reduce public health measures equally and simultaneously across Canada. The epidemic varies across the provinces and territories, and even within the same region.

Health Canada's Interim Order facilitates and expedites the importation and sale of certain medical devices, such as laboratory diagnostic kits, in Canada. Point-of-care diagnostic tests will become available as a result of this Interim Order, allowing patients to be tested more conveniently and quickly. Rapid results will enable health care professionals and patients to take action more quickly, helping slow the spread of the disease.

Q213. **Does PHAC recommend temperature checks before people enter public places? If not, why not? Will this be implemented when activities begin to gradually resume?**

In the Infection prevention and control for COVID-19: Interim guidance for long term care homes, PHAC recommends the implementation of employee testing 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 measures focused solely on fever detection are not recommended.

During the outbreak of 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 those intensive screening efforts, this method did not detect any cases of SARS. That is why it is not recommended that temperature checks be conducted at the border before people enter Canada.

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.

Q214. **Which specific tests to screen for COVID-19 are currently authorized in Canada?**

With the introduction of new diagnostic tests for the novel severe acute respiratory syndrome coronavirus 2 virus, Canadian public health laboratories have used the collective strengths of their network to assess the accuracy of those tests while building capacity to rapidly distribute testing capacity across Canada.

After the genetic sequence of the virus was published in January, multiple molecular tests (polymerase chain reaction) could immediately be developed to 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 proof of the presence of severe acute respiratory syndrome coronavirus 2. Through the use of multiple testing methods and multi-site testing—like when tests were presumptively positive in the provinces and then confirmed by the National Microbiology Laboratory—Canada was able to ensure that each confirmed case was an actual case.

We have a certain level of confidence in the tests, but we need to streamline their approach so they can be conducted in additional laboratories in Canada. The case definition has therefore been successively adjusted to confirm cases using a single molecular test. The choice of this test was based on knowledge of the performance of the different tests carried out in the various 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 the virus takes during infections. The quantities of detectable viruses could be low very early or very late in infections, and current molecular tests may not detect those cases. However, as the response to this epidemic shows, laboratories will continually strive to improve their approaches to testing based on evidence.

In addition, the current molecular tests that are used across the country, which are the result of collective sharing of information and tools by laboratories, will soon become the benchmark against which to compare and implement the next phase of testing, as rapid point-of-care tests

are implemented to enable testing in health care facilities rather than requiring specimens to be sent to a laboratory for testing.

Q215. **Are Spartan tests an effective way to diagnose COVID-19? What are the false positive and false negative rates?**

Spartan Bioscience's diagnostic test kit has been authorized by Health Canada under an Interim Order in Council issued by the Minister to allow exceptional importations and sales of medical products as part of the response to the COVID‑19 outbreak. The authorization follows a scientific assessment by Health Canada reviewers to ensure that the devices meet safety and effectiveness standards; for diagnostic devices, this means they must meet the requirements to accurately identify COVID‑19 cases and minimize the risk of false positives and false negatives. The authorization also requires Spartan Bioscience to submit data on an ongoing basis as additional test results become available.

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

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

(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 U.S. FDA on March 12, 2020.

Q216. **Will the tests be accessible to anyone who wants to be tested?**

Rapid and accurate testing is an essential component of the public health response to this pandemic. It provides for early detection of cases to prevent having to control the spread of the disease. The Government of Canada is taking steps to increase testing capacity as quickly as possible so that Canada's public health laboratories and other diagnostic laboratories have the resources they need to test people infected with COVID-19. Several commercial reagents approved by Health Canada can be used to test for COVID-19. However, there is a global shortage of many of these reagents, which affects the testing capacity of laboratories. We need Canadian solutions to tackle this problem. This shortage is affecting Canada's testing capacity. PHAC’s NML has developed a reagent to help address this shortage. The reagent is mass-produced by LuminUltra Technologies Ltd., a New Brunswick company. Even with increased capacity, testing priorities will need to be met order to achieve appropriate public health goals.

Q217. **Does the lack of sampling and analytical equipment prevent more tests from being performed?**

The Government of Canada has ordered more than 11 million swabs from various domestic and international suppliers. The swabs are delivered in batches each week. The government purchases and produces other laboratory supplies that are needed for overall laboratory testing efforts by the provinces and territories. We are also exploring options to ensure a continuous supply of sterile swabs, including the possibility of producing swabs in Canada.

Q218. **What is the greatest challenge in increasing screening capacity to test a larger proportion of the population?**

The Government of Canada is investing $150 million to support federal public health measures such as enhanced surveillance, increased testing capacity at the NML and continued support for preparedness in First Nations and Inuit communities. This important work will support the administration of diagnostic tests across Canada and the research, testing and implementation of new diagnostic tests and methods; it will also coordinate with provincial and territorial authorities the procurement and distribution of reagents and laboratory supplies to increase testing capacity across the country.

Q219. **Which universities and manufacturers are currently involved in creating sampling or testing equipment, or otherwise contributing to testing?**

To date, Innovation, Science and Economic Development Canada has received close to 6,000 responses to its call for action from companies across the country. Now that we have received these responses, we are contacting the respondents to assess how they can meet the urgent needs of Canadians and frontline health care workers. Canadian industry plays a major role in increasing national testing capacity. It is important to note that LuminUltra (New Brunswick) provides an extraction reagent to federal and provincial laboratories across the country and is continually boosting our diagnostic testing capacity. Spartan Bioscience also offers a Health Canada approved non-laboratory diagnostic test that will support testing in rural and remote areas.

Q220. **How does Health Canada's COVID-19 symptom list compare to the CDC list? How up to date is the list and how important is it to Canadians who are monitoring for signs of the disease 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 new virus is better understood. We continue to review the latest scientific evidence and work with our provincial, territorial and other public health partners across the country and around the world to learn more. PHAC 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 whereas the provinces and territories, which manage and deliver health services, can provide more detailed advice based on their epidemiological data, risk assessments and availability of health services. As for 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.

Q221. **How do laboratories send information about positive test results to public health authorities?**

The ways provincial public health officials collect and disseminate information about positive test results for COVID-19 vary across provinces. The provinces are better positioned to provide additional information on the methods they use.
However, the provinces and territories send their laboratory test results to PHAC for national follow-up.

Canadian public health laboratories work together through the Canadian Public Health Laboratory Network (CPHLN), which includes federal, provincial and territorial public health laboratory professionals working together to strengthen Canada's public health system through coordinated laboratory services and sound management. The provinces and territories report their daily laboratory results for COVID-19 through the CPHLN, 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). The CNPHI is a scientific platform for public health informatics and biomonitoring 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 tests.

Q222. **Is the authorization of the real-time fluorescent marker test kit (RT-PCR) for the detection of SARS 2019-nCOV limited to research or other use? How does it work?**

The sale and importation of this test has been authorized under the Interim order respecting the importation and sale of medical devices for use in relation to COVID-19. The use of this device is not limited to research. The RT-PCR for the detection of SARS 2019-nCOV is a nucleic acid-based diagnostic test for COVID-19.

The RT-PCR for the detection of the 2019-nCoV (SARS-CoV-2) is a nucleic acid-based diagnostic test used to detect SARS-CoV-2 in people suspected of having COVID-19. It is intended for use by trained clinical laboratory staff. This is a type of polymerase chain reaction test, known as a PCR, which is the most common and accurate type of test to determine whether a person is infected with the coronavirus.

The test uses a throat or sputum swab from a patient that is placed in a machine called a thermal cycler. The thermal cycler uses the temperature cycle to amplify any SARS-CoV-2 nucleic acid present in the sample. If a patient sample contains SARS-CoV-2, the genetic material of the virus will be amplified and the device will give a positive result. If the sample does not contain SARS-CoV-2 the device will give a negative result.

There were three conditions put on the authorization of this device. The company has already revised the documents to meet the first two conditions relating to 1) the length of time the product is declared stable and 2) the need for additional information in the previous instructions. Health Canada is assessing whether the information provided by the company is sufficient to remove those conditions. The third condition is that the company provide data on bacterial cross-reactivity. The company has undertaken to provide such data.

Q223. Are the federal government, Health Canada and the Public Health Agency of Canada considering combining samples for COVID-19 testing? Is this a viable option for Canada, or for a particular province or territory, or for any region of a province or territory? If so, please specify the circumstances that would allow for samples to be combined for testing in Canada in places where it would work best. If not, please explain why.

Sample pooling is a diagnostic approach in which samples are put together in batches before being analyzed by a screening machine. If a negative result is obtained for the batch, laboratory professionals can set aside all samples as negative. If a positive result is obtained for the batch, each sample is tested individually to determine if it is positive. Conceptually, sample pooling is an approach used to increase capacity and conserve laboratory supplies. The challenge is to make sure that the results are always accurate (i.e. precise and sensitive). Before pooling the samples, laboratory professionals must conduct research studies to confirm the accuracy of the results.

PHAC's National Microbiology Laboratory (NML) works with provincial and territorial public health laboratories to ensure that diagnostic tests are of high quality and meet laboratory standards. With their provincial and territorial counterparts, NML scientists are exploring how best to increase COVID‑19 testing capacity, particularly in remote areas, including Indigenous communities. NML scientists are conducting research studies to test whether pooling laboratory specimens for point-of-care devices, which are used in clinical and remote settings, will produce accurate results, since there is a worldwide shortage of laboratory supplies for these devices.

The NML does not pool samples for its molecular polymerase chain reaction (PCR) tests for COVID‑19, nor for its routine diagnostic approach for other infectious diseases. The NML is Canada's reference laboratory. In general, it provides laboratory support to other provincial and territorial public health laboratories to confirm initial test results, ensure quality assurance and perform in-depth analysis of difficult-to-diagnose specimens. Pooling of batches is not recommended for those types of samples.

Please contact a province or territory directly to determine whether laboratories are using sample pooling as part of their testing strategy for COVID‑19 or other infectious diseases.

Q224. Did the NML check all the tests conducted in Canada in January and February?

PSAC’s NML conducted tests in January and in the first few weeks of February 2020 to verify presumptive positive results from provincial public health laboratories, after which it provided confirmed results. The NML did confirmatory testing because this is a previously unknown virus and it is good practice to do additional testing to confirm initial laboratory results. British Columbia launched its own confirmatory testing procedures on February 24, 2020, followed by Ontario on February 25, 2020. At that time, the results for all other provinces were tested further at the NML.

The provincial laboratories have incorporated confirmatory testing into their testing procedures, in consultation with the NML, based on successful validation and assessment of the tests in the province and confirmatory testing conducted simultaneously at the NML on a certain number of samples. The NML also continues to provide laboratory reference services to all provinces and territories. Testing services provide various forms of support to provincial and territorial laboratories, including quality assurance and in-depth analysis of difficult-to-diagnose samples. The NML also continues to provide control samples to help provincial and territorial partners assess their ongoing performance, while also providing additional tests such as virus sequencing in COVID-19 cases.

Remdesivir for the treatment of COVID-19

Q225. **Can remdesivir be used for any patient infected with COVID-19? Will it be effective for everyone?**

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

Q226. **Are clinical trials under way 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 treating COVID-19 is through clinical trials. Clinical trials provide Canadians with access to new treatments for COVID-19, and provide an opportunity for the medical community to systematically collect information on the efficacy of treatments and the associated risks. To date, Health Canada has approved two COVID-19 clinical trials for remdesivir 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 about the trials 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 the clinical trials and new results concerning remdesivir.

Q227. **What is the emergency use authorization (EUA) in the United States? Does this mean that the drug has been approved for the treatment of COVID-19?**

On May 1, 2020, the U.S. Food and Drug Administration (FDA) announced that it had granted an emergency use authorization for remdesivir, an experimental antiviral intended to treat COVID-19. According to information released 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 can be found on the FDA website.

Q228. **What is a continuing review? If it is faster, why not use this process all the time?**

Continuing review is one of the regulatory tools available to Health Canada to expedite the assessment of a drug submission in urgent public health situations.

Under normal circumstances, all data in support of an application for marketing authorization must be submitted at the beginning of the assessment process. In the case of a continuing review, the Department reviews the data as they become available. Several continuing review cycles may be conducted during the assessment of a product as data continue to emerge. New data that become available for assessment during a continuing review will have to be studied in the context of all other existing data; the study will have to determine the benefits and risks of a drug as quickly as possible.

Though it is impossible to predict a specific timeline for a continuing review, this approach will allow for earlier submission of applications and will enable Health Canada to initiate a review earlier without compromising its high safety, efficacy and quality standards.

Continuing reviews can enable Health Canada to review drug submissions more easily than in the case of a standard drug review. They also require more review work due to multiple review cycles. That is why they are a rarely used regulatory flexibility reserved for urgent public health situations.

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

Q229. **Are you satisfied with the current level of access to remdesivir in Canada through clinical trials and the Special Access Program (SAP)?**

Health Canada has closely monitored developments regarding potential treatments for COVID-19, including remdesivir. Remdesivir is an experimental drug that is administered by intravenous infusion to some hospitalized patients with COVID-19. In Canada, remdesivir is available through approved clinical trials, which are the most appropriate way to access experimental therapies. Clinical trials give Canadians access to new therapies for treating COVID-19 and provide an opportunity for the health care community to systematically collect information on treatment effectiveness and the associated risks.

To date, two clinical trials have been approved for remdesivir in the context of COVID-19 in Canada, and are taking place at several sites across the country. More information on the approved trials can be found on the Health Canada website. Information from these clinical trials may help support a submission to Health Canada.

Health Canada has authorized 12 requests for remdesivir through its SAP; through this program, it is currently providing remdesivir to pregnant women and children with confirmed COVID-19 coupled with a serious illness.

Q230. **Are you concerned that Canada's access to remdesivir will be limited in the future?**

Health Canada has been in regular communication with Gilead Sciences Canada Inc. about access to remdesivir in Canada and the company's plans to file a submission for review. Once Gilead Sciences Canada Inc. has filed a submission to Health Canada for remdesivir, Health Canada will exercise regulatory flexibility to expedite the review of the submission so Canadians can have access to the drug, while at the same time ensuring its safety, efficacy and quality. Health Canada has also worked with international regulatory agencies, including the U.S. Food and Drug Administration, to share scientific information on drugs and vaccines for COVID-19, including remdesivir, and to align safety and efficacy requirements wherever practicable in order to expedite the review and approval process.

Home tests

Q231. **What type of tests have been proposed for home use?**

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

Lateral flow antibody tests, commonly referred to 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 in the form of a coloured band on a small stick. However, Health Canada has not authorized the sale or import of any such test. These tests are not recommended because patients do not have access to a medical professional who can interpret the results.

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

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

Q232. **What is Health Canada doing to prevent the sale of unauthorized COVID-19 tests?**

Health Canada is continuing to monitor the use of unlicensed medical home testing kits, including those for COVID-19, and is taking appropriate action to stop their sale as needed. When Health Canada becomes aware of a possible case of 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 a notice advising Canadians not to use or rely on unlicensed COVID-19 test kits intended for sale or personal use.

Q233. **Are home testing kits for COVID-19 available in other countries?**

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

It was recently mentioned in the media that the FDA had approved its first home testing kit, but that is inaccurate. The FDA has approved the COVID-19 RT-PCR test for which only a fluid sample is taken at home. After collection, the swabs must be sent to a laboratory for analysis. They are subject to strict transportation requirements.

Q234. **What type of tests for COVID-19 have been authorized by Health Canada or are under consideration?**

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

Changes to the Spartan test kit authorization

Q235. **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 conducts the test using Spartan COVID-19 detection cartridges and company-exclusive swabs. The kit makes it possible to diagnose COVID-19 in less than an hour without having to send the sample to a laboratory.

Q236. **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 standards of proof may be required. While no problems are anticipated at this time, Health Canada will not hesitate to take appropriate action should problems arise.

Q237. **When Health Canada says it approves devices "that may not fully meet regulatory requirements," what specific requirements is it prepared to set aside or reduce?**

Regulatory Framework for Medical Devices in Canada: In Canada, medical devices are regulated under the *Medical Devices Regulations* and are classified into four classes based on the risk associated with their use. Class I devices present the lowest risk (e.g. tongue depressors, masks, gowns) and Class IV devices present the highest risk (e.g. pacemakers).

Health Canada issues two types of medical device licences:

- Medical Device License (MDL):

    - Issued for specific products, authorizing manufacturers to sell a Class II, III or IV medical device in Canada.
- Medical Device Establishment License (MDEL):
    - Issued to manufacturers of Class I medical devices, as well as importers or distributors of the four classes of medical devices, to allow them to import or sell medical devices in Canada.

Additional information on how medical devices are approved and authorized in Canada under the *Medical Devices Regulations* is available here.

In the context of COVID-19: The health and safety of Canadians is Health Canada's number one priority, and the department is facilitating access to products needed to fight COVID-19, including medical devices. Three different measures have been introduced in order to expedite the availability of medical devices in support of efforts to combat COVID-19:

1. The Interim order respecting the importation and sale of medical devices for use in relation to COVID-19, signed by the Minister of Health on March 18, 2020, provides an expedited authorization pathway for Health Canada to quickly review and authorize medical devices for use in Canada. This pathway, applicable to manufacturers of Class I to IV medical devices, requires scientific assessment to ensure the safety and efficacy of the medical devices. Information on how to submit an application for medical devices under this interim order can be found in our guidance document. The requirements for serological antibody tests submitted under the interim order are also available online.

2. The Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19, signed by the Minister of Health on March 30, 2020, builds on existing practice to facilitate access to alternative sources of supply for health products and enhances the transparency of Health Canada's work with multiple stakeholders to prevent and mitigate shortages resulting directly or indirectly from COVID-19. Products on the list of medical devices for exceptional importation and sale include those that do not fully meet the usual regulatory requirements of the *Medical Devices Regulations*, such as those related to labelling. Health Canada will add products to the list only if there is no impact on the health and safety of Canadians. Currently, most of the products listed are Class I personal protective equipment, such as masks and gowns. An MDEL is still mandatory for the import and sale of these products, and the regulatory requirements remain in effect, including those related to record keeping, complaint handling, mandatory problem reporting, distribution records and recalls, per sections 44 to 65.1 of the *Medical Devices Regulations*. Importers must also notify Health Canada at least five days before importing, giving details about the devices and making them available to consumers, if applicable.

3. Health Canada is also expediting the review of applications and the issuance of MDELs for companies applying to manufacture Class I medical devices or to import or distribute Class I medical devices to support efforts to fight COVID-19. Manufacturers, importers and distributors of medical devices continue to be subject to all applicable requirements set out in the *Medical Devices Regulations* and are responsible for ensuring that the medical devices (of all classes) they sell meet the safety and effectiveness requirements set out in the Regulations.

As with all health products, including medical devices, Health Canada will assess and continue to monitor the safety and efficacy of these products once they are on the market. Health Canada will take appropriate compliance and enforcement measures, as required, to protect the health and safety of Canadians.

Q238. **Have kits been used to diagnose patients?**

Spartan Bioscience 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 be required to confirm again whether or not its kits were used for diagnostic purposes.

Q239. **Why are Spartan tests no longer approved for use other than research? How and when did the problem arise?**

On March 26, 2020, Health Canada issued a conditional approval for Spartan Bioscience Inc. Spartan Cubes, 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 under an expedited scientific review process, according to minimum requirements.

On April 11, 2020, Health Canada completed its scientific review to ensure that the device was supported by evidence demonstrating that it met safety and efficacy requirements. Health Canada's scientific review was based on analytical data from laboratory studies that the company submitted, and took into consideration that additional clinical validation would be performed by public health laboratories to determine performance in a clinical setting. Health Canada amended the terms of the authorization, allowing the Spartan Cube to be sold, but requiring that data from additional technical studies and sales information be provided.

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 under clinical conditions to collect samples from patients. These clinical trials were essential to identify performance issues that could not be identified in a laboratory. The report indicated that, although the Spartan Cube worked in the laboratory according to the manufacturer's specifications, performance issues were identified during the clinical trial. These problems appear to be related to the patented swab, which may not collect enough mucous matter for testing.

In light of these clinical results, Health Canada placed conditions on the company's authorization, restricting the product to use 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 no tests were used for diagnostic purposes.

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

Q240. **Why didn't Health Canada wait for the clinical study results before authorizing the Spartan kit for sale?**

The scientific review of the Spartan test kit was expedited as part of the interim order announced on March 18, 2020.

Health Canada's regulatory decision was based on laboratory testing conducted on the kit, not on efficacy-related clinical trial data. The review took into consideration that public health laboratories would perform additional testing to determine performance in a clinical setting. This is consistent with the approach that other reputable regulators have adopted.

As planned, Health Canada continued to monitor and assess the safety and efficacy of these rapid field test kits to ensure that they work properly and provide accurate results. In light of the clinical results, Health Canada has amended the conditions of the product's authorization to

restrict its sale 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.

Q241. **Did the NML test any or all of the Spartan samples? When was this done, how many samples were tested and where?**

PHAC's NML collaborated with provincial partners—Alberta, Ontario and Manitoba—to test the Spartan Cube using Spartan swabs under clinical conditions to collect samples directly from patients. These tests were conducted in April, and the NML submitted the final report to Health Canada on May 1.

Samples were taken from patients already known to be COVID-19-positive (i.e., confirmed by existing and validated tests). Those samples were then tested in parallel on the Spartan Cube and other diagnostic platforms currently under review. It is important to note that the samples collected from the Spartan Cube systems were part of a clinical and scientific examination to test the efficacy of the Spartan Cube, so the results were not considered in diagnostic decisions of positive or negative results.

Q242. **Have other administrations received the Spartan Cube? Has Health Canada told them to stop using the device?**

Spartan Bioscience has confirmed that it distributed 5,500 test kits solely for research purposes in clinical settings to four public health agencies, including the Public Health Agency of Canada.

These organizations are aware of the new conditions imposed by Health Canada on Spartan's authorization. Health Canada asked the company to recall its products to prevent them from being used in diagnostic settings at this time. The company indicated that it was willing to do so. The Department sent a regulatory letter to the company on May 2, 2020, indicating the new conditions in accordance with Article 7 of the Interim Order. The letter also outlined the steps the company was to follow for the voluntary recall. Health Canada has limited the sale of the test kits to research use until adequate evidence of clinical effectiveness can be provided and assessed.

Q243. **Is there a minimum level of specificity and sensitivity that a test must have in order to be approved by Health Canada?**

Health Canada takes into account the U.S. Food and Drug Administration's Emergency Use Authorization Guide Document to ensure that molecular-based test kits are appropriate for identifying tests that are both sufficiently sensitive and specific. However, this guide is just a starting point; Health Canada's scientific review also considers other factors (e.g. the number of samples tested, the type of sample recommended [nasopharyngeal as opposed to nasal, as opposed to sputum], whether the samples were developed clinically or in the laboratory [spiked with known quantities of virus], etc.). Health Canada's review also takes into account the urgent

public health need for access to testing devices in the COVID-19 pandemic context. It is a new virus and a new disease. As the research evolves, we are acquiring key data that will help us determine optimal specificity and sensitivity by taking into account all these factors. Health Canada reviews each application on a case-by-case basis and conducts the scientific review based on the information the manufacturer provides. The Department monitors efficacy once a test is authorized and takes action if a test does not perform as expected.

Serology

Q244. **What are serological tests used for?**

Serological tests are essential in understanding the immune response to viral infection. They will play a key role in determining the extent of exposure to the virus through serological surveillance studies.
Serological tests are not authorized for diagnosing COVID-19 because they detect antibodies developed in a patient by immune reaction. These antibodies most likely do not develop until later stages of infection, which means the test will often return false negative results.
With diagnostic tests, molecular tests on swab samples are preferred to test directly for evidence of the virus during the infection.

Q245. **How will the serological test results be used?**

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

On April 23, the Government of Canada established the COVID-19 Immunity Task Force to lead the collaborative effort across Canada to test blood samples for evidence of COVID-19.
Rapid and representative national studies will provide an overview of where we are now and what to expect if a second wave of infection strikes. They can also shed light on the possible immunity status of the population and vulnerable people, including Indigenous communities and residents of nursing homes and long-term care facilities.

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

Q246. **Is the government considering the possibility of issuing passports or certificates of immunity or negative serological test results to allow for free movement?**

Internationally, efforts are under way to assess whether people who have recovered from the disease can safely resume their daily activities.
More research is needed before making this decision in Canada.

Other respiratory viruses generally do not give a person full immunity after recovery.

At this time, we simply do not know if people who have recovered from COVID-19 will be completely immune, how long their immunity will last, or whether people may experience less severe or potentially more severe symptoms if they contract COVID-19 a second time.

Q247. How does Canada screen patients suspected of having COVID-19?

The provinces and territories perform diagnostic tests to detect the virus that causes COVID-19. Canada's National Microbiology Laboratory collaborates with provincial and territorial public health laboratories to ensure that diagnostic tests are of high quality and meet laboratory standards.

Q248. How will Health Canada ensure that test kits are safe and effective?

The Interim Order creates a tailored authorization process to import and sell medical devices for use in relation to COVID-19 in Canada. This Interim Order and the resulting authorization process gives the Minister the flexibility to take into account circumstances related to the urgent need for the medical device, authorizations already granted by foreign regulatory authorities, or potential new uses for medical devices already approved in Canada.

As with all drugs and medical devices, Health Canada will assess and monitor the safety and efficacy of all products certified as a result of this Interim Order, and take immediate action to protect the health and safety of Canadians.

Manufacturers will still be required to comply with strict post-market safety requirements, such as mandatory problem reporting, recall procedures and complaint handling.

Q249. Why did Health Canada take so long to authorize a serological test?

Communicating accurate information to Canadians about immune status and appropriate public health measures is a cornerstone of Canada's response to the pandemic.
Canada has maintained a science-based approach to pandemic management, including maintaining pre-market authorization requirements for COVID-19 diagnostic tests.
Health Canada authorized the test after conducting an evidence-based scientific review to ensure that the test will provide accurate and reliable results. More than a dozen COVID-19-diagnosing test devices are now available in Canada. The list of authorized testing devices is published on Health Canada's website.

If pressed:

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

Q250. What is the difference between swab and serological tests? How are they used differently?

Serological tests are used to determine if 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; it is the presence of these antibodies in blood samples that forms the basis of serological tests. Conversely, evidence of the virus itself, rather than the human immune response, is the basis of molecular tests that are now used to diagnose COVID-19 from swab samples.

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

It is not recommended to use serological tests to diagnose COVID-19 infections, as antibodies are unlikely to develop until later stages of the infection, often resulting in false negative results. For diagnostic tests, it is preferable to test directly for evidence of the virus while there is infection.

Q251. **I think I had COVID, but I was never tested. What do I need to do to get a serological test that will tell me whether or not I am immune?**

Canadian laboratories will be able to use serological tests to detect COVID-19-specific antibodies. Provincial and territorial public health authorities will determine which serological tests they wish to use. For the time being, serological tests will not be used to make a diagnosis, but rather to collect useful data if someone is newly infected or has already been infected. Molecular tests are currently used to screen for active COVID-19 infections.

If you think you have COVID-19, please contact your health care professional or public health authority for advice on how to proceed.

You can also use the following self-assessment tool to determine if you need help or take a test https://ca.thrive.health/covid19/en.

Contact tracing

Q252. **Can you tell me more about the federal government's program to recruit people for contact tracing?**

As part of the overall federal, provincial and territorial government response to COVID-19, the Government of Canada is supporting the provinces and territories by facilitating a virtual directory to recruit and mobilize qualified Canadians to ensure there will be additional capacity during peak demand in key areas.

The Government of Canada is working with the provinces and territories to determine their needs. They identified contact tracing and case registration as areas where they need help. Therefore, skills required include case management, data collection and management, public awareness and telephone interviewing. Further calls may be made when administrations identify new areas requiring assistance. As needs evolve, support will be provided in other areas requiring assistance.

The Government of Canada is reaching out in phases. The first and second phases are already under way. The first phase consisted of bringing in qualified federal public servants who do not currently hold essential jobs in ongoing federal projects to work in the administrations that are feeling the most pressure. The second phase consists of building on the directory developed as part of the National COVID-19 Volunteer Recruitment Campaign, as well as contacting health, public health and science faculties across the country to issue a call to those interested in being added to this directory. A third phase will target retirees or individuals from all professional

health and health science associations who are not currently participating in the COVID-19 response.

Q253. **How many volunteers will be accepted within the framework of the National COVID-19 Volunteer Recruitment Campaign, and how many of those volunteers will be responsible for contact tracing? When will they be deployed to the field?**

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

Q254. **Is the Department considering the use of digital data technologies such as cell phone applications to improve contact tracing? What type of digital data model is the Department studying?**

Mobile apps can help promote physical distancing by enabling Canadians to change their activities and reduce high-risk behaviours. They could be used in addition to other public health measures intended to flatten the curve, such as:

- avoiding crowded areas and non-essential gatherings
- washing hands frequently with soap and water for at least 20 seconds
- avoiding touching your eyes, nose or mouth without having first washed your hands

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

Q255. **A company partially based in Canada has developed a smartphone app that helps with contact tracing, similar to the one in place in Singapore. Would the government adopt this type of technology to facilitate contact tracing?**

Contact tracing is an important public health measure to identify individuals potentially exposed to COVID-19 and to ensure that these individuals 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 epidemic. Although it is an essential public health tool, contact tracing is resource-intensive. Phone apps using location or proximity data to help alert those who have been in contact with patients who have tested positive for COVID-19 can be a useful tool in fighting the 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

Q256. **Does Canada have a sufficient number of diagnostic tests**?

We expect the quantity of diagnostic kits will be sufficient.

Health Canada is working with manufacturers to enable marketing of commercial diagnostic devices, which will increase Canada's COVID-19 diagnosis capacity.

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

Thanks to this Interim Order, two new diagnostic tests are now readily available in Canada:

- Cobas SARS-CoV-2 diagnostic test from Roche Molecular Systems Inc.
- COVID-19 Combo Kit from ThermoFisher Scientific TaqPath™

This will improve access to medical devices that could make it easier and faster for patients to be screened in Canada.

Point-of-care diagnostic tests are being developed and may become available as a result of this Interim Order, which would also speed up and facilitate patient screening.

Q257. **Is Health Canada looking to the cannabis industry for additional COVID-19 tests?**

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 additional laboratory capacity that 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 licensees, asking those who are interested in helping and have additional laboratory capacity to inform the Department by email. Several laboratories responded indicating their willingness to assist. The Department is currently confirming the next steps, including whether these laboratories have the appropriate equipment, certifications and protocols to be of assistance.

Q258. **Is the government considering increasing the influenza vaccine supply for the next flu season, in light of the demand arising from the COVID-19 pandemic?**

PHAC is preparing for the possibility of simultaneous outbreaks of influenza and COVID-19 infections in Canada this fall. To help minimize the challenges that this possibility would cause for the health care system, the 2020 flu campaign will focus on at-risk populations such as the elderly, those who are immuno-compromised and those underlying health conditions.

PHAC is involved in coordinating and overseeing the delivery of flu vaccines for public programs in collaboration with Public Services and Procurement Canada, vaccine manufacturers, as well as federal, provincial and territorial partners. PHAC does not decide how many vaccines the 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 if they are sufficient or if they should be increased. It is still possible to increase orders before final commitments are made.

Q259. Is Health Canada aware of a potential shortage of medical devices as a result of COVID-19, and what is being done to monitor supply?

Currently, Health Canada has not received any reports from medical device manufacturers of medical device shortages due to COVID-19.

Stakeholders in the medical devices industry have promised the Department that they will watch for early signs that could indicate supply shortages; none have been reported to date. Health Canada continues to monitor the situation and will take appropriate action, if necessary, to mitigate the impact on Canadians.

Q260. 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 (UK, US, Italy, China) may use different manufacturing techniques to address supply issues.

Together with other federal organizations and the private sector, Health Canada is facilitating an assessment of current 3D printing capacity in Canada and will help identify the 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 network of 3D printing suppliers in the medical device industry, hospitals, universities, colleges and industrial manufacturing facilities. As of March 20, 34 organizations with experience in 3D printing have responded, indicating they are willing to help.

Q261. Is there an estimated number of intensive care beds that Canada will need when the epidemic peaks, and how many intensive care beds are currently available?

According to the Canadian Institute for Health Information (CIHI), Canada (excluding Quebec, Nunavut and Yukon) had 3,902 intensive 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 care systems, including the supply and demand for essential goods such as intensive 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 alternate level of care patients to other sites to improve their acute care capacity in hospitals.

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

Q262. **How many ventilators does Canada currently have? How many will be needed when the epidemic reaches its peak?**

The procurement order between the federal, provincial and territorial governments also includes ventilators. The federal government has signed contracts for more than 1,500 ventilators and is working to facilitate the acquisition of 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 evolves.

Q263. **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 swabs, and hand sanitizer.

The Government of Canada (Innovation, Science and Economic Development Canada, Public Services and Procurement Canada, Health Canada and the Public Health Agency of Canada) is engaged in ongoing discussions to explore various avenues for procuring PPE and increasing 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 frontline responses, Health Canada and the Public Health Agency of Canada are now conducting technical assessments. This is in line with the Interim Order, recently signed by the Minister of Health, which allows accelerated access to medical devices related to COVID-19. The list of authorized devices for diagnosing COVID-19 (with dates of authorization) can be found here, and medical devices licensed in Canada are included in the Medical Devices Active Licence Listing.

Q264. **Has Health Canada reached out to the RCMP's three 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. The government works directly with the provinces and territories to determine their needs and leverage their collective buying power through bulk purchases. The government is also accepting donations, increasing domestic industrial capacity and expediting the regulatory process to ensure that urgently needed products are brought to the Canadian market.

Q265. **Is the federal government considering a plan to expedite its assessment of medical supply donations to address the shortage of medical equipment?**

PHAC 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 has implemented interim measures to expedite imports of medical equipment and products, including disinfectants, hand sanitizers, personal protective equipment (masks, gowns) and swabs. More information on this topic can be found here.

Q266. **Does Canada have a stockpile of syringes, needles and other equipment required for a pandemic vaccination campaign?**

Currently, the National Emergency Strategic Stockpile (NESS) contains supplies to respond to a variety of threats and risks which could be used for a pandemic vaccination campaign, including sterile needles, syringes and gauze swabs, as well as personal protective equipment. These supplies could be used to supplement those held by the provinces and territories. It is not NESS's practice to disclose the 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.

Q267. **Will Health Canada procure adequate vaccination supplies in anticipation of the COVID-19 vaccine's availability?**

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 national COVID‑19 mass vaccination campaigns.

PHAC will continue to work with its provincial and territorial partners to identify potential supply chain gaps. It will be prepared to support the rapid procurement of additional supplies such as needles, syringes, PPE and medications which will be needed for COVID‑19 mass vaccination campaigns in Canada.

Q268. **What is the current wait time for Canadian PPE manufacturers (not importers) to obtain authorization for selling and distributing their products to health care facilities? How many companies are currently waiting for this authorization?**

Canada's *Medical Devices Regulations* (MDR) uses a system that separates medical devices into one of four classes – Class I representing the lowest risk and Class IV representing the highest risk.
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 importers or distributors of all four device classes to permit importation or distribution (sale) of a medical device in Canada.

The regulatory review process for authorizing medical devices has been modified in the context of the COVID‑19 pandemic. On March 18, 2020, the Minister of Health approved the Interim order respecting the importation and sale of medical devices for use in relation to COVID‑19. The Interim Order allows for an expedited review of medical devices required for the diagnosis, treatment, mitigation or prevention of COVID‑19, 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

There are currently 359 PPE applications being processed under the Interim Order. Most of these applications are on hold as Health Canada awaits additional evidence demonstrating that the devices meet the necessary requirements. The time needed to authorize an application related to COVID‑19 is highly dependent on the quality of the application and the supporting information provided to Health Canada. It currently takes approximately nine days on average to process an application with no deficiencies. The list of diagnostic devices authorized by Health Canada to test for COVID‑19 can be found on the following Health Canada web page: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/medical-devices/authorized/list.html.

Medical Device Establishment Licence Applications

Most PPE (e.g. masks, face shields, gowns) are Class I medical devices and are therefore considered low risk compared to other classes. Companies that wish to manufacture, import or distribute PPE must obtain an MDEL if they do not have an authorization number from the Interim Order. Health Canada's usual service standard for issuing an MDEL is 120 days. That said, our goal is to process MDELs related to COVID‑19 as quickly as possible in order to facilitate access to necessary medical devices.

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

As of April 27, 2020, Health Canada had expedited the issuance of more than 750 MDELs such as masks, gowns and respirators, with approximately 450 applications still pending.

To facilitate timely access to the supplies needed to help combat COVID‑19, Health Canada has established a temporary discretionary measure by assigning MDEL applicants an interim submission number while it continues to process applications as quickly as possible. The submission number allows an applicant to carry out licensable activities pending the issuance of the MDEL. As of April 27, more than 380 submission numbers have been assigned to applicants, while their MDEL applications continue to be processed. This interim 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 MDR and must ensure that the medical devices (Classes I to IV) they sell comply with the safety and effectiveness requirements set out in sections 10 to 20 of the MDR. Health Canada takes a risk-based approach to compliance and enforcement, the

primary objective being the mitigation of 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 import and sale of any non-compliant product. Examples of compliance and enforcement tools include written notices (regulatory letters and warning letters), inspections, public notices, seizures or impoundments at the border, and recalls, as outlined in Health Canada's document, *Guidance on Medical Device Compliance and Enforcement (GUI-0073).*

All authorized MDELs are posted on the *Medical devices establishment licence listing* website.

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).

Q269. **What has been the response to the federal government's call to respond to the need for medical supplies (https://www.ic.gc.ca/eic/site/080.nsf/eng/00048.html)?**

As a public health emergency measure, 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 to allow for expedited processing of medical devices related to COVID-19. The Interim Order will help ensure that medical devices related to COVID-19 are available to treat, mitigate or prevent COVID-19, if required.

As part of its response to the COVID-19 pandemic, the Government of Canada adopted the *COVID-19 Emergency Response Act* on March 25. Changes to the *Food and Drugs Act* allow Health Canada to implement more robust tools to help mitigate shortages and prevent shortages where practicable. 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, permitting the exceptional import 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 import of specific drugs that do not fully comply with Canadian regulatory requirements, such as bilingual labelling, but are manufactured to comparable standards, in order to secure Canada's drug supply and protect the health of Canadians during this period.

We are aware of the shortage of PPE and medical supplies in Canada and are committed to doing whatever it takes to protect the health of Canadians, especially frontline health care workers, from COVID-19. The Government of Canada continues to work with provincial and territorial governments to quickly assess the need for PPE including N95 masks, surgical masks, face shields, nitrile gloves, gowns and other protective clothing, and medical supplies such as disinfectant, ventilators, swabs and testing 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 tests. We have also received donations from national and international organizations. In addition, Health Canada has considered PPE conservation strategies, including the decontamination of respirators and the use of expired masks, to ensure these devices' ongoing availability.

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.

Q270. How has Canada solved the mask shortage while the United States has not?

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

To meet these needs, PHAC works with Public Services and Procurement Canada to process bulk supply orders. It allocates PPE and medical supplies to the provinces and territories using an approach agreed to by federal, provincial and territorial Ministers of Health. PHAC also sends PPE and respirators from the National Emergency Strategic Stockpile (NESS) to provinces and territories requesting assistance. NESS helps complement provincial and territorial resources by providing back-up support.

PPE shortages are an ongoing concern as global demand remains high. This 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.

Q271. What is PHAC's forecast for the amount of PPE required across various business lines in order to fully reopen the economy? Is there a breakdown by sector and region?

The government has adopted a multi-pronged approach to ensure access to medical supplies and PPE with the following measures:

- Researching and procuring PPE domestically and internationally
- Strengthening national production capacity
- Expediting regulatory approvals
- Publishing guidelines on the appropriate use of PPE
- Conducting quality reviews

Health Canada and PHAC are working closely with the provinces and territories to understand their needs for PPE in the health care sector and to allocate PPE appropriately.

Federal departments remain in regular contact with business leaders and industry associations in all sectors of the economy to better understand their PPE needs and strategies. Federal departments are also working with experts to better understand and assess the PPE needs of Canadian society and the economy, taking into account the latest public health guidelines.

A departmental working group on COVID-19 dedicated to personal protective equipment, chaired by the Minister of Public Services and Procurement, has been established to examine needs and consider PPE support for essential services beyond those provided by health care and frontline federal workers. This working group has also been tasked with identifying potential new areas of concern for future action.

For more information on the government's efforts to obtain equipment and supplies in response to COVID-19, including new and existing sources of supply, both domestic and international, please visit https://www.tpsgc-pwgsc.gc.ca/comm/aic-scr/provisions-supplies-eng.html.

Distribution and Quality Control

Q272. **When did Canada begin procuring personal protective equipment and supplies in response to COVID-19?**

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

Q273. **How much PPE was exported to China from mid-January to March 31, through all known channels (institutional, retail, community)?**

As announced on February 9, 2020, the Government of Canada deployed approximately 16 tonnes of personal protective equipment to China, in collaboration with the Canadian Red Cross and the Red Cross Society of China. You will find more information on these shipments here.

Q274. **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. It will also 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 frontline health care workers.

Q275. **As of May 1, how many shipments of PPE had been sent to the provinces through Amazon Canada?**

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

Q276. **Do you have any doubts about the quality of medical equipment donated to Canada?**

The Government of Canada receives medical supplies donated by companies in Canada and abroad and is working to make them available to frontline health care workers.

Currently, PHAC manages donations. A number of partners assist PHAC in processing all donations as efficiently as possible and in distributing 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 assessment committee was established to assess donated medical supplies. The committee verifies that these supplies 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. The evaluation process varies depending on the medical device.

The multidisciplinary and interdepartmental technical assessment committee comprises representatives of the Public Health Agency of Canada, in particular the National Microbiology Laboratory, as well as Health Canada and the National Research Council of Canada.

Q277. **Has the Public Health Agency of Canada rejected donations of supplies that it has assessed for quality? Has any equipment failed quality control tests in the last two months?**

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 their compliance with the Government of Canada's COVID‑19 technical specifications. When PHAC cannot account for the equipment's quality, the equipment is not allocated to the provinces and territories for primary health care purposes.

Some supplies received by PHAC have not met Government of Canada specifications for health care facilities. When supplies do not meet the specifications for primary health care, they are assessed 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. Since the arrival of COVID-19, PHAC has received a small amount of PPE that was not distributed because it was damaged in transit, and PHAC continues to assess PPE as it is received. The same applies to donations received by PHAC.

If pressed for more details:

Due to the intense global competition for PPE and medical supplies, countries are engaging with a number of new and diverse suppliers and manufacturers to meet the demands of the COVID‑19 response effort. PHAC therefore exercises due diligence with respect to products purchased by PSPC by verifying the quality of the supplies purchased and donated when it receives them. To date, PHAC has reported approximately one million KN95 masks as being non-compliant with specifications for health care facilities. These masks were not distributed to the provinces and territories for primary health care purposes, and the use of these masks in non-health care settings will be assessed at a later date.

Q278. What happens to items that do not pass inspection? Are they destroyed? Are they returned to the donor country?

PPE requirements for health care workers are more stringent than those applied to non-health care settings. Equipment that fails to meet specifications for health care facilities will be further evaluated for possible use in the community.

Q279. How many shipments of N95 masks were inspected and (a) accepted and (b) rejected?

The number of N95 and equivalent respiratory masks (e.g. KN95 respiratory masks) received changes daily, as does the number of respirators tested. N95 masks that do not meet COVID-19 technical specifications for health care facilities are not distributed to the provinces and territories and are subsequently assessed for use in non-medical settings.

If pressed:

To date (May 8), of the approximately 11.5 million N95 masks received, about 1.5 million masks met the COVID-19 technical specifications for health care facilities; approximately 8.5 million did not meet the specifications; 1.5 million of these masks are currently being tested.

Q280. Does the government require medical supplies used by local health agencies to meet certain standards? If so, what are they?

PHAC encourages suppliers to inquire online regarding in-demand products (including their specifications) and the expedited process to be followed.

Q281. How many swabs has Canada received to date and how many have been distributed?

The Government of Canada has ordered more than 11 million swabs from various domestic and international suppliers that are delivered in batches each week. In addition, we are 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 that are needed by 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 strives to allocate these swabs to the provinces and territories on a per capita basis without delay.

Q282. **Recent media coverage indicated 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? Will we receive other medical supplies from China that may not be usable because they do not meet Health Canada's criteria?**

When the provinces and territories identified problems with the swab stocks in question, the product was recalled by the company, which committed to taking corrective action and replacing the swabs.

The Government of Canada is examining options to provide a secure supply of sterile swabs for laboratory testing, including the possibility of producing swabs in Canada. The Government of Canada has ordered more than 11 million swabs and is supporting the provinces and territories in their laboratory testing efforts to ensure that the demand for swabs is met.

PHAC assesses personal protective equipment and other medical supplies received by the Government of Canada, whether donated or purchased, to ensure their compliance with the Government of Canada's COVID-19 technical specifications before they are shipped to the provinces and territories. If PHAC cannot account for the quality of equipment or supplies, it does not distribute them for primary health care purposes. The verification process varies depending on the medical device. For example, KN95 respirators, which are an accepted alternative to N95 respirators, are visually inspected for any design or construction defects and tested to confirm that they meet facepiece filtering specifications. Surgical masks and gowns 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 the specifications for primary health care, but they are subsequently assessed for potential use in non-health care settings.

Q283. **Has an investigation been launched to determine why ESBE Scientific's contaminated scientific equipment was sent to Canada?**

From March 28 to April 3, 2020, ESBE Scientific shipped 380,000 EZ Pro swabs to various locations in Canada. 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 the recall went smoothly. The Department posts all health product recalls in its Recalls and Safety Alerts Database. Information on the EZ Pro swab recall can be found here.

ESBE Scientific holds a valid Medical Device Establishment Licence (Business Number 103659). Health Canada will continue to work with the manufacturer to ensure it takes the necessary corrective actions and adheres to the appropriate protocols.

It was established that a treatment with ethylene oxide sterilizes the swabs. All provincial public health laboratories were notified on April 13, 2020. PHAC immediately made arrangements with

a company to sterilize the swabs. Health Canada authorized this sterilization process under the Interim Order signed on March 18, 2020. Provinces and territories can choose to either sterilize or discard the swabs.

The Government of Canada has ordered more than 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 examining ways to ensure a continuous and secure supply of sterile swabs, including options for producing and sterilizing swabs in Canada.

A contract was signed with PAMA Manufacturing and Sterilization (located in Mirabel, Quebec) for swab sterilization.

PHAC continues to work directly with the provinces and territories to identify their medical supply needs in order to place bulk orders. Public Services and Procurement Canada continues its work to identify all suppliers capable of meeting Canada's needs.

Q284. **Since 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, such as licensing and bilingual labelling, Health Canada is allowing these low-risk products to be distributed in Canada to meet the current, unprecedented demand and 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 any necessary appropriate action to protect the health and safety of Canadians.

Health Canada will continue to use all tools at its disposal to accelerate the delivery of safe and effective COVID-19-related health products. However, the Department does not provide 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 reactions associated with health products to Health Canada.

Q285. **Has Health Canada or PHAC received complaints about a batch of masks provided to Alberta health care facilities?**

PHAC is not aware of the circumstances surrounding the purchase and is therefore not in a position to comment. We have contacted Alberta to see if we can provide assistance.

Q286. **Are there concerns about 3D-printed medical devices that don't undergo the usual quality control or certification processes?**

COVID-19-related medical devices sold, imported or distributed in Canada must meet the safety, efficacy and quality requirements set out in the *Medical Devices Regulations* or the

Interim Order. Regulated devices include medical devices manufactured by 3D printing. Health Canada is 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.

Risks arise when devices such as personal protective equipment are not of sufficient quality to adequately protect patients and health care workers. We collaborate 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.

Q287. **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 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 PHAC and Health Canada is to help the provinces and territories get the PPE they need for frontline health care workers. PHAC has developed a guide for employers and employees on preventing the transmission of COVID-19 in the workplace. The most important measures are physical distancing, strict hand hygiene, respiratory etiquette, cleaning and disinfection of surfaces and objects, physical barriers, and restructuring the work space to ensure physical distancing.
The Government of Canada is working to assess needs in critical service sectors and to increase national capacity for PPE manufacturing.

Invitation to submit an expression of interest to provide logistics services

Q288. **What tasks will be assigned to the logistics service provider?**

The logistics service provider will manage customs documentation, secure storage, inventory management, as well as the declaration and transportation of personal protective equipment to various locations in each of the provinces and territories.

The logistics service provider will also be required to manage shipments by all modes of transportation, including receiving and transporting products from seaports, airports, train stations and commercial transition points.

Q289. **What is the term of the contract?**

Logistics services will be provided for one year and may be extended. Questions regarding the contract and the bidding process should be directed to PSPC.

Q290. **How is the Government of Canada currently managing the import and distribution of PPE in Canada?**

The Government of Canada is using existing National Emergency Stockpile System (NESS) locations and resources. In addition, on April 1, 2020, Amazon was awarded a contract to facilitate the distribution of large quantities of PPE and medical supplies to support the fight against COVID-19.

Q291. **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 does another agreement need to be established through 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 in support of the fight against COVID-19. Amazon is working directly with the Government of Canada and Canada Post to manage storage of products for frontline health care workers, and with Purolator to deliver these products 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 current agreement with Amazon. However, this new solution is intended to complement the services Amazon is currently providing; the service provider selected will also be able to use Amazon's technology.

Q292. **How is the NESS being used to store PPE and distribute it to the provinces and territories?**

Canada's NESS contains supplies that the provinces and territories can request in emergencies when their own resources are insufficient, such as during outbreaks of infectious diseases, natural disasters or other public health incidents. The purpose of the NESS is to provide emergency support to the provinces and territories; it is not intended to replace supplies that the provinces and territories have or procure. The provinces and territories are responsible for preparing and maintaining their own procurement capabilities.

Drug shortages

Q293. **What factors put us at risk of a drug shortage?**

Several factors can affect the availability of a drug and increase the risk of a shortage, including manufacturing disruptions, ingredient availability, supply chain disruptions and increased demand. Health Canada is working with companies and partners to determine the root cause of the shortages and mitigate the impact on patients as quickly as possible. Recently, the Department advised Canadians not to buy more drugs than necessary and advised health care professionals to avoid prescribing or supplying more drugs than necessary in an effort to help prevent shortages resulting from increased demand.

Q294. **What is the difference between an "actual drug shortage" and an "anticipated drug shortage"?**

An actual shortage refers to a situation where a market authorization holder for a drug is unable to meet the current demand for the drug in question. An anticipated shortage refers to a

situation where a market authorization holder for a drug can meet short-term demand but anticipates a disruption.

Q295. **What is the extent of COVID-19-related drug shortages, and what measures have been implemented to address them? What is the current drug shortage situation in Canada?**

One of Health Canada's top priorities is to ensure that Canadians have access to the medications they need during the COVID-19 pandemic.

Health Canada is actively monitoring the impact of COVID-19 pandemic on drug supply in Canada and is aware that increased demand has led to supply constraints and reported shortages. The Department is proactively reviewing the Canadian supply chain to identify areas where supply could be vulnerable and to address these vulnerabilities before shortages occur.

Our efforts have identified a significant increase in demand for certain products used to help patients with COVID-19. In some cases, manufacturers are reporting anticipated or actual shortages on https://www.drugshortagescanada.ca/, a website where companies are required to report shortages to help the health care system prepare for and respond to drug shortages.

These enhanced monitoring efforts include regular communication with the provinces and territories, industry, as well as health care and patient groups, in some cases on a daily basis. Health Canada also works with other international regulatory agencies, 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 on any global supply disruptions. This mobilization helped us better identify the early signs of shortages and possible mitigation strategies, and coordinate the response.

As part of the whole-of-government response to the COVID-19 pandemic, the *COVID-19 Emergency Response Act* was adopted on March 25. Changes to the *Food and Drugs Act* allowed Health Canada to implement more robust tools to support efforts to mitigate shortages that arise and to prevent shortages where practicable. For example, on March 30, the Minister of Health signed an Interim Order to help prevent or mitigate COVID-19-related shortages. This order allows for the exceptional import and sale of drugs, medical devices and food for special dietary purposes that may not fully meet Canadian licensing and labelling requirements, but are manufactured to comparable standards. Information for companies on how to request that a drug be added to the *List of drugs for exceptional importation and sale* are available on Health Canada's website.

Drug shortages identified as Tier 3 shortages may be added to the *list of drugs for exceptional importation and sale*. Tier 3 shortages are those that would have the greatest impact on both the drug supply and the Canadian health care system and that, in collaboration with the provinces and territories, as well as industry and health care professionals, are actively managed by Health Canada to identify measures that will mitigate patient impact. Currently, the Tier 3 list includes drugs used in therapy for 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 the Tier Assignment Committee, which includes federal, provincial and territorial government representatives, health professionals and industry stakeholders.

Collaboration with businesses to address current shortages and mitigate patient impact is Health Canada's top priority. The Department is also reviewing 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 supplies of these essential drugs.

The RFIs will be used to identify additional supplies not already reserved, to meet Canada's current needs. The Government of Canada is not seeking information about products that were already identified to alleviate a current supply constraint or shortage, but rather additional products to strengthen overall supply. RFIs were published for salbutamol, cisatracurium, fentanyl for injection, propofol, norepinephrine, epinephrine and azithromycin. The RFIs indicate that the government wishes to procure a supply of up to 12 months, which could be acquired gradually, at high levels of demand. The government will consider additional 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 of COVID-19-related shortages on Canadians. These efforts will help ensure that Canadians have access to the medicines they need during the COVID-19 pandemic now, and as the situation continues to evolve.

Q296. **When you say you're working with drug suppliers, what are you actually doing?**

Health Canada is working with industry, provinces, territories and other health sector partners to mitigate the impact of COVID-19-related shortages on Canadians. When Health Canada is notified of an anticipated or actual shortage, the Department works with companies throughout the supply chain to better understand the root causes, develop plans to address the shortage, and implement measures to mitigate impact on Canadians. If a critical national shortage were to arise, Health Canada would then collaborate with the company reporting the shortage, as well as other companies supplying the Canadian market, to explore all options to meet Canadian demand. This includes options to facilitate access to alternative sources based on need, and working with businesses that could increase their supply to Canadians.
Health Canada is also working with other federal departments, provincial and territorial governments, international partners and industry stakeholders to ensure that Canadians have access to the drugs and medical devices they need during the COVID-19 pandemic.

Q297. **How can the provinces and territories be vigilant about potential shortages in their jurisdictions?**

Addressing the complex problem of drug shortages is a shared responsibility that requires concerted action from the provinces, territories, manufacturers, distributors, health care professionals and the federal government. Health Canada works closely with the provinces and territories when they notify it of shortages that may be problematic.

In the event of a critical drug shortage, Health Canada works with stakeholders across the drug supply chain to coordinate effective communication of information and identify mitigation strategies. To determine the potential impact and what appropriate actions should be taken, the Department analyzes factors such as whether the shortage affects the country as a whole, whether there are alternative sources of supply, as well as the medical significance of the drug.

More information on roles and responsibilities regarding drug shortages can be found on our website.

Q298. **What is Canada doing to protect its drug supply?**

Health Canada tracks the source country of all drugs and active pharmaceutical ingredients (APIs) marketed in Canada, including those that are manufactured in China or APIs manufactured in China. Of the approximately 10,000 human drugs actively marketed in Canada, about 10% contain an API produced in China.

Q299. **Are there any concerns about the quality of drugs from China?**

Before approving a drug product for sale in Canada, Health Canada ensures that the formulation and the companies that manufacture it meet Canada's strict requirements for safety, efficacy and quality, regardless of whether the drug is manufactured in Canada or abroad. A company must obtain a Drug Establishment Licence (DEL) from the Department to manufacture, package, label, import, distribute, sell wholesale or test a drug intended for the Canadian market. When a drug product is manufactured, packaged and labelled or tested outside of Canada, the foreign establishment where these activities take place must be listed on the Canadian importer's DEL for legal importation of a drug product. For the foreign establishment to be listed on the DEL, it must comply with the Good Manufacturing Practices (GMP) set out in Part C, Division 2 of the *Food and Drug Regulations*.

The GMP compose a quality assurance system used to ensure that drugs, including APIs, are always manufactured, packaged, labelled, tested, stored, imported and distributed in accordance with strict safety and international quality standards. Any company wishing to sell a drug in Canada must comply with GMP before it can manufacture, import or sell the drug.

Health Canada reviews DEL submissions to determine whether an applicant meets the requirements set out in the *Food and Drug Regulations*, including GMP.

Importers are required to have detailed quality agreements with the appropriate parties, including foreign sites, to ensure that responsibilities are clearly defined and GMP-compliant. The agreements include a requirement to report to the importer any change or event that may affect the quality, safety or efficacy of a drug. Importers are in turn required to inform Health Canada of any significant changes in the quality, safety or efficacy of a drug so that Health Canada can verify that the changes are implemented correctly.

Health Canada authorizes the sale in Canada of drug products (including those imported for sale from foreign sites) only after it has sufficient data showing that GMP standards have been met. In Canada, all drug manufacturers are inspected by Health Canada. For foreign manufacturing sites, Health Canada conducts inspections or evaluates the results of inspections by trusted international regulatory partners, such as the U.S. Food and Drug Administration. Health Canada posts these inspection results on its website: https://www.drug-inspections.canada.ca/gmp/index-en.html.

While Health Canada, like other regulators, has temporarily suspended non-critical on-site inspections during the pandemic, we continue to work with the Canada Border Services Agency to verify compliance of imported shipments and are conducting remote GMP assessments, as required, to review records for compliance with GMP requirements.

Q300. **Can you confirm whether or not Health Canada is looking for alternative sources for salbutamol or Ventolin?**

Health Canada is aware that an increase in demand has led to shortages of a number of salbutamol inhalers, including Ventolin. Information about these shortages is available at https://www.drugshortagescanada.ca.

Health Canada is working closely with the industry, other federal departments, provinces, territories and other stakeholders such as the Canadian Thoracic Society to identify and implement mitigation options. This includes working with companies that can increase supply in the Canadian market and examining international supply options to ensure a continuous supply in Canada.

The Department has recently recommended that Canadians not buy more drugs than necessary, and urged health care professionals to avoid prescribing or dispensing more drugs than necessary, to ensure that all Canadians continue to have access to the drugs they need and to prevent shortages caused by increased demand.

Q301. **What is the current inventory of the following drugs: chloroquine and hydroxychloroquine; ritonavir/lopinavir; and ritonavir/lopinavir and interferon beta?**

Health Canada closely monitors the supply of any potential COVID-19 treatments and works with companies to ensure a continuous supply of those drugs in Canada, most specifically by collaborating 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 the drug.

Chloroquine is marketed in Canada by Teva, which reports a shortage of this drug. The expected end date of that shortage is December 31, 2022, due to an active ingredient shortage.

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 the drug.

Health Canada will continue to closely monitor the supply of these drugs in Canada and will continue to take the necessary steps in collaboration 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 inventory of specific drugs and should be contacted with questions about the market situation and availability of a particular drug. Canadians can also visit https://www.drugshortagescanada.ca for the latest information on reporting drug shortages in Canada.

Q302. What is Canada doing to ensure that there is an adequate supply of remdesivir in Canada? Do you currently have any or plan to get some? Would you consider a mandatory license if there is a shortage here?

Remdesivir is an experimental drug administered by intravenous infusion to certain patients hospitalized with COVID-19. Health Canada is closely monitoring the development of various treatment options for COVID-19, including remdesivir. The best way to access experimental therapies that could be used for the treatment of COVID-19 is through a clinical trial. Clinical trials provide Canadians with access to new treatments to prevent or treat COVID-19, giving the health care community the opportunity to gather information on the efficacy of the treatments and associated risks.

In Canada, remdesivir is available in two ways: through approved clinical trials and the Special Access Program (SAP).

To date, two clinical trials in several locations across Canada have been approved to use remdesivir to treat COVID-19. More information on approved testing is available on our website. Information from these clinical trials may help support a presentation 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 resubmission to Health Canada, Health Canada will exercise regulatory flexibility to expedite review and ensure Canadians have faster access to it, without compromising the safety, efficacy and quality of the drug. 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 wherever practicable, in order to expedite the review and approval process.

Prior to authorizing clinical trials, and for certain groups who may not have been eligible to access remdesivir in the trials, it 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. For individual professionals treating a patient with serious or life-threatening diseases and for whom traditional therapies have failed, are unsuitable or unavailable, the SAP can provide emergency access to unauthorized and non-marketed drugs. In some situations, it is possible to apply for a non-marketed drug, such as remdesivir, through the SAP. Each SAP application is reviewed on a case-by-case basis. To date, Health Canada has authorized twelve requests for remdesivir under the SAP.

Q303. Why did the federal government issue information requests asking pharmaceutical companies for data on the supply and demand of fentanyl, salbutamol, propofol and methotrimeprazine?

Health Canada is actively monitoring the impact of the COVID-19 pandemic on the drug supply in Canada and is aware that increased demand has led to supply constraints and reported shortages.

The Department has proactively studied the Canadian supply chain to identify areas where supply may be vulnerable and address such vulnerabilities before shortages develop. These increased monitoring efforts include regular engagement with provinces and territories, industry,

health care and patient groups, sometimes 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 on any global supply disruption. This engagement has allowed us to better identify early signs of shortages, develop potential mitigation strategies and coordinate response efforts.

A number of drugs, including fentanyl for injection, salbutamol, propofol and methotrimeprazine, have been identified as Tier 3 shortage drugs. Tier 3 shortage drugs are those that are currently in short supply or high demand and have the greatest potential impact on Canada's drug supply and health care system. Tier 3 shortage drugs are actively managed by Health Canada, together with the provinces and territories, industry and health professionals, to determine the steps they should take to mitigate the impact on patients. The Tier 3 list currently includes drugs used to help patients with COVID-19 such as muscle relaxants, inhalers, sedatives, blood pressure stabilizers, antibiotics and analgesics. It is updated as needs change. Tier 3 allocations are determined based on recommendations from the Tier Assignment Committee (TAC), which includes federal and provincial/territorial governments, health professionals and industry stakeholders.

The Government of Canada is currently studying the information submitted by companies in response to information requests. Health Canada will continue to work with other federal departments, provincial and territorial governments, international partners and industry to mitigate the impact of any COVID-19 related shortages on Canadians. These efforts will help ensure that Canadians have access to the drugs they need during the COVID-19 pandemic now and as the situation continues to evolve.

Q304. **Is there a shortage of fentanyl? Can you tell us who is affected by the shortage and why more is needed?**

Health Canada is actively monitoring the impact of the COVID-19 pandemic on the drug supply in Canada and is aware that increased demand has led to supply constraints and reported shortages.

The Department has proactively studied the Canadian supply chain to identify areas where supply may be vulnerable and address such vulnerabilities before shortages develop. These increased monitoring efforts include regular engagement with provinces and territories, industry, health care and patient groups, sometimes 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 on any sign of global supply disruption. This engagement has allowed us to better identify early signs of shortages, develop potential mitigation strategies and coordinate response efforts.

Fentanyl for injection has been identified as a Tier 3 shortage drug. Tier 3 shortage drugs are those that are currently in short supply or high demand and have the greatest potential impact on Canada's drug supply and health care system. They are actively managed by Health Canada, together with provinces and territories, industry and health professionals, to determine the steps they should take to mitigate the impact on patients. The Tier 3 list currently includes drugs used to help patients with COVID-19, such as muscle relaxants, inhalers, sedatives, blood pressure stabilizers, antibiotics and analgesics (including fentanyl for injection) and is

updated as required. Tier 3 allocations are determined based on recommendations from the Tier Assignment Committee (TAC), which includes federal and provincial/territorial governments, health professionals and industry stakeholders.

Health Canada will continue to work with other federal departments, provincial and territorial governments, international partners and industry to mitigate the impact of any COVID-19 related shortages on Canadians. These efforts will help ensure that Canadians have access to the drugs they need during the COVID-19 pandemic now and as the situation continues to evolve.

Misinformation

Q305. **What is Health Canada doing about ads or sales of products that make false or misleading claims about COVID-19?**

As of April 15, Health Canada has tracked nearly 200 cases of health products making false or misleading claims related to COVID‑19 through proactive monitoring or complaints received.

Health Canada has contacted everyone who has engaged in non-compliant marketing and asked them to immediately stop making illegal, false or misleading claims and remove the ads. If anyone refused, Health Canada would take stronger action, which could include stopping the sale of the product, site visits, public announcements, recalls or seizing products and advertising materials.

Health Canada has not approved any product to treat or cure COVID-19. In Canada it is illegal to sell or advertise health products that make false or misleading claims, as stated in the *Food and Drugs Act*.

On March 27, Health Canada posted an advisory to warn Canadians of the risks associated with products that make false or misleading claims related to COVID-19. The Department encourages anyone who has information about potentially non-compliant marketing of any health product that has not been approved by Health Canada to report it to the Department using the online complaint form. Health Canada will continue to keep Canadians informed by updating its online table of products with non-compliant advertising and the corresponding companies or advertising media.

When Health Canada becomes aware of a potential case of non-compliance with the *Food and Drugs Act* or its regulations, it takes steps to confirm or invalidate the non-compliance and intervenes if there is a risk to the health of Canadians. The Department will continue to monitor the situation and respond when needed to ensure that health products with false and misleading claims about the diagnosis, prevention, treatment or cure of COVID-19 are removed from the market.

Q306. **Is there a list of offending parties that the public can consult?**

To uphold its commitment to transparency, Health Canada publishes a weekly updated list of products for which the Department has acted or is acting with respect to non-compliant marketing and the parties who engage in it. Health Canada considers several factors when determining the appropriate steps in cases of non-compliance, including the compliance history of companies. The Department will continue to use the most appropriate measures to address cases of non-compliance and reduce risks to Canadians.

Q307. Has Health Canada been made aware of any misinformation or false claims about alcohol-based hand sanitizers?

In Canada, alcohol-based hand sanitizers are considered natural health products. Alcohol-based hand sanitizers that have been authorized for sale by Health Canada will have an eight-digit Natural Product Number (NPN) on the product label.

Health Canada has received complaints about health products that make false or misleading claims related to COVID-19. The Department is currently addressing these cases and has directed companies to remove such claims from their websites and advertising materials. Health Canada continues to monitor websites for these claims and is working with online retailers to ensure that the related products are removed. Selling or advertising health products with false or misleading claims is illegal. The Department takes this issue seriously and will do whatever it can to put an end to these activities.

On March 18, 2020, in light of the unprecedented demand and urgent need for products that can help limit the spread of COVID-19, Health Canada issued an advisory announcing that the Department is facilitating access to products that may not fully meet current regulatory requirements, as an interim measure. This includes hand sanitizers, disinfectants and personal protective equipment (e.g. masks and gowns), as well as swabs. While these products are typically subject to regulatory requirements such as licensing and bilingual labelling, the Department is allowing some products to be sold in Canada under this interim measure that may not fully meet all requirements. Health Canada has an updated list of products sold in Canada on its website for consumers to consult.

Health Canada is also expediting approvals of products and the granting of establishment and site licenses related to these types of products. A list of more than 550 authorized hand sanitizers has been published on the Department's website. The list is updated daily and includes information on both alcohol-based and non-alcohol-based hand sanitizers approved by Health Canada. If consumers see a disinfectant or hand sanitizer for sale that is making false or misleading claims, they are asked to report it to Health Canada via its online complaint form.

More information to help inform Canadians on buying and using drug and health products safely is available on the Buying and using drug and health products safely website.

Q308. Has Health Canada sent masks for analysis to ensure they are safe and not fraudulent?

With intense global competition for personal protective equipment (PPE) and other medical supplies, countries have had to contract 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 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 the supplies it purchases upon receipt. To date, PHAC has not found any fraudulent product. However, it has assessed some items that did not meet the technical specifications for use in health care settings in response to COVID-19. Those items were not distributed to the

provinces and territories for primary health care interventions and were subsequently assessed for use in non-health-related settings.

The Canada Border Services Agency (CBSA) may, at its discretion, send imported health products to Health Canada for review. When Health Canada receives a product, it assesses 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 steps to solve problems in connection with false and misleading claims related to COVID-19, including working with the Competition Bureau, PHAC and CBSA. Health Canada remains committed to managing risks to the public and has procedures in place to prevent these imported products from entering the Canadian market.

On April 14 Health Canada issued a warning after receiving reports that fraudulent and unlicensed N95 respirators that falsely claim to protect consumers against 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 with false and misleading claims related to COVID-19. The Department takes this issue seriously and will do whatever it can to put an end to these activities.

Q309. **Will Immune-Tami be authorized for sale in Canada?**

Health Canada has not authorized any Immune-Tami brand products and has not received any license application from MeOn Supplements.

Health Canada has opened a file after receiving a complaint about this product and will take steps to address any confirmed non-compliance with the *Food and Drugs Act* or Regulations.

Q310. **Is MonaLisa Healing licensed or authorized to produce products containing CBD in Canada?**

MonaLisa Healing is not authorized to conduct cannabis-related activities in Canada. The list of federal cannabis license holders can be found here.

On March 24, 2020 Health Canada sent a warning to MonaLisa Healing raising concerns about what appeared to be cannabis-related activities without a valid license and the non-compliant promotion of cannabis.

In its response to Health Canada, MonaLisa Healing confirmed that it has completely suspended all licensable activities with hemp CBD, including the prohibited promotion, that it will not conduct any licensable activity with hemp CBD without a valid license, and that it will not engage in any prohibited promotion to Canadians.

Health Canada can confirm that changes have been made to MonaLisa Healing's online presence, including the addition of a pop-up window informing website users that MonaLisa Healing CBD is not a cure or preventative for COVID-19.

If other instances of non-compliance with the *Cannabis Act* are found, the Department will take steps as required.

Q311. Has Health Canada seen other examples of claims about CBD in relation to COVID-19?

Health Canada continuously monitors the promotion of cannabis. No other cannabis product promotions related to COVID-19 have been identified at this time.

Health Canada publishes an updated weekly list of health products and e-commerce companies/platforms that do not comply with the *Food and Drugs Act* (FDA). If Health Canada becomes aware of false or misleading advertisements for products subject to the FDA, it will take all necessary compliance and enforcement measures to ensure compliance, which may include seizing the advertised product.

Cannabis products and their promotion are subject to the *Cannabis Act* and its regulations. Compliance and enforcement measures, including warning letters under the *Cannabis Act*, are outlined in Health Canada's quarterly inspection data reports. This information is currently being updated, and Health Canada plans to complete the update in the coming weeks.

Health Canada is committed to protecting the health and safety of Canadians and encourages Canadians to report any information or evidence of violations to the *Cannabis Act* by using this contact information.

Is Health Canada aware that MonaLisa Healing was selling CBD-infused products without a license and that a health claim was disseminated in an email to the effect that the products could 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 that is likely to create an erroneous impression about the product's attributes, including its health effects or health risks. Such promotion would include claims that a product may prevent or treat COVID-19.

When reviewing regulated activities to ascertain compliance with the *Cannabis Act*, Health Canada collects information and facts and studies each case separately. When it finds a potential offence with respect to promotion prohibitions as defined by the Act, Health Canada works with the individuals or companies concerned to promote compliance by making them aware of the prohibitions and giving them the opportunity to comply with their legal obligations.

The *Cannabis Act* contains a number of enforcement tools that may be considered in determining the appropriate actions to prevent or address cases of non-compliance, based on a review of the situation and all relevant information, including the health or safety risk and the compliance history of the individual or company.

Measures range from compliance promotion and awareness, which are intended to provide information and prevent non-compliance, up to measures intended to correct non-compliance or

address a public health or safety risk, such as a warning letter, suspension or revocation of a federal license, a ministerial order or an administrative monetary penalty (up to $1 million).

The Department took steps when it learned that MonaLisa Healing was announcing that its CBD product could help prevent COVID-19.

Health Canada sent a warning letter to MonaLisa Healing on March 24, 2020, expressing its concerns about what appeared to be cannabis-related activities without a valid license and the non-compliant promotion of cannabis.

In its response to Health Canada, MonaLisa Healing confirmed that it had completely suspended all licensable activities with hemp CBD, including the prohibited promotion, that it would not conduct any licensable activity with hemp CBD without a valid license, and that it would not engage in any prohibited promotion to Canadians.

Health Canada can confirm that changes have been made to MonaLisa Healing's online presence, including the addition of a pop-up window informing website 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 found, the Department will take action as required.

Q312. **Can you tell me if those of us who spend less time in the sun during the pandemic should be taking vitamin D supplements? Is there a link between the vitamin and virus?**

Sunlight is a source of vitamin D for Canadians, but it can also be obtained from supplements and food. For more information on vitamin D, including food sources and supplement advice, refer to the following page. Health Canada recommends talking to your health professional about taking a supplement if you think you are not getting enough vitamin D. More information on vitamin D, including Health Canada's current supplement guidelines, can be found at https://www.canada.ca/en/health-canada/services/nutrients/vitamin-d.html

Vitamin D plays many roles in the body, including building and maintaining strong bones and teeth and helping your body absorb calcium. In the absence of definitive randomized controlled trials, Health Canada cannot attribute any role or benefit to taking vitamin D supplements to build resistance to COVID-19. Health Canada is committed to prioritizing the acceleration of clinical trials for potential COVID-19 treatments or preventive drugs.

Health Canada recognizes the importance of promoting healthy eating and overall nutritional well-being, as well as the challenges that Canadians face with regard to COVID-19. Health Canada has created the following new Web pages to help Canadians make healthy food choices and apply food skills such as meal planning and mindful eating during the COVID-19 pandemic:

- https://www.canada.ca/en/health-canada/services/food-nutrition/healthy-eating/covid-19.html
- https://www.canada.ca/en/health-canada/services/food-nutrition/healthy-eating/covid-19/your-eating-habits.html

https://www.canada.ca/en/health-canada/services/food-nutrition/healthy-eating/covid-19/meal-planning.html

While healthy eating is important to your overall health, there are no specific foods or supplements that can help prevent COVID-19.

Reagents

Q313. How much supply of the chemical reagents used in testing to diagnose COVID-19 does Canada need?

Canada's response to COVID-19 depends on lab testing designed to quickly detect infection so that effective public health measures can be taken to reduce the spread. Canada's public health laboratories are working together within the Canadian Public Health Laboratory Network to make it easier to diagnose COVID-19 in accordance with validated testing protocols. The global shortage of testing reagents is affecting laboratory capacity. The Public Health Agency of Canada's National Microbiology Lab is meeting the provinces' needs for testing reagents by developing in-house reagents as an interim solution and by working with the industry to procure bulk supplies as soon as reagents are available. Our priorities are: access to reagents for testing, assessment of rapid tests at points of service and access to authorized test kits so that the provinces and territories are equipped to increase tests as needed.

Q314. Is bioMérieux's reagent the only one you made? Are you going to reproduce others?

Health Canada has been working with the Public Health Agency of Canada, other federal departments and the provinces and territories since the beginning of the COVID-19 outbreak to ensure a coordinated response to anticipate and meet Canadians' health product needs. The Department has been working diligently with manufacturers in Canada to market 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 recipes have been published and that can be used with existing testing devices, laboratory film and new models of NP (nasal) swabs.

Q315. Has bioMérieux sent its exclusive formula to the Public Health Agency of Canada?

bioMérieux Canada has granted the Government of Canada the right to manufacture its products for COVID-19 testing in Canada as part of an innovative public-private partnership.

The agreement with bioMérieux Canada provides for a temporary license. 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 run they will return to their normal functions.

Q316. Is Canada paying for bioMérieux's temporary license?

The Public Health Agency of Canada has signed a temporary license agreement with bioMérieux Canada to receive the rights and formulation of its reagents used in the diagnosis of COVID-19 at no cost. The production systems used to manufacture these reagents are in various stages of development and testing with a view to alleviating some of the shortages of reagents in the near future. If successful, this will improve access to COVID-19 test kits.

Q317. **Why has LuminUltra not yet supplied reagents to the certified labs?**

LuminUltra has made an agreement with the provinces to manufacture reagents that can conduct up to 500,000 tests per week, and the company is fulfilling this obligation. LuminUltra shipped enough reagents for the equivalent of 1,542,240 tests on May 11.

LuminUltra shipped its first reagent lot on April 10, 2020, and is coordinating the shipment of reagents to public health labs across the country. Please contact LuminUltra for an update on its distribution plans.

Masks

Q318. **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 facepiece respirators as equivalent to standard N95 respirators in the context of the pandemic.

Q319. **Is the KN95 respirator NIOSH approved? Does it meet another equivalent medical standard?**

No. KN95 respirators are not NIOSH approved. They meet the GB2626-2006 standard, which is equivalent to NIOSH-42CFR84. For more information on equivalent masks and other supplies, please visit https://buyandsell.gc.ca/specifications-for-COVID-19-products

Q320. **Can a mask be sold that is advertised for non-medical use? Does it matter if there is no English text on the mask?**

If they are not used in clinical settings and are clearly labelled as being for non-medical use (for example, “not for medical use,” “industrial use only”), masks and respirators are not considered medical devices and are, therefore, not regulated by Health Canada.

Q321. **What is the status of Health Canada’s review of the “WOODBRIDGE INOAC MASK” and its potential for use in hospitals?**

Health Canada authorized the “WOODBRIDGE INOAC MASK” on April 4, 2020. It is designed to limit the wearer's exposure to hazardous particles. It is not a NG5 respirator, it is a level 3 surgical mask that can be used in a hospital setting in accordance with the manufacturer’s instructions.

Decontamination and reuse - N95 masks

Q322. **What possible decontamination methods are being evaluated?**

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 Flow Health Care Mini by Clean Works, and Bioquell hydrogen peroxide vapour generator) use a variety of methods, including vapourized hydrogen peroxide, ozone or ultraviolet light. New decontamination methods are being evaluated as applications are submitted under the interim order for medical devices.

Health Canada evaluates the proposed methods to ensure that they meet safety, quality and efficacy standards, and that key performance and safety requirements ensuring the integrity of N95 masks are maintained after reprocessing up to the validated limit of reprocessing cycles.

Q323. **Is there evidence to support these methods?**

Although the virus that causes COVID-19 is a new virus, evidence from previous studies using similar viruses supports the safety and efficacy of certain reprocessing methods.

Manufacturers will be required to provide evidence demonstrating the safety and effectiveness of the 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;
- proof that there are no residual chemical hazards associated with reprocessing;
- adequate labelling that describes the validated methods and reprocessing conditions performed on the respirator.

Q324. **What are the disadvantages of reprocessing compared to new masks?**

Health Canada recognizes that reprocessing single-use masks is one possible solution for ensuring a continued supply of masks for health care workers who rely on them for protection.

The guidelines from each authorized decontamination device manufacturer must be followed.

The fit is an extremely important aspect of using an N95 mask. The disadvantage of a reprocessed N95 mask compared to a new mask is that the nose has been folded and may not allow proper fit. For this reason, PHAC recommends that the respirator be returned to the original user to increase the likelihood of a good fit. If the reprocessed mask is returned to general circulation, it is critical to perform the standard seal check for the new user and ensure they only use a mask that fits their face properly.

Q325. **Is vapourized hydrogen peroxide already used in hospitals across the country to sterilize N95 masks? If so, since when? If not, when will this be possible?**

Hospitals have been permitted to use a vapourized hydrogen peroxide system to decontaminate N95 respirators since April 5, 2020.

Q326. **How can a health care worker be assured that an N95 mask that has been sterilized four times is as safe as a new mask? Is it 100% guaranteed?**

Decontaminating an N95 respirator with vapourized hydrogen peroxide is one method of removing pathogens from the respirator if the respirator needs to be reused in order to reduce the amount of equipment consumed. Decontamination is an acceptable way to make masks safe for reuse. N95 respirators can be decontaminated from one to twenty times, depending on the decontamination process used and as stipulated on the manufacturer's labelling.

Q327. **Have other regulatory agencies approved decontamination methods? Do we take this into account as well?**

Health Canada is aware that a number of devices have received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration for reprocessing N95 masks (link). Health Canada continues to evaluate guidelines from other agencies, such as the U.S. Centers for Disease Control and Prevention (CDC), to optimize the reuse of respirators.

Chloroquine/hydroxychloroquine

Q328. **What is this medicine usually used to treat? What are its approved indications?**

Hydroxychloroquine is an antiparasitic drug indicated for treatment of malaria and auto-immune diseases such as rheumatoid arthritis and lupus.

Q329. **Are there any clinical trials underway to determine if this drug is effective in children?**

Yes, Health Canada has authorized a clinical trial for the use of hydroxychloroquine to treat COVID-19 in children in Canada. The Department is also closely monitoring the progress of other clinical trials underway elsewhere in the world.

Companies and health care professionals involved in treating patients with COVID‑19 who are interested in conducting a clinical trial on the efficacy of this or other drugs are encouraged to contact Health Canada.

A list of approved clinical trials for the prevention or treatment of COVID‑19 or its complications can be found at the following address https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/list-authorized-trials.html.

Q330. **Can hydroxychloroquine be used to treat any patient with COVID-19? Would it work for everyone?**

There is some evidence that hydroxychloroquine may be effective in some patients. However, these are preliminary findings from a few small-scale studies. Furthermore, there is very little information on the safety and efficacy of hydroxychloroquine in children.

Q331. **Hasn't hydroxychloroquine been demonstrated as ineffective against COVID-19?**

Preliminary results of clinical trials for hydroxychloroquine vary. Each trial is designed to study the drug when it is used in specific patient groups for a specific purpose. The effect of hydroxychloroquine varies depending on its intended use (prevention or treatment of mild cases or treatment of severe cases in hospitalized patients). There is little information on its effectiveness in children who are very ill with COVID-19. The CATCO trial involves using hydroxychloroquine to treat children hospitalized with COVID-19. Collecting information through clinical trials remains the best way to determine whether hydroxychloroquine may have a benefit in preventing or treating COVID-19, and whether this benefit outweighs the risks associated with its use.

Q332. **Has Health Canada been informed of the amount of chloroquine that has been imported into Canada? How well equipped are we to control these imports, given the danger this product poses to the health of Canadians?**

Health Canada works closely with the Canada Border Services Agency (CBSA) to ensure that imported health products meet the regulatory requirements of the *Food and Drugs Act* and its implementing 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 if it complies with Canadian regulations. Imported health products that are found to be non-compliant are refused entry into Canada or may be seized by Health Canada. Chloroquine is a prescription drug in Canada used to treat malaria and extra-intestinal amebiasis. Under the *Food and Drug Regulations*, prescription drugs can only be imported by a practitioner, drug manufacturer, wholesale pharmacist, 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 90-day supply of a prescription drug, according to instructions for use, whichever is less. Any other importation of prescription drugs is illegal in Canada. In recent weeks, the CBSA has forwarded a higher number of commercial imports of chloroquine to Health Canada. Imports 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 into Canada.

When Health Canada finds a product to be non-compliant, it always takes appropriate action – including working with the CBSA – to prevent its importation. In 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 on the importation, sale or advertising of any health product that is not in compliance to report it through the online complaint form.

Q333. Has Health Canada investigated or charged anyone selling chloroquine or hydroxychloroquine as a treatment for COVID-19? Has Health Canada seized unauthorized hydroxychloroquine or chloroquine?

Health Canada has not approved any products to treat or cure COVID-19. The sale and advertising of health products that are unauthorized or that make false or misleading claims is illegal in Canada under the *Food and Drugs Act* (FDA). It is also illegal to promote, directly or indirectly, experimental therapies or the off-label use of authorized drugs.

Health Canada has begun to proactively monitor for health products that make false or misleading claims related to COVID-19. A list of products and companies/media that are deemed non-compliant is updated on a regular basis. To date, the Department has not discovered any cases of illegal, false or misleading advertising for chloroquine or hydroxychloroquine through its proactive monitoring of online sites.

Health Canada works closely with the Canada Border Services Agency (CBSA) to ensure that imported health products meet the regulatory requirements of the FDA and its implementing 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 if it complies with Canadian regulations. Imported health products that are found to be non-compliant are refused entry into Canada or may be seized by Health Canada.

As a result of a shipment of products from the CBSA, Health Canada seized a shipment of chloroquine that did not comply with applicable laws.

Canadians should not take any prescription drugs that have not been prescribed by a health care professional who can assess and counsel the patient about possible side effects – including serious side effects – and drug interactions. Health Canada has recently released a safety alert for Canadians regarding 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 purchase health products that claim, without authorization, to prevent, treat or cure COVID-19.

The Department takes this matter seriously and will not hesitate to use all means at its disposal to put an end to these activities. When Health Canada determines the existence or is notified of a potential non-compliance with the FDA or its associated regulations, it takes action to confirm whether non-compliance has occurred and then acts based on the risk to Canadians' health. A number of compliance and enforcement options are available to manage the risk to public health and safety posed by false or misleading claims associated with 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 take the necessary steps to ensure that health products making false and misleading claims with respect to the diagnosis, prevention, treatment or cure of COVID-19 are removed from the market. Any information

regarding the sale or advertising of potentially non-compliant chloroquine, hydroxychloroquine or any other health product as a treatment for COVID-19 should be reported to Health Canada through the online complaint form.

Q334. **Given the known health effects of chloroquine, if this drug is taken inappropriately or mixed with another drug it shouldn't be taken with, what advice does Health Canada have for Canadians who ship it here to take it as a precautionary measure to help prevent COVID-19?**

It is illegal to promote, directly or indirectly, experimental therapies or the off-label use of authorized drugs. If Health Canada becomes aware of the illegal promotion of an experimental therapy, it will contact the party involved to immediately stop the advertising and take whatever enforcement actions necessary to ensure compliance, which could include seizure of the advertised product.

Canadians should not take any prescription drugs that have not been prescribed by a health care professional who can assess and counsel the patient about possible side effects – including serious side effects – and drug interactions. Several serious side effects are associated with chloroquine, including heart rhythm problems, very low blood pressure, as well as 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 purchase health products that claim, without authorization, to prevent, treat or cure COVID-19.

Q335. **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); and
    - PSPs provide direct interaction with patients, caregivers and health care professionals to support patient care for a specific health care product. Hydroxychloroquine is often one of the suspect products in these adverse reaction reports.
- the large number of duplicate reports submitted to Health Canada in January and February 2020.
    - This can occur when an adverse reaction report is submitted 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 report for their product as a suspect product through, among others, another manufacturer or the Canada Vigilance adverse reaction online database.

Warnings:

- It is often impossible to determine if an adverse reaction reported to Health Canada is the result of the use of a specific health product. A person's health problems or other

health products they are using at the same time are other factors that could contribute to the reaction in question.

- Adverse reaction reports are suspected associations reflecting the opinion or observation of the person making the report. The information does not reflect any evaluation by Health Canada of the relationship between the health product and the reaction(s).
- Please refer to the following link for additional warnings regarding interpretation of information about suspected adverse reactions collected by the Canada Vigilance Program.

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

Q336. How will Health Canada assess the safety, security and efficacy of these health products?

The Interim Order permits 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 drugs and medical devices, Health Canada will assess and monitor the safety, security, quality and efficacy of all products that may be imported and sold under the interim order.

Manufacturers of drugs and medical devices will be required to meet strict monitoring requirements.

Q337. Is Canada assured of receiving an adequate supply of these items?

Difficulties in the supply of drugs, 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 sanitizers, to ensure that Canadians have continued access to these products.

Q338. How does the Interim Order compare to the interim measure the Department announced last week allowing 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 medical device shortages.

Q339. 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 as to what products can be imported and provide additional powers, such as the ability to authorize another company to manufacture, use or sell a patent-protected drug or medical device 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.

Q340. **What are the new requirements for reporting medical device shortages?**

Manufacturers and importers will be required to inform the Minister of any shortages in medical devices considered essential during the COVID-19 pandemic. Manufacturers and importers will have up to five days to inform Health Canada of an actual 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 actual and anticipated shortages of medical devices and drugs will help the Minister select products to be authorized for import and sale.

Q341. **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.

Q342. **What does the phrase "food for special dietary use" in the Interim Order refer to, besides infant formula?**

Foods for special dietary use 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 formula and other liquid formula designed for those who cannot eat solid foods.

Q343. **How will access to hand sanitizers and antiseptics be accelerated?**

The Interim Order amends a requirement that applied to applications for certification of biocide drugs (disinfectants for hard surfaces and certain hand sanitizers), in an effort to expedite the review and authorization process. Furthermore, the Interim Order removes the requirement for an establishment licence for certain hand sanitizers regulated under the *Food and Drug Regulations*.

Q344. **What is the government currently doing to address drug and medical device shortages that may be related to COVID-19?**

Health Canada is closely monitoring the potential impact that the COVID-19 pandemic could have on the supply of drugs and medical devices in Canada.

The Department continues to liaise with the pharmaceutical and medical device industry, as well as the provinces and territories, to identify signs of supply disruptions in Canada. The Department is also working with other 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 on any global supply disruptions.

Canadian regulations require pharmaceutical companies to report publicly on actual and anticipated drug shortages and terminations of sales on the drugshortagescanada.ca website within a specified time period. Provinces, territories, health care professionals or the public can also inform Health Canada of any signs drug and medical device shortages.

Health Canada has contacted all drug establishment licence holders in Canada to remind them of their obligation to report actual or anticipated drug shortages and to inform them 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 COVID-19 treatments and works with companies to ensure a continuous supply of those drugs in Canada, most specifically by collaborating with companies that are able to increase Canadian market supply.

The Department will continue to closely monitor this situation and take the necessary steps in collaboration with industry, provinces, territories and other stakeholders to ensure that Canada's drug supply is not interrupted.

Q345. **How will these changes help the government increase its capacity to manage drug shortages?**

These amendments will allow the Canadian government to implement better tools to help prevent and address shortages. For example, they are helping the government implement, through the Interim Order, a regulatory framework to authorize the importation of drugs and medical devices needed to prevent or address a COVID-19-related shortage.

Q346. **Will Health Canada use amendments to the *Patent Act* to circumvent patent protection (sometimes called compulsory licences) and allow other companies to produce patented drugs?**

The Government of Canada respects patent rights and their importance to business, and knows that industry will do everything in its power to meet Canadians' needs.

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 patent-protected drug or medical device in order to meet demand, when necessary supplies cannot be obtained from the patent holder.

Patent Act amendments introduced the week of March 22, 2020 would only be used in exceptional situations, and include several safeguards to protect the interests of patent holders, including guarantees that the patent holders receive adequate remuneration for the use of their patents and imposed limits on the duration of authorization.

The Minister of Health will be able to seek authorization for third party manufacturers to produce any necessary patented inventions through September 30, 2020.

To date, the Minister of Health has not had to exercise the powers provided for in Bill C-13 with respect to *Patent Act* amendments.

Expedited access to disinfectants, hand sanitizers and personal protective equipment, as well as swabs for testing

Q347. **Have these changes been made through a new regulation?**

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, including hand sanitizers, disinfectants and personal protective equipment (e.g. masks and gowns). This is not a new regulation.

Q348. **What does this new rule mean?**

This is an interim measure and an accelerated approach. It is intended to 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 authorize the sale of certain products in Canada under this interim measure, including:

- Products that are already authorized for sale in Canada, but do not fully comply with Health Canada requirements (e.g. labelling in only one official language, packaging that differs from licensed packaging).
- Products that are not authorized for sale in Canada, but are authorized or licensed in other countries with regulatory and quality assurance frameworks similar to those in Canada.

Health Canada will authorize the distribution of these low-risk products in Canada to address the current shortage of supplies. The expedited process requires that a certification form be completed. This 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 any necessary, appropriate action to protect the health and safety of Canadians.

Q349. **Is Health Canada making efforts to contact manufacturers to encourage them to import more products?**

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 authorized for sale under this interim measure are added to the list posted on the website from Health Canada. At the time the notice was posted on March 18, only hand sanitizers and disinfectants had met the criteria for sale under this interim measure. Since then, medical devices have been found and will be added to the list in the coming days.

Q350. **How are medical devices regulated in Canada? What is a Class I device?**

Canada takes a risk-based approach to regulating medical devices, where the level of review prior to approval depends on the risk incurred when the device is used. This approach balances the need to provide the health system with rapid access to new and innovative technologies with the level of surveillance and time required to assess safety and effectiveness.

In Canada, medical devices are classified into four groups, based on the level of risk associated with their use. Class I devices present the lowest potential risk (e.g. mask or gown), while Class IV devices present the largest potential risk (e.g. pacemakers). To be sold in Canada, Class II, III and IV medical devices must be licensed. Companies that sell Class I medical devices in Canada are required to hold a Medical Device Establishment Licence. However, during the current pandemic, Class I to IV devices may instead be authorized under 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-related medical device. Furthermore, as is the case with hand sanitizers and disinfectant products, Class I medical devices that may not fully meet all regulatory requirements and that are reported to Health Canada under this interim measure are authorized for sale on the market.

How can consumers tell the difference between a fraudulent product and a product imported under this interim measure?

Health Canada will post an updated list of products sold in Canada under this measure on its website for consumers to consult.

Hand sanitizers and disinfectants authorized for sale by Health Canada have an eight-digit Drug Identification Number (DIN) or Natural Product Number (NPN) on the product label. These products are listed 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 being offered 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 authorized for sale by Health Canada are listed on the Health Canada website.

Q352. What other steps is Health Canada taking to improve the supply of health products during the COVID-19 pandemic?

The Minister of Health signed an interim order on March 18, 2020, to expedite access to medical devices related to COVID-19. The list of medical devices related to COVID-19 authorized under this interim order is available on the Health Canada website.

Q353. Is it possible to access medical devices and drugs that have not been authorized in Canada but are available in other countries?

Health care professionals can request access to medical devices related to COVID-19 that have not yet been authorized in Canada and medications related to the management of patients with COVID-19 through Health Canada's Special Access Program (SAP). Requests are evaluated on a case-by-case basis.

If you have any questions about the SAP for medical devices please contact the program by email.

Interim Order Regarding Medical Devices Related to COVID-19

Q354. When will Health Canada be in a position to approve the first test kits for COVID-19 as medical devices?

Health Canada is working with manufacturers to allow commercially available diagnostic devices to enter the market in order to strengthen Canada's diagnostic capacity for COVID-19.

On March 13, 2020, Health Canada received two applications for diagnostic devices: one from Roche Diagnostics and one from Thermo Fisher Scientific. These applications were fast-tracked for approval. Health care professionals now have access to these devices through our Special Access Program (SAP).

Health Canada will immediately inform the appropriate laboratories, the Public Health Agency of Canada and the provincial and territorial ministries of health of the availability of these diagnostic devices.

Health Canada is also working with many other companies that are preparing information for the Department's review. These applications will also be fast-tracked for review.

Q355. How long does it take to review the applications sent to Health Canada regarding diagnostic tests for COVID-19?

Health Canada is working to increase access to diagnostic tests in Canada through an expedited review process. The list of authorized devices for diagnosing COVID-19 (with dates of authorization) can be found here, and medical devices licenced in Canada are included in the Medical Devices Active Licence Listing.

On March 18, 2020, the Minister of Health signed an Interim Order to allow expedited access to COVID-19-related medical devices for use by healthcare providers, including test kits. This is an important development in the fight against COVID-19. The Interim Order will help ensure quicker and more flexible approval of the importation and sale of medical devices that are necessary for Canada's response to COVID-19, including test kits.

Q356. 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 diagnostic laboratory test kits, in Canada. It will help ensure access to medical devices that will make screening faster and more convenient, especially as samples will not have to be sent to the National Microbiology Laboratory in Winnipeg. Thus, the test results will be available more quickly.

Point-of-care diagnostic tests are under development and could be used as a result of this Interim Order. This would allow patients to be tested more quickly and conveniently. Rapid results will allow health care professionals and patients to take prompt action to help reduce the spread of the disease.

Q357. **How often are Interim Orders used?**

In recent years, Interim Orders have been necessary on a few occasions to allow rapid access to health products in exceptional circumstances, thereby mitigating a significant health or safety risk.

The last Interim Order was issued in August 2018 to facilitate the immediate importation and sale of AUVI-Q epinephrine auto-injectors as an emergency measure during a significant national shortage of EpiPens.

Another Interim Order was issued in July 2016 to allow immediate temporary access to naloxone nasal spray until a review for Canadian authorization was completed.

Q358. **How will Health Canada ensure that these kits are safe and effective?**

The Interim Order creates a tailored approval process for the importation and sale of medical devices that support Canada's response to COVID-19. The Interim Order and the related approval process provide the Minister with the flexibility to consider urgent circumstances surrounding the need for the device, authorizations from 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 authorized 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 strict post-market product safety requirements, including mandatory reporting of any problems, recall procedures and complaint handling.

Q359. **Is there a guarantee that Canada will receive a sufficient supply of diagnostic kits?**

We expect to receive a sufficient supply of diagnostic tests. It will be up to the company to provide kits if demand exceeds supply.

Q360. **Why is the use of the Altona RealStar SARS-CoV-2 PCR kit compliant 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 at the provincial level.

Q361. **Why are tests labelled "for research purposes only" exempt from the Medical Devices Regulations?**

Tests labelled "for research 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 for the Risk-based Classification System for In Vitro Diagnostic Devices.

National Emergency Stockpile System (NESS)

Q362. **Who manages the NESS? Where are the NESS's storage facilities located?**

The Public Health Agency of Canada (PHAC) manages the National Emergency Stockpile System (NESS). The NESS's facilities consist of a central repository in the National Capital Region and warehouses strategically located across Canada. For security reasons, we do not publish their locations.

Q363. **Is the stockpiling of PPE for NESS part of PHAC's mandate?**

In Canada, public health is a shared responsibility between local, provincial and federal levels of government. During a public health emergency, most needs will be addressed at the local level. The role of the federal National Emergency Stockpile System (NESS) is based on this shared responsibility.

The NESS provides surge capacity for emergencies when local and provincial/territorial resources have been depleted and is the sole provider of niche resources needed for rare public health events. As a result, the NESS stocks a moderate amount of personal protective equipment. However, in response to COVID-19, the Public Health Agency of Canada (PHAC) has made efforts to secure additional supply, including taking advantage of bulk purchasing mechanisms and working with domestic suppliers to support production. This includes playing a key coordinating role in the Government of Canada's pandemic response efforts by arranging for the distribution of inbound shipments to provinces and territories for their immediate health care use. This work is done in collaboration with various federal departments, including Public Services and Procurement Canada, Health Canada, Innovation, Science and Economic Development Canada and Indigenous Services Canada, as well as the provinces and territories.

Q364. **How large is the reserve and how will supplies be allocated and distributed?**

The Public Health Agency of Canada (PHAC) does not routinely release details on the stockpile contained in the National Emergency Stockpile System (NESS).

The NESS contains personal protective equipment and ventilators. In the current situation, the quantity of inventory is constantly changing as supplies are redistributed at the request of the provinces and territories to help them deal with peak demands.

Bulk orders for PPE and medical supplies have been delivered and the Government of Canada is rapidly allocating supplies to the provinces and territories 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 Stockpile System (NESS), the

Government of Canada supported the distribution of 6.8 million Medicom surgical masks, which were shipped directly to the provinces and territories. Ontario received its 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 guidelines 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 close to 300,000 expired N95 masks to the provinces and territories.

Q365. **Which provinces and territories obtained supplies from the NESS? What supplies are these?**

In order to meet immediate short-term needs, PHAC distributes NESS supplies based on requests for assistance. By April 6, the National Emergency Stockpile System had received and processed 23 requests for assistance from the provinces and territories. Items shipped by the NESS included N95 masks, surgical masks, face shields, gloves, gowns and ventilators. To maintain the NESS's inventory, a portion of the collaborative federal, provincial and territorial supply is kept on hand to provide surge support in response to urgent provincial and territorial needs.

Q366. **Modelling data from Alberta indicate that Alberta is waiting for six ventilators from the Public Health Agency of Canada. Are they from the NESS or another source?**

The Public Health Agency of Canada (PHAC) continues to deploy personal protective equipment and ventilators from the National Emergency Stockpile System (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.

Q367. **How many surgical masks and N95 masks does Canada currently have? How many will be needed when the outbreak reaches its peak?**

The National Emergency Stockpile System 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 efforts between the federal government and the provinces and territories are focused on acquiring large quantities of PPE, such as N95 respirators. Orders for PPE are starting to come in, and jurisdictions are discussing approaches for the allocation of this equipment that will ensure an effective health system response to COVID-19.

On May 8, of the approximately 11.5 million N95 respirators and equivalents (e.g. KN95 respirators) received to date, about 1.5 million met the technical specifications for health care facilities to respond to COVID-19, approximately 8.5 million did not, and 1.5 million respirators are currently being tested.

The N95 respirators and equivalents (e.g. KN95 respirators) that do not meet the technical specifications for health care facilities to respond to COVID-19 are not distributed to the provinces and territories and are then evaluated for use in non-medical facilities.

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, including ensuring that health care workers have the PPE they need to protect themselves and their patients' health.

Q368. **Why is the NESS facility in Regina closed and have the masks and gloves been replaced?**

The Regina warehouse was closed as a result of an independent assessment of the National Emergency Stockpile System (NESS) federal warehouse network, which concluded that using six warehouses instead of nine in Canada would ensure more efficient distribution without sacrificing response capability. For example, since the inception of NESS, Canada's transportation infrastructure has improved, making it easier to maintain the same 24-hour delivery target with fewer warehouses.

In addition to masks and gloves, other 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 also considered the value of the supplies versus the cost of shipping elsewhere.

Q369. **How many masks and gloves were discarded and why?**

The National Emergency Stockpile System (NESS) regularly reviews its inventory of material and, as part of this review, expired material is disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel. In 2019, approximately 2 million expired masks and 440,000 expired gloves were disposed of with the closure of the National Emergency Stockpile System (NESS) warehouse in Regina. The masks and gloves had been purchased in 2009 and had exceeded the five-year limit for their use as recommended by the manufacturer.

Although the World Health Organization allows the donation of personal protective equipment, it requires that any equipment must still be supported by the manufacturer for at least two years. This means that the equipment must be donated two years before it expires.

The Public Health Agency of Canada (PHAC) follows strict guidelines when it deploys equipment. If the Agency cannot report on the quality of the equipment, it will not deploy it. Even in the current circumstances of the COVID-19 pandemic, where Health Canada guidance authorizes the deployment of expired personal protective equipment, the Agency would look very closely at any equipment that is five years old or older. This practice is consistent with manufacturers' recommendations.

Q370. **How many other NESS warehouses and inventories have been disposed of or closed in Canada in recent years? How many remain?**

Over the past few years, the NESS has gone from nine warehouses in Canada to six. The independent assessment indicated that the six strategic locations would allow the NESS to continue its back-up support role in a timely manner.

Q371. **Has the number of PPE supplies decreased as a result of the reduction in the number of NESS warehouses or has the same level of PPE supplies simply been consolidated in the smaller number of locations?**

The quantity of personal protective equipment supplies stored by the National Emergency Stockpile System is not directly correlated to the number of warehouses across the country. When a warehouse was closed, everything that was usable was moved to a new location, and anything that was damaged, expired, unusable or obsolete was disposed of in accordance with the Treasury Board Directive on Disposal of Surplus Materiel.

Q372. **Why doesn't Ottawa have a plan to release NESS medical supplies to other users before they expire (i.e. provincial health care systems)?**

NESS's mandate is to provide back-up support to the provinces and territories, as well as federal populations such as the Correctional Service of Canada. NESS provides supplies that provinces and territories can request in emergencies when their own resources are insufficient, such as infectious disease outbreaks, natural disasters and other public health events.

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. The NESS will explore ways to optimize life-cycle management of products to minimize the disposal of obsolete inventory, while continuing to prioritize end-user safety.

Q373. **How is personal protective equipment distributed and how is it prioritized?**

The Government of Canada and the provinces and territories have agreed on a strategy for the distribution of personal protective equipment.

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 testing supplies. The allocation of these supplies is the subject of a collective (F/P/T) decision that is helping the Canadian 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 Stockpile System (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 items from NESS, provinces and territories must submit a Request for Assistance (RFA). PHAC responds to RFAs when it receives them and allocates supplies to provide surge support to provinces and territories while maintaining a prudent inventory in the NESS for surge

support. In the current situation, due to the high demand for PPE worldwide, it is recommended that provinces and territories submit RFAs for short lead times (e.g. peak needs for one or two weeks) with the flexibility to send additional RFAs as the epidemic unfolds.

Q374. **Is the Government of Canada responsible for replenishing the National Emergency Stockpile System or is this the responsibility of the provinces or territories?**

The NESS's mandate is to provide crisis support to the provinces and territories, as well as to federal agencies such as Correctional Service of Canada.

PHAC, in conjunction with Public Services and Procurement Canada, has placed bulk orders of PPE to meet the needs of the provinces and territories, which are working very hard on their own to ensure they have the necessary equipment for front-line health care workers.

Canada receives orders for supplies and redistributes the majority of them to the provinces and territories, but retains a small portion to replenish the NESS for future peak demands.

Q375. **Have NESS inventories been increased since the COVID-19 outbreak?**

Orders for personal protective equipment (PPE) and medical supplies were placed early on by the federal government and the provinces and territories to supplement their current inventory. On March 9, the Prime Minister and the Deputy Prime Minister wrote to all provincial and territorial premiers announcing 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 orders for PPE supplies to meet the needs of the provinces and territories, which, in turn, are actively trying to obtain the equipment they need to deliver front-line health care.

Canada is receiving supply orders and jurisdictions are working together to ensure the health system's ability to respond to COVID-19 while replenishing the NESS's inventory to meet peak demands.

We continue to do our best to keep the public informed of the widely varying numbers of PPE; however, our priority is to obtain this protective equipment and distribute it to the provinces so that health care workers who need it most can access it.

Q376. **Is the NESS fully integrated with other medical device repositories in Canada?**

NESS's mandate is to provide emergency assistance to the provinces and territories, as well as federal populations such as the Correctional Service of Canada. However, as part of the response to COVID-19, PHAC also accepts donations of medical supplies from other government departments, companies or countries for distribution.

Furthermore, under the Plan to Mobilize Industry to fight COVID‑19, the Government of Canada is directly assisting companies to accelerate 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 rapid assistance to Canadian companies conducting large-scale research with promising future outcomes and development projects to identify medical counter-measures to COVID-19, including vaccines and essential medical supplies.

Q377. **Was the notice recently posted on the government's Buy and Sell site a call for applications to find additional suppliers for the NESS?**

The Government of Canada is exploring all options for medical supplies, including personal protective equipment (PPE), to prepare for and respond to the COVID-19 outbreak.

The notice posted on the Buy and Sell website to identify additional suppliers will benefit federal, provincial and territorial governments, including the National Emergency Stockpile System (NESS).

More information on the Government of Canada's response can be found here.

Q378. **Does PHAC have to solicit bids to renew NESS supplies, or can PHAC use the emergency rule to purchase directly?**

PHAC follows the appropriate legislation, policies and guidelines with respect to 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 received a national security exception for the procurement of goods and services required by the Government of Canada to respond to the COVID-19 outbreak. With this authority, PHAC will not be required to solicit bids to renew NESS supplies and will work with Public Services and Procurement Canada to determine the best procurement strategy.

Q379. **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 evidence of the inventory?**

Following the 2010 audit, the Public Health Agency of Canada (PHAC) implemented an electronic inventory system to track the National Emergency Stockpile System (NESS) inventory. The provinces and territories are aware of the NESS's resources; however, for security reasons, PHAC does not release the NESS inventory to the public.

Q380. **What has changed since the 2011 NESS evaluation report?**

Since the 2011 evaluation, NESS has evolved to better align with the ever-changing risk environment and invests in strategic assets such as medical countermeasures and mini-clinics to increase the Agency's ability to respond to surge capacity requests during health emergencies. In addition, provincial and territorial partners and other stakeholders have been increasingly engaged to raise their awareness of NESS's capabilities. **Can you explain why the number of warehouses storing supplies from the National Emergency Strategic Stockpile has been reduced, and whether this has resulted in a reduction in the amount of personal protective equipment (PPE) stored by the federal government?**

Canada's National Emergency Strategic Stockpile (NESS) contains supplies that are made available to provinces and territories for emergencies when their own resources are insufficient, such as when infectious disease outbreaks, natural disasters and other public health events occur. The purpose of the NESS is to provide backup to the provinces and territories; the stockpile system is not intended to replace supplies held or procured by the provinces and territories. 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 the NESS. For example, blankets used to be part of the stockpile, but are now available through other mechanisms, so the NESS no longer needs to stockpile as many of them. As the NESS has modernized, it has focused on storing strategic medical supplies that are not generally held by provinces and territories, such as drugs and vaccines that require controlled environmental conditions.

Following an independent assessment of the federal warehouse network, the NESS has decreased from nine to six warehouses across Canada to provide the most efficient distribution system possible without compromising response capability. For example, since the creation of the NESS, Canada's transportation infrastructure has improved, making it easier to maintain the same 24-hour delivery target with fewer warehouses.

The 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 the supplies needed to respond to a potential outbreak in Canada.

Q382. **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 were deployed to Nova Scotia and Newfoundland and Labrador. What happened to these stocks?**

The National Emergency Strategic Stockpile (NESS) was established during the Cold War to provide medical and social service supplies in response to public health emergencies, particularly nuclear disasters. Mobile field hospitals were a relic of that era and no longer met today's standards of care in Canada. As of 2013, the inventory from these field hospitals was either reallocated for continued use in the 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 retained 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 retained an entire field hospital as an artifact.

Q383. **In the early 2000s, there were ten regional warehouses; there are now five. Why was the decision made to decrease the number of locations?**

Until 2011, the NESS consisted of a series of 11 warehouses in 9 locations. The decision to modernize and optimize the warehouses was taken in 2013. These measures were introduced to reflect changes to the NESS's new operating environment, which included improving the capacity of partners (federal, provincial/territorial and non-governmental organizations) and improving transportation infrastructure, thereby reducing the time it takes to deliver goods across Canada. An independent evaluation of the NESS's federal warehouse network concluded that using six warehouses across Canada instead of nine would ensure more efficient distribution without sacrificing response capability.

In 2019, all the 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 response to COVID-19.

Q384. **Has the NESS changed in the last 10 years? Has it declined or deteriorated since 2015 and have governments made any particular policy or funding changes?**

The National Emergency Strategic Stockpile (NESS) provides emergency health resources for surge capacity when local, provincial or territorial resources have been depleted. The NESS is not intended to replace supplies that provinces and territories hold or procure. The provinces and territories are responsible for preparing and maintaining their own procurement capabilities.

Since its inception, the NESS has adapted to the changing risk environment in Canada. For example, in the 1980s and 1990s, the NESS's scope expanded to include the capacity to respond to natural disasters and other emergencies by stockpiling supplies needed to support evacuations and care for displaced people—such as kits for reception centres. The 2000s was a period of dramatic change in the nature of threats to international security and public health, marked by the terrorist attacks of September 11, 2001, the 2003 SARS outbreak and the 2009 H1N1 pandemic. During this period, the composition of the NESS expanded to include supplies to respond to chemical, biological, radiological and nuclear threats. The NESS's composition began to move away from stockpiles of social service supplies (beds and blankets) to increase its stockpile of medical countermeasures and antiviral drugs—an essential treatment in response to viral outbreaks such as influenza pandemics. While the NESS's mandate has always been to provide emergency supplies to the provinces and territories as a surge capacity, it was during this period that its focus evolved to include improving the procurement of niche supplies. At the same time, the NESS's role in the procurement arena has been better

defined—both as a potential collaborative procurement organization and as a clearinghouse, paving the way for potential bulk purchases.

The NESS is used to store essential medical countermeasures (vaccines and other therapies) to respond to potential biological threats, as well as other consumer items, such as generators, cots, blankets, and mini-clinics, which the federal government or the provinces and territories may need. Historically, the NESS retained only small quantities of personal protective equipment (PPE), as all jurisdictions have traditionally procured PPE directly from known suppliers.

Since 2012-2013, the annual base funding for the NESS has remained stable at approximately $3 million a year. This funding is included in the overall funding identified for the Health Security Infrastructure program area reported in the Public Accounts. In addition to the NESS's core operating budget, investments have been made for specific initiatives, supply inventories and medical countermeasures. Over the last 10 years, these investments have varied year over year, and have amounted to over $79 million. This includes funding linked to specific purchases, such as a three-year investment in the smallpox vaccine that began in 2013-14 and the Ebola vaccine in 2014-15.

Q385. **Streamlining of the NESS stockpile has focused more on pharmaceuticals than medical equipment. Can you confirm this and explain why?**

That's right. The role of the NESS is to provide surge capacity in support of provincial and territorial emergency response. The acquisition of assets by the NESS is guided by the evolving threats and risks associated with emergency preparedness and response. The NESS focuses on its role as the primary provider of medical countermeasures not normally stockpiled by the provinces and territories. It also holds a stockpile of antivirals to support provincial and territorial surge capacity in the event of an influenza pandemic.

Provincial and territorial governments are primarily responsible for supplying equipment for health care services. In light of the unprecedented shortages of PPE due 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 allow for the delivery of supplies;
- Establish domestic production of certain supplies.

VACCINE AND TREATMENT

Q386. **Is there a vaccine that protects humans against coronaviruses? Although no vaccine is currently approved, are any vaccines being developed or tested?**

Currently, there is no approved vaccine that protects humans against coronaviruses.

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 vaccines for COVID-19.

The Public Health Agency of Canada and the Canadian Institutes of Health Research, in consultation with international partners, including WHO and the Global Research Collaboration for Infectious Disease Preparedness, are assessing how our National Microbiology Laboratory scientists, along with Canada's research community, can help in the global research efforts.

Q387. **Canada is spending millions of dollars to fund vaccine research. If a Canadian task force succeeds in developing a vaccine, will the first doses go to Canadians first? Is this an explicit condition of any Canadian funding?**

The Government of Canada recognizes that access to the right tools and technologies to combat COVID-19, such as vaccines, will be critical to our response. Canada has joined other G20 countries in committing to bolster coordination towards rapid development, manufacturing and distribution of vaccines, while adhering to the objectives of efficacy, safety, equity, accessibility and affordability.

The federal government invests 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. The government's support for vaccine development will put Canada in a better position to quickly access a vaccine 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 results of the research they fund and do not control the commercialization of the research, as it is the researchers receiving the funds and their organizations that are responsible for them. Therefore, researchers and their institutions would be the initial holders of intellectual property rights.

Getting the vaccine to Canadians first was not a condition of CIHR and NSERC funding. Conditions apply primarily to the free sharing of research findings and data related to the COVID-19 epidemic, for example in peer-reviewed journals and among researchers. All CIHR funding conditions can be found on the CIHR website.

One of the conditions of NSERC funding was that applicants had to demonstrate that the proposed research would benefit Canada. Applicants were required to make this demonstration based on the characteristics of each project they proposed. In the context of the COVID-19 grants, researchers were informed that the discoveries would be open access and would be proactively communicated to government authorities who could use them appropriately to produce results for Canada in a timely fashion.

The National Research Council’s Human Health Therapeutics Research Centre also conducts vaccine research. When this work is done in collaboration with external partners, our collaboration and technology transfer agreements ensure benefits for Canadians. If NRC-supported activities result in a candidate vaccine or new analytical tests, specific distribution

plans will be developed in consultation with the Public Health Agency of Canada, where appropriate.

Q388. **Which company is associated with the vaccine candidate that the Prime Minister referred to today (May 19) when he announced that the first Canadian clinical trials have been approved to begin? Is it the same vaccine as the one mentioned here in the Health Canada news release? Can you give us some details about these trials; for example, when will they begin?**

Previously approved media response from media lines to answer both questions:

On May 15, 2020, Health Canada approved a clinical trial application from CanSino Biologics for a COVID-19 vaccine. This is the first clinical trial application in Canada for a vaccine specifically designed to prevent COVID-19. This decision followed a comprehensive review of the application, which Health Canada determined met the necessary safety and quality requirements. A list of authorized clinical trials in Canada with supportive care or treatment for COVID-19 is available online.

Health Canada is committed to protecting the health and safety of Canadians and has a rigorous scientific review process in place to ensure that authorized vaccines are safe and effective in preventing the diseases they target. The Government of Canada continues to monitor and support emerging science, and is committed to ensuring that our domestic efforts and international contribution are supported by the best available evidence and aligned with global efforts.

Q389. **Would Canada impose limits on vaccine exports to ensure that Canadian-made products are available to Canadians?**

To date, Canada has not imposed any new export restrictions in response to COVID-19 and has been working to facilitate trade through temporary duty and tax exemptions to encourage the importation of supplies that public health authorities, health care centres (e.g., hospitals, testing sites) and first response organizations desperately need 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 have access to the medicines, 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 (VIDO-InterVac);

- is 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;

- is providing support through the Strategic Innovation Fund to Medicago, a company that has identified a viable plant-based vaccine candidate currently at the pre-clinical testing phase, to allow it to rapidly move forward on clinical trials and then quickly shift to scaling up production for pandemic response;

- purchases materials from other countries and, only if necessary, establishes targeted, proportionate, transparent and temporary import and export measures.

Q390. **Has Canada committed to donating 10% of its reserve to WHO? What is Canada doing to ensure that vaccines will be available where they are most needed?**

In addition to domestic efforts, Canada is also a major contributor to international vaccine development initiatives. Through its funding of the Coalition for Epidemic Preparedness Innovations (CEPI), which is working closely with the World Health Organization to develop a vaccine against COVID-19, Canada is committed to supporting global efforts to develop and manufacture vaccines against COVID-19 that will be equitably available to all.

A cornerstone of CEPI is to ensure equitable access to vaccines for all affected populations during pandemics. In the context of the COVID-19 pandemic, this means that relevant vaccines developed through CEPI-funded initiatives will first be made available to populations when and where they are most needed to control an outbreak, regardless of geography or ability to pay.

The Government of Canada is a signatory to the Pandemic Influenza Preparedness Framework. Under this framework, manufacturers of vaccines or antivirals must commit to at least two of six options in exchange for biological materials needed to develop and test vaccines or antivirals. One of the six options is to donate at least 10% of real time pandemic vaccine production to WHO.

Q391. **Does Canada have a contract in place for the purchase of a pandemic vaccine with a supplier that can produce large quantities of vaccine in a timely fashion?**

There is currently no vaccine against COVID-19. Therefore, Canada cannot set up a procurement contract for the supply of a COVID-19 vaccine. Through investments of over $1 billion in medical research, the federal government supports multiple organizations working to develop vaccine candidates. There are currently more than 100 vaccine candidates in various stages of development by academics, small and medium-sized enterprises and large multinational pharmaceutical companies around the world, 10 of which are in Canada. It remains to be determined which of these vaccine candidates will be successful. Through its support for vaccine development, the government will be well positioned to gain rapid access to 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 only cover the production of egg-based influenza vaccines.

Q392. 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, which means that a person can be re-infected after recovering from an initial infection.

While the development of a vaccine that offers long-term immunity remains problematic, it may be possible to develop a vaccine that can offer short-term protection (similar to a pandemic influenza vaccine) to respond to a new coronavirus outbreak.

In the case of a vaccine against a particular coronavirus, it could take years for researchers to develop it.

For example, there is currently no licensed vaccine or specific treatment for the Middle Eastern Respiratory Syndrome Coronavirus (MERS-CoV), a particular coronavirus that was first identified in 2012. We know that work is being done elsewhere to better understand how to prevent MERS-CoV infections and to develop a vaccine against this virus. This includes vaccine development efforts coordinated by WHO and the Coalition for Epidemic Preparedness Innovations (CEPI).

Q393. How will Canada be able to guarantee a supply of a potential COVID-19 vaccine in an open market where other countries are also seeking to secure their own supply?

There are currently several vaccines in the research and development stage and it is not yet possible to determine which one(s) will be successful in preventing COVID-19 infection. As a result, the Government of Canada is supporting multiple organizations that are working at unprecedented speed to develop vaccine candidates. Government support for vaccine research and development, bio-manufacturing requirements to support large-scale production, improving capacity and access to clinical trials, and finding solutions for domestic capacity will all help to better position Canada to access a vaccine quickly once it becomes available. The Government of Canada is closely monitoring vaccine development efforts, both domestically and internationally, and will strive to quickly negotiate purchase agreements with the vaccine manufacturer(s) to make the vaccine available to all Canadians as soon as possible.

Q394. Once a COVID-19 vaccine is available, how will Canada produce or obtain the doses needed for Canada?

The Government of Canada is investing in promising projects to advance the development of vaccines and treatments, and improve access to them for Canadians. At the same time, the government is working to ensure the supply of a potential vaccine and other promising

treatments. While Canada already has industrial biomanufacturing capacity, a comprehensive process is underway to build domestic capacity and plan for the eventual global discovery of a proven vaccine as a result of the massive global efforts underway that will protect us from COVID-19.

Q395. **Could the PVC13 pneumonia vaccine be used to treat COVID-19?**

There is currently no vaccine or other health product licensed specifically for the prevention or treatment of COVID-19, as it is a relatively new virus.

In the case of vaccines or other health products that show promise for the treatment of COVID-19, including secondary infections associated with the disease, clinical trials are the best way to proceed, as they allow the health care community to systematically collect data on the effectiveness of treatments and the risks that may be associated with them. To date, Health Canada has not received any applications for clinical trials for the application of pneumonia vaccines as treatments for infections associated with COVID-19.

Health Canada is working closely with many potential sponsors of clinical trials for COVID-19 to facilitate access for Canadians. In order to facilitate faster access to therapeutic products needed to treat or prevent COVID-19, Health Canada will fast-track the regulatory process for any health product associated with COVID-19, including reviews and approval of clinical trial applications, while continuing to ensure the safety of trial participants. In addition to the work done by the professional societies, clinical trials are coordinated internationally and with the Health Portfolio in Canada.

Q396. **How are infected people treated?**

At this time, there are no drugs or medicines available to treat people who have contracted a new coronavirus infection. Researchers are examining the effectiveness of existing antiviral treatments.

The World Health Organization has provided advice to health care professionals, including recommendations for early supportive therapies, symptom management and prevention of complications.

The new coronavirus causes a range of symptoms from mild to severe depending on the individual. Therefore, if you have travelled abroad, it is important that you monitor your health when you return home. During your trip, you may have come into contact with the new coronavirus. PHAC advises you to monitor for fever, cough or breathing difficulties for 14 days after you return home. If you develop any of these symptoms, contact your health care provider or local public health authority to inform them. This person will advise you on what you should do.

Q397. **Is Health Canada investigating these reports, and are there any current guidelines regarding the use of vitamin C as a defence or treatment against coronavirus?**

Since the COVID-19 outbreak, Health Canada has taken steps to help Canadians access the health products they need to treat or prevent COVID-19. Currently, there are no drugs specifically approved for the treatment of COVID-19 because it is a relatively new virus. Much effort is being made to investigate possible new therapies, including drugs that may have been authorized for the treatment of diseases other than COVID-19. For drugs that show promise in the treatment of COVID-19, the best way to access therapies is through clinical trials that 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 progression.

In order to facilitate faster access to therapeutic products needed to treat or prevent COVID-19, Health Canada will fast-track the regulatory process for any health product associated with COVID-19, including reviews and approval of clinical trial applications. In addition to the work done by professional corporations, clinical trials are being coordinated across the health portfolio in Canada and around the world. The landscape is changing rapidly and the Health Portfolio is striving to adapt to changing needs.

Q398. **Are there any safety issues related to the use of ibuprofen by people with COVID-19?**

There is currently no scientific evidence linking ibuprofen, or other non-steroidal anti-inflammatory drugs (NSAIDs), to the worsening of COVID-19 symptoms.

If you have symptoms of COVID-19, talk to your health care provider about the most appropriate health products to relieve fever or pain. If you are currently taking ibuprofen, especially to treat a chronic disease, continue to do so.

Q399. **Can hydroxychloroquine and azithromycin be used to treat any patient infected with coronavirus? Will they work for everyone?**

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.

Evidence shows 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 disorder. A health care professional may choose to use these drugs off label, depending on the patient's situation, including the severity of their illness, if the potential benefits outweigh the known risks of the drugs.

In Canada, a doctor’s decision to prescribe a particular drug to a patient, whether for an approved indication or off label, is part of the routine medical practice. Although Health Canada regulates drugs, it is the responsibility of health care professionals, when prescribing a drug, to take into account data published in medical journals, reports, and peer-reviewed studies.

Q400. **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 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 remains to be confirmed. For drugs that show promise in the treatment of COVID-19, the best way to bring them to Canadians is through clinical trials. Clinical trials allow the health care community to systematically collect information about the efficacy of treatments and their associated risks. Therefore, Health Canada encourages manufacturers to work with researchers so that these drugs can be made available to patients with COVID-19 in the context of clinical trials.

As of April 8, 2020, Health Canada has approved two clinical trials for the use of hydroxychloroquine in the treatment of COVID-19. Health Canada has also approved nine other clinical trials using other potential therapies. A list of approved clinical trials for the prevention or treatment of COVID-19 and associated complications can be found in Health Canada's Clinical Trials Database. This database can be searched by entering "COVID" in the "Medical condition" field.

Q401. **What is Health Canada doing about products that claim to prevent, treat, or cure COVID-19?**

There are currently no vaccines for COVID-19 and no natural health products, including traditional Chinese medicines, licensed to treat or prevent COVID-19.

The sale of unauthorized health products or the making of false or misleading claims regarding the prevention, treatment, or cure of COVID-19 is illegal in Canada. The Department takes this issue very seriously and will take steps to put an end to this activity. To date, Health Canada has not approved any products to treat or cure COVID-19. Health products that have been authorized 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 related to products not authorized for sale on the Canadian market that make false or misleading claims regarding the treatment, prevention or cure of COVID-19.

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 through our online complaint form.

When Health Canada identifies or becomes aware of a potential non-compliance with the *Food and Drugs Act* or its regulations, it takes action to confirm whether non-compliance has occurred and takes action based on the risk to the health of Canadians. A number of compliance and enforcement options are available to correct non-compliance or mitigate a risk to Canadians, including site visits, public communications, recalls, and the seizure of products and promotional materials. 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.

Q402. **What action will Health Canada take in the event of non-compliance in relation to health products claiming to cure, treat, or prevent COVID-19?**

Under the *Food and Drugs Act*, the free distribution of a health product is considered advertising. If Health Canada becomes aware that companies are distributing free samples of unauthorized products or free samples of authorized products that make false and misleading claims, it will ask the parties involved to immediately put an end to this distribution and will take all necessary compliance and enforcement measures to ensure compliance, which may include seizure of the product.
As previously mentioned, Health Canada has not approved any products for the treatment or cure of COVID-19, including any traditional Chinese medicines. The sale of unauthorized health products or making false or misleading claims about COVID-19, its prevention, treatment, or cure, is illegal in Canada.
The distribution of free samples of authorized products making false and misleading claims or any other form of advertising making such claims is illegal and considered false and misleading. The Department takes this matter seriously and will not hesitate to use all the tools at its disposal to put an end to such activities.
Health Canada is currently reviewing this advertising issue and will take any enforcement measures necessary if non-compliance with the Act or Regulations is found.
The Department encourages anyone who has information regarding the sale or potentially non-compliant advertising of any health product claiming to treat, prevent or cure COVID-19 to report it using the online complaint form.

Q403. **Are there any natural health products, including traditional Chinese medicines, Ayurvedic medicines and homeopathic products, that protect against or treat this virus?**

No authorized natural health product is licensed to protect against or treat COVID-19. This includes traditional Chinese medicines, Ayurvedic medicines and homeopathic products.

Q404. **Is Avigan or favipiravir licensed in Canada? Is Canada taking steps to approve them?**

Avigan is the brand name for favipiravir. This antiviral drug has been approved in Japan and China for the treatment of influenza. Currently, no products containing favipiravir are approved in Canada.

Since the beginning of the COVID-19 epidemic, Health Canada has taken steps to facilitate Canadians' access to the health products they need to either treat or prevent COVID-19. In order to provide faster access to a vaccine or therapy for COVID-19, Health Canada will expedite its regulatory process for all COVID-19-related health products, including the review of submissions and authorization of clinical trial applications.

Health Canada has initiated discussions with companies whose products show promise in the fight against COVID-19, including the company that manufactures favipiravir. However, to date, Health Canada has not received any submissions for products containing favipiravir. It is

ultimately up to the manufacturer to decide whether they wish to obtain a marketing authorization for their product in Canada.

For drugs that have some potential for the treatment of COVID-19, such as favipiravir, Health Canada encourages sponsors to collaborate with researchers and offer drugs to patients in the context of clinical trials. This would ensure the informed consent of patients and allow the health care community to find out whether treatments are effective and what the associated risks are.

Q405. **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 are effective in treating COVID-19?**

At this time, there is insufficient evidence to recommend specific treatment for patients with a confirmed diagnosis of COVID-19 who are not participating in clinical trials. Clinical trials are under way to test a variety of experimental antivirals listed on https://clinicaltrials.gov/ or on the Chinese Clinical Trial Registry (http://www.chictr.org.cn/abouten.aspx). The development of clinical guidelines is under way with the support of the Association of Medical Microbiology and Infectious Disease Canada and the Canadian Critical Care Society.

It is possible to access drugs that are not available in Canada through clinical trials or the Special Access Program. In the event that there are sufficient data to support the efficacy of a drug in treating COVID-19 to submit an application to Health Canada, and this application is approved, the 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.

Q406. **What other regulatory flexibilities is Health Canada considering in addition to this ongoing review model?**

Companies interested in filing a submission for a drug to treat or prevent COVID-19 are encouraged to contact Health Canada to discuss the details of their submission and to indicate if there are other flexibilities that Health Canada should consider for their submission in response to the COVID-19 pandemic.

Fluzone High-Dose in long-term care facilities during COVID-19

Q407. **Does Fluzone High-Dose protect elderly people against COVID-19?**

No. There is currently no vaccine for COVID-19. However, by protecting elderly people in long-term care facilities from the flu, we are ensuring that this vulnerable group remains as healthy as possible and that our health care system is able to treat those who need it most.

Q408. **Will provinces and territories be allowed to use Fluzone® High-Dose purchased on their behalf for other groups within their jurisdiction?**

The doses of Fluzone® High-Dose purchased will be distributed equally to all interested provinces and territories for use in long-term care facilities. The COVID-19 pandemic places a

heavy burden of illness and death on the residents of these facilities. Given the concern that the spread of influenza in the fall and winter months could add significantly to this burden, the one-off initiative to secure a supply of Fluzone® High-Dose is designed to ensure that residents in long-term care facilities have the best possible protection.

If there are surplus doses during the flu season, only then will provinces and territories be free to use these surplus doses to vaccinate other eligible individuals in a manner that they deem best in accordance with the objectives of their vaccination program.

Q409. **Given the added protection that Fluzone® High-Dose provides to vulnerable elderly people in long-term care facilities, will the Government provide annual funding to the provinces and territories for the purchase of this vaccine?**

This is a one-off federal contribution to help the provinces and territories manage health care system capacity during the upcoming flu season in the context of the ongoing COVID-19 pandemic. Provinces and territories are responsible for the delivery of influenza vaccination programs and are in the best position to decide which vaccination products should be used in their programs and which populations should be covered.

Q410. **Will provinces and territories be able to purchase Fluzone High-Dose for other Canadians aged 65 years and older who do not reside in long-term care facilities?**

The COVID-19 pandemic places a heavy burden on the residents of these facilities in terms of illness and death. Given the concern that the spread of influenza in the fall and winter could add significantly to this burden, the one-off initiative to secure a supply of Fluzone® High-Dose is designed to ensure that residents in long-term care facilities have the best possible protection this fall and winter. The primary objective is that the amount of Fluzone® High-Dose purchased by the Government of Canada is distributed to all interested long-term care facilities for use in their facilities.

Each province and territory determines which populations will be covered by its public vaccination program. Provinces and territories that wish to offer Fluzone® High-Dose to Canadians aged 65 years and older who do not reside in long-term care facilities will be responsible for procuring their own additional doses. Each province and territory should be contacted directly for more information on the scope of their influenza vaccination program.

However, if provinces or territories have surplus doses, they will be free to use them to vaccinate other eligible individuals in the manner that they deem best in accordance with the objectives of their vaccination program.

Clinical trials

Q411. **Are clinical trials under way 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 under way around the world.

Companies and health care professionals involved in treating patients with COVID-19 who wish to conduct a clinical trial on the efficacy of these drugs or other substances are encouraged to contact Health Canada.

A list of approved clinical trials for the prevention or treatment of COVID-19 or its complications can be found in Health Canada's Clinical Trials Database by entering "COVID" in the "Medical condition" field.

Q412. **Are hydroxychloroquine or chloroquine being used in Canadian hospitals for trials or treatment?**

Two Canadian-approved clinical trials are being conducted at several locations across the country.

Since both hydroxychloroquine and chloroquine have been approved in Canada for the treatment of other diseases, medical practitioners may prescribe these drugs outside of their approved indications (off-label use). The use of unlabelled medications is within the scope of medical practice and is regulated at the provincial level.

Q413. **Are "human challenge trials" ever authorized by Health Canada? Is this WHO document one of the reference tools used by Health Canada in the development of its "human challenge trials" regulations? Or is there something else more up to date from WHO in this area?**

There are no COVID-19 vaccine trials currently under way in Canada, and Health Canada has not received any requests relating to challenge studies. The list of clinical trials authorized by Health Canada for COVID-19 is available online.

Under the *Food and Drug Regulations*, a clinical trial must be conducted in accordance with good clinical practices, with the approval of a research ethics board, with informed consent, and with extensive safety monitoring to protect the participant. If carefully controlled, it may be possible to conduct a challenge study to evaluate the efficacy of a vaccine. Health Canada's approach would generally comply with international best practices, such as guidelines from the World Health Organization and other major regulatory organizations.

Q414. **Can you give us details on how plasma therapy for COVID-19 works before it is approved?**

Health Canada has worked closely with clinical trial sponsors and blood suppliers, Canadian Blood Services and Héma-Québec, to provide regulatory and scientific advice in support of the development of this blood plasma trial 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 clinical trial applications for COVID-19, the review of this application

has been prioritized and is being expedited. The usual timelines for authorization of clinical trials depend on the information submitted in support of the trial and can be up to 30 days. Priority review timelines vary, but it is expected that this review will be completed within one to two weeks. The purpose of the Health Canada review is to protect the health of study participants or others, to ensure that the trial is in the best interests of the study participants, and to determine whether the objectives of the study will be met.

Q415. **What are the plasma donation criteria for men who have had sex with men (MSM) in the last three months? Will they be allowed to donate plasma, or is it the status quo?**

In order to conduct a clinical trial in Canada—including a trial using convalescent plasma from people who have recovered from COVID-19—a sponsor must submit a Clinical Trial Application (CTA) to Health Canada for review and authorization. The purpose of the Health Canada review is to determine whether the trial could endanger the health of the study participant or the health of others, whether the trial is in the best interest of the study participant, and whether the objectives of the study will be met. Regardless of the Health Canada review, the trial must also be approved by the research ethics boards associated with the trial sites before patients can be recruited. As a result, it is the responsibility of the sponsor of the CTA to determine the protocols for the conduct of the trial in their application. For trials involving plasma or blood products, this would include donor selection criteria.

To date, Health Canada has authorized a clinical trial on convalescent plasma for the treatment of COVID-19. This multi-centre trial is designed to determine the safety and efficacy of COVID-19 convalescent plasma collected from donors who have recovered from a COVID-19 infection to reduce the risk of intubation or death in adults admitted to hospital for a respiratory disease due to COVID-19. Canadian Blood Services and Héma-Québec will be responsible for supplying donor plasma for this clinical trial. Plasma will be collected and processed according to protocols already in place under Health Canada authorizations, including the current donor deferral for men who have had sex with another man in the past three months.

Q416. **Is Canada participating in the Solidarity II project led by WHO?**

As part of the World Health Organization (WHO) R&D Blueprint and response efforts in the fight against COVID-19, WHO has launched a multinational clinical trial to investigate possible treatments for COVID‑19.

The signatory countries to date are Canada, Argentina, Bahrain, France, Iran, Norway, South Africa, Spain, Switzerland and Thailand. Other countries may join later.

The objective is to generate reliable data by applying the same study protocol at multiple sites in order to obtain statistically reliable results from a sufficient number of patients.

The main researcher in Canada is Dr. Srinivas Murthy from British Columbia. There are currently 31 Canadian hospitals in various stages of activation to conduct this clinical trial.

Dr. Murthy received a grant of $954,936 from the Canadian Institutes of Health Research to study treatments through observational studies and randomized controlled trials.

Initial interventions to be included are: 1) a combination of lopinavir/ritonavir currently marketed for HIV versus standard of care; and 2) hydroxychloroquine, currently marketed for malaria, which will be added to the protocol at a later date.

Q417. **Are there trials involving human volunteers (people who volunteer for live vaccine trials) for COVID-19?**

Health Canada has not received any requests involving research on human volunteers for vaccines for COVID‑19. The list of clinical trials authorized by Health Canada for COVID‑19 is available online.

Under the *Food and Drug Regulations*, a clinical trial must be conducted in accordance with good clinical practices, with the approval of a research ethics board, with informed consent, and with extensive safety monitoring to protect the participants. If carefully controlled, it may be possible to conduct studies on human volunteers to evaluate the efficacy of a vaccine. However, before doing so, we need to have enough information about the risks of the virus and how to mitigate them. Global scientific and clinical knowledge of this new virus, including its impact on people, continues to evolve. Health Canada closely monitors vaccine development around the world and collaborates with its international counterparts to share scientific knowledge. If an application for human volunteer trials is submitted to Health Canada, some of the factors to be considered in the assessment would also include international best practices.

Lianhua Qingwen capsules

Q418. **Have Lianhua Qingwen capsules been approved for sale in Canada? If yes, why?**

Lianhua Qingwen capsules have been licensed by Health Canada with the following recommended use: “This Traditional Chinese Medicine helps remove heat-toxin invasion of the lung, including symptoms such as fever, aversion to cold, muscular soreness, stuffy and runny nose, dry and sore throat, red tongue with yellow and greasy coating.”

All natural health products sold in Canada must meet the requirements of the *Food and Drugs Act* and the *Natural Health Products Regulations*. Health Canada evaluates the safety, efficacy, and quality of natural health products based on 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 the Lianhua Qingwen capsules (NPN 80033781) is available in Health Canada’s publicly accessible Licensed Natural Health Products Database.

Q419. **Are the Lianhua Qingwen capsules effective in curing COVID-19, as the manufacturer claims?**

At this time, no health products, including traditional Chinese medicines, have been authorized by Health Canada to treat or protect against COVID-19.

It is illegal in Canada 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 put an end to this activity. To date, Health Canada has not approved any products to treat, prevent, or cure COVID-19. The Department is taking steps to address complaints about unauthorized products on the Canadian market that make false or misleading claims regarding the treatment, prevention or cure of COVID-19.

Health Canada is in the process of reviewing this advertising issue and will take any enforcement measures necessary if non-compliance with the Act or Regulations is 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 through the online complaint form.

Q420. **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. Monograph: Ephedra provides detailed information on the requirements that must be met to ensure the safety of this ingredient in natural health products. All natural health products, including products containing ephedra, must be authorized by Health Canada and have a valid eight-digit Natural Product Number (NPN) or Homeopathic Medicine Number (DIN-HM) to be legally sold in Canada.

Q421. **Has Health Canada received any complaints about Lianhua Qingwen capsules?**

As of April 21, 2020, Health Canada has received two complaints regarding Lianhua Qingwen capsules. As a result of these complaints, Health Canada has opened files and is taking steps to verify if there have been any instances of non-compliance. Given that these are active and ongoing files, the Department is unable to provide details on the compliance and enforcement actions it might consider.

When Health Canada identifies or is notified of potential non-compliance with the *Food and Drugs Act* or its associated regulations, it takes action to confirm non-compliance and then takes action based on the risk to the health of Canadians. There are a number of compliance and enforcement options to correct non-compliance or mitigate a risk to Canadians, including site visits, public communications, recalls, and seizure of products and promotional materials. The Department encourages anyone who has information about a potentially non-compliant advertisement for a health product claiming to treat, prevent or cure COVID-19 to report it by sending us an email at drug-device-marketing@canada.ca or using the online complaint form.

Temporary Exemptions for Medical Treatment under the **Controlled Drugs and Substances Act**

Q422. **Has this exemption been requested by the provinces and territories?**

A few jurisdictions 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 to avoid potential problems with access to medical treatment during the pandemic.

Q423. 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 allowing pharmacists, registered and licensed to practise under the laws of their province or territory and who are authorized to perform activities with controlled substances, to exercise certain new activities. They will be able to carry out 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 contacting provincial and territorial regulatory authorities for more information.

Given the seriousness of the COVID-19 outbreak, Health Canada is working to take prompt action to help jurisdictions ensure Canadians have continued access to medicine.

Q424. What activities are pharmacists currently licensed to practise?

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. According to regulations under the *Controlled Drugs and Substances Act,* a pharmacist is authorized to sell or provide a controlled substance to a person if they have received a prescription or written order from a practitioner.

While these regulations do not allow pharmacists to prescribe drugs, other related activities included in the meaning of “sell” and “provide” are permitted as long as the quantity dispensed does not exceed the quantity originally authorized. These activities include, but are not limited to:

- **Adjusting the preparation:** Adjusting the dosage form of the prescribed medication
    - E.g. liquid formulation rather than pills
- **Adjusting dose and dosing regimen:** A structured plan that specifies how often a dose of medication should be ingested
    - E.g. from 20 mg per day for 5 weeks to 10 mg per day for 10 weeks
- **De-prescribing:** A planned and supervised process to reduce or stop the use of a drug
- **Part-filling:** Dispensing less than the total amount of the medication authorized by the practitioner
    - For clarification, this includes partial prescriptions requested by the patient, situations where there is a shortage in the pharmacy, or other situations where part-filling is the result of a discussion between the pharmacist and the patient.

In order to ensure better drug management and Canadians’ health and safety, Health Canada has provided pharmacists with an interpretation 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*.

Q425. If a patient does not have a prescription, can a pharmacist now prescribe a new medication?

This exemption allows pharmacists to renew or extend a prescription in order to provide the patient with access to a drug. Pharmacists are not permitted to prescribe new medical treatment involving controlled substances (e.g. narcotics).

Q426. **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 narcotics verbally (depending on the prescriber's scope of practice and provincial/territorial authorization).

Q427. **Is there a plan to permanently expand the activities that pharmacists can practise?**

Pharmacists are medication experts and play an important role in monitoring patients and medications to ensure their safe and optimal use.

To ensure better management of drugs and protect the health and safety of Canadians, in March 2019, Health Canada launched an official consultation to obtain input on how to modernize the role of pharmacists in the health care system. The Department is currently analyzing all comments received. There will still be an opportunity to comment on any draft regulation in the *Canada Gazette*, Part I. Health Canada invites everyone to participate in the consultation.

Q428. **Are there specific measures in place to assist supervised consumption sites during the COVID-19 pandemic?**

Health Canada recognizes that local pandemic precautionary measures may affect the operation of services and supervised consumption sites. The Department continues to work directly with site operators to assess situations on a case-by-case basis and determine appropriate modifications to their protocols and practices. Operators are encouraged to contact the Exemption Section of the Office of Controlled Substances by e-mail (hc.exemption.sc@canada.ca).

VIRUS TRANSMISSION

Q429. **How is COVID-19 transmitted?**

Based on current evidence, COVID-19 is most often transmitted from an infected person:

- through respiratory droplets produced when an infected person coughs or sneezes
- through close personal contact with an infected person, such as direct contact or a handshake
- by contact with surfaces contaminated with the virus, followed by contact of unwashed hands with the mouth, nose or eyes.

Generally speaking, coronaviruses form a large family of viruses, some of which cause disease in humans, while others circulate in animals, including camels, cats and bats.

Q430. **What is the current base reproduction number in Canada for the coronavirus outbreak?**

The most recent estimate of the rate of transmission (reproduction number) across Canada is less than one, meaning that an infected person infects less than one person. This indicates that the epidemic is now getting under control in Canada. This rate decreased from more than two (i.e. one infected person infects more than two others, on average) in early March. The reduction in the rate of transmission is a result of the public health measures implemented, including physical distancing, and the high degree to which Canadians have complied with these measures. To keep the rate of transmission low, Canadians must continue to practise physical distancing, wash their hands frequently, cough or sneeze into a tissue or elbow, and stay home and away from others when ill.

Note that the estimate of the reproduction number depends on the monitoring data and the method used to calculate it. Changes in the reproduction number over a period of at least one week are more revealing of what is happening in the COVID-19 epidemic than examining single-day estimates.

Q431. **Can COVID-19 be transmitted even when a person has no symptoms?**

Now that more countries have recorded numerous cases and analyzed the methods by which the virus spreads, recent studies prove that infected people can transmit the virus even before they have symptoms. This is what we call *pre-symptomatic transmission*.

Data also shows that some infected people can transmit the virus without ever having symptoms. This phenomenon is called *asymptomatic transmission.* At this time, we do not know to what extent pre-symptomatic and asymptomatic transmission plays a role in the spread of the epidemic, but we do know that this type of transmission occurs in people who have close contact or share a restricted physical environment.

The main vectors of the global COVID-19 pandemic are individuals with visible symptoms, since coughing and respiratory droplets are the main ways the virus spreads. However, since the existence of asymptomatic transmission is now proven, it is important that every person, even those who do not feel sick, applies proven methods to prevent transmission.

- The following measures are the best way to prevent spreading COVID-19:
  - Stay home, away from others, when you are sick.
  - Wash your hands often.
  - Cough into a tissue or sleeve.
  - Practise physical distancing.
  - Clean and disinfect all surfaces and objects.
  - Protect those most at risk of contracting the virus.

Q432. **What should you do if you have been exposed to a confirmed case of COVID-19?**

If you **do not have any symptoms**, but think you may have been exposed to a source of COVID-19, the Public Health Agency of Canada is asking you to take the following actions for

the next 14 days:

- Monitor your health to detect the onset of **fever**, **coughing** 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 **show COVID-19 symptoms**, please isolate from others as soon as possible. Immediately call 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 advise you on what steps to take.

Q433. What are the statistics on asymptomatic cases in Canada?

The Public Health Agency of Canada (PHAC) and provincial and territorial public health authorities work collaboratively 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 case report forms received as of April 22 at 11:00 a.m. EDT, PHAC is aware of 220 cases that were classified as asymptomatic, representing 2.7% of cases for which symptom status was known (n=7,879). It should be noted that the presence of symptoms was unknown in 65% of cases reported to PHAC.

This is not an accurate representation of asymptomatic cases due to incomplete data and the fact that COVID-19 screening focuses on symptomatic individuals. In addition, the data on the cases in the case report form are preliminary and may have missing values for characteristics of interest. Provinces and territories may not systematically update the detailed data. Although a patient's condition may change as the disease progresses, PHAC does not receive regular updates on the patient's status.

Q434. Are Canadians at risk of contracting COVID-19 if they touch a surface that may be contaminated?

Generally, 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.
- Routinely use good hand hygiene measures, which include frequent hand-washing with soap and warm water for at least 20 seconds, or the use of 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 washing your hands immediately after coughing or sneezing with soap or alcohol-based hand sanitizer when soap and water are not available.

- Frequently clean and disinfect surfaces that people touch often, such as toilets, bedside tables, doorknobs, telephones and television remotes with regular household cleaners or diluted bleach (one part bleach to nine parts water).

Q435. **Are Canadians at risk of contracting COVID-19 from products shipped from Canada or abroad?**

It is not yet known how long the virus that causes COVID-19 lives 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
- surface type
- ambient humidity.

Products shipped from Canada or abroad may also be contaminated. However, as it usually takes several days or weeks for packages to be delivered, and as these are transported at room temperature, the risk of spreading 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:

- Apply good hygiene measures.
- Clean and disinfect surfaces regularly.
- Do not touch your eyes, nose and mouth.

Q436. **Can COVID-19 be transmitted through food or water?**

There is currently no evidence to suggest that food may be a likely source or route of virus transmission, and there are no reports of transmission of COVID-19 through food 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 CFIA becomes aware of a food safety risk, appropriate action will be taken to ensure the safety of Canada's food supply.

Animals

Q437. **Is it possible to contract the virus from an animal in Canada?**

At this time, 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.

Q438. **Can pets and other domestic animals get the virus?**

It is possible that some types of animals may be able to get infected with the coronavirus that causes the disease, but we don't yet know if they would get sick.

As a precautionary measure, if you have symptoms of COVID-19 or if you are in self-isolation due to contact with a case of COVID-19, you should apply similar recommendations with animals as with people.

- Avoid close contact with animals while you are sick.
    - Maintain good hand hygiene and avoid coughing or sneezing on your pets.
    - Do not visit farms and avoid contact with livestock.
- If possible, have another member of the household take care of your pets.
    - If this is not possible, always wash your hands before and after touching animals and their food and supplies; follow good respiratory hygiene practices when coughing or sneezing.
- Limit contact between your pets and people and animals that are not part of your household until you are no longer sick.

These measures, which are basic practices to prevent the transmission of disease between humans and animals, are recommended as a precautionary measure. If you have any concerns, consult a veterinarian or public health professional who can help you find answers to your questions.

More information about animals and COVID-19 can be found on the Canadian Food Inspection Agency (CFIA) website.

Q439. **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 are no requirements in place in Canada to restrict the importation of animals in light of the COVID-19 outbreak, as 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 delay 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 them of the situation. Contact them first by phone to ensure that they are 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 they can

advise you on the care and vaccinations needed to keep it healthy and protect the health of your family members.
Take the following precautions to prevent the transmission of diseases from animals to humans:

- Always wash your hands after touching an animal, its food or items, and after picking up its feces or cleaning its bedding.
- Don't kiss animals, share food with them or let them lick your face.
- Make sure to regularly clean and disinfect the areas where the animals live.

To learn more about animals and COVID-19, visit the following addresses:

- 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

Q440. **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 population groups in order to understand its transmission dynamics. Children have been shown to be important vectors in the transmission of other respiratory diseases (e.g. influenza). Therefore, it is interesting to examine whether there is evidence that SARS-CoV-2 is more or less prevalent among children than among other age groups.

Q441. **What is multisystem inflammatory syndrome in children?**

Multisystem inflammatory syndrome in children is a rare acute inflammatory disease that primarily affects children.

Q442. **What are the symptoms of multisystem inflammatory syndrome in children?**

Symptoms of multisystem inflammatory syndrome in children include persistent fever, inflammation, malfunction of one or more organs, and other clinical manifestations and laboratory findings.

Q443. **What causes multisystem inflammatory syndrome in children?**

Multisystem inflammatory syndrome in children occurs after a viral or bacterial infection.

Q444. **What is the treatment for multisystem inflammatory syndrome in children?**

In Canada, treatment for multisystem inflammatory syndrome in children depends on the severity of the disease. It may include, but is not limited to, corticosteroids, intravenous immunoglobulins and anti-inflammatory drugs.

Specialists in infectious diseases, rheumatology, immunology, cardiology and intensive care must be consulted to determine the best possible treatment for each child with multisystem inflammatory syndrome.

Q445. **How common is multisystem inflammatory syndrome in children in Canada?**

Multisystem inflammatory syndrome in children is rare in Canada.

Q446. **Does PHAC know the current number of cases and incidence rate in Canada?**

PHAC does not have this information at this time. For more information, please contact local, provincial and territorial public health authorities.

Q447. **Where can I find national data on the incidence of multisystem inflammatory syndrome in children related to COVID-19? Is there data for Canada and British Columbia on the incidence of heart and brain damage associated with COVID-19?**

PHAC continues to conduct surveillance, collect information and mobilize the international community to inform Canada's public health actions.

PHAC has multiple systems in place to monitor community spread and serious results related to COVID-19 in paediatric populations.

As part of PHAC's surveillance for COVID-19, the syndrome is monitored by:

1. a national reporting system in which all cases are reported to the provinces and territories and then to PHAC
2. a network of paediatric emergency physicians in children's hospitals who report COVID-19 cases
3. the Canadian Paediatric Surveillance Program (CPSP), a collaboration between PHAC and the Canadian Paediatric Society.

In order to increase the data available on this emerging disease, the CPSP's COVID-19 surveillance protocol is being modified to include cases of multisystem inflammatory syndrome in children, even in the absence of a positive COVID-19 test result.

PHAC does not have this information at this time. For more information, contact your local provincial and territorial public health authorities.

Q448. **In Canada, what link exists between COVID-19 and multisystem inflammatory syndrome in children?**

Many children with this inflammatory syndrome have not tested positive for COVID-19. Nasal swab tests for the virus that causes COVID-19 were often negative, and antibody detection tests were sometimes positive, but not always. The fact that some patients tested negative for the virus and positive for antibodies suggests that inflammatory complications occurred when the virus was no longer detectable by nasal swabbing.

So far, most of the affected children have recovered completely. Some had to be admitted to intensive care.

We do not yet know why these cases are only now appearing and what the cause is. We believe that an immune response to COVID-19 triggers an inflammatory process in children with a genetic predisposition. The international paediatric community is rushing to study the problem.

Health care providers in Canada are aware of the possibilities of the syndrome and are vigilant in detecting cases.

To date, there have been fewer cases of COVID-19 in children than in adults. On the other hand, the disease can have serious consequences for children. Therefore, it is important for everyone to take precautions to prevent infection.

Q449. **Is there a timeline for the publication of the transmission review 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 rapid review of the evidence on transmission in children. PHAC will provide the detailed results of the literature review through reputable scientific publications and websites. The process for such publications is already under way.

Q450. **Is the information being revised or is the government working with partners?**

These rapid 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 National Collaborating Centres for Public Health and with other external partners to gather evidence to guide Canada's response to COVID-19.

PREVENTION AND RISKS

Q451. **How can I protect myself against this virus?**

Here are some tips to stay healthy and prevent the spread of infections:

- Wash your hands often with soap and running water 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 and mouth until after you have washed your hands.
- Avoid contact with sick people, especially if they have a fever, a cough or difficulty breathing.
- Cough or sneeze into the crook of the arm to reduce the risk of spreading germs.
- Stay home if you are sick to avoid spreading the disease to others.

Q452. **Are people in Canada required to wear masks to protect themselves from this virus?**

The following measures are the best way to prevent the spread of COVID-19:

- Stay home, away from others, when you are sick.
- Wash your hands often.
- Cough into a tissue or sleeve.
- Practise physical distancing.
- Clean and disinfect all surfaces and objects.
- Protect those most at risk of contracting the virus.

Health care workers need medical masks, including surgical masks, procedure masks and respirators such as N95 masks. It is extremely important that these masks be reserved for health care workers, as they are urgently needed for medical procedures and to care for people with COVID-19.

There is no evidence that wearing a non-medical mask or face covering (i.e. made to completely cover the nose and mouth and tightly fitted to the face, held in place with ties behind the ears or behind the head and neck) in the community protects the wearer. However, wearing a non-medical mask or face covering is an extra measure 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. Just like covering your mouth with a tissue or sleeve when you cough, a cloth mask or face covering can reduce the risk of others being exposed to your respiratory droplets.

For short periods of time when it is not possible to physically remove yourself in public (e.g. at the grocery store or in cramped areas such as when travelling on public transit), wearing a non-medical mask is one way to protect those around you.

Young children under two years of age, as well as people who have breathing problems, are unconscious, or are unable to remove a mask on their own, should not wear a non-medical mask or other face covering.

Q453. **What was the idea behind the change in advice regarding mask wearing? What prompted this advice?**

Canadian public health guidelines for COVID-19 have evolved in response to the accumulation of evidence and understanding of the new virus. We continually review the latest scientific evidence as it becomes available and work with our partners across the country and around the world to learn more. From the outset of the COVID-19 outbreak, masks were recommended to symptomatic individuals who were known to have COVID-19 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.

The thinking on the use of masks evolved with the emergence of evidence that the virus can be transmitted by infected people before symptoms appear (pre-symptomatic transmission). There is also evidence that some infected people who never develop symptoms are also able to transmit the virus (asymptomatic transmission). The extent to which pre-symptomatic and asymptomatic transmission plays a role in the spread of the COVID-19 epidemic is not yet

known, but it is known to occur in people who are in close contact or who share a restricted physical environment. This evidence has led to the advice of the Council of Chief Medical Officers of Health that individuals may wear non-medical masks and face coverings as an additional layer of protection in environments where physical distance may not be possible.

Health care workers on the front lines of the COVID-19 pandemic require 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 covering in the community protects the person wearing it, it is an additional measure that individuals can take to protect those around them.

Wearing a non-medical mask is another way to cover the mouth and nose to prevent respiratory droplets from contaminating others or landing on surfaces. A cloth mask or face covering can reduce the risk of others coming into contact with your respiratory droplets, just as 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, such as:

- Staying home when you are sick;
- Practising physical distancing;
- Washing your hands;
- Protecting the most vulnerable people from infection and limiting their exposure to others;
- Covering your cough with a non-medical mask or coughing into tissues or a sleeve.

Q454. **Does the Public Health Agency of Canada recommend the use of disposable gloves to avoid contracting or transmitting COVID-19? I'm talking about the general public and whether they should wear gloves when shopping or carrying out their daily activities.**

PHAC recommends above all, frequently washing your hands, avoiding touching your face and practising good respiratory etiquette (e.g. coughing into a tissue or sleeve) at all times. Hand hygiene involves washing hands with soap and water for at least 20 seconds or using an alcohol-based hand sanitizer (at least 60% alcohol) or a Health Canada-approved alcohol-free hand sanitizer.

Regular hand washing or bare hand disinfection offers better protection against COVID-19 than wearing non-medical gloves. Non-medical gloves can be contaminated by touching contaminated objects or surfaces, and if a wearer touches their face while wearing them, they can infect themselves.

Disposable gloves should be discarded and not reused once removed.

Food service establishments must adhere to established safe food handling practices and requirements. PHAC recommends frequent hand washing in *all* workplaces, including food service establishments. Wearing disposable gloves does not eliminate the need for frequent hand washing. In some workplaces where personal protective equipment (including gloves) may

be recommended, employees must be trained in the equipment's proper use. Hands should be washed just before putting on gloves and immediately after removing them.

PHAC encourages employers to promote personal preventive measures such as hand washing, not touching the face, and respiratory etiquette. Employers might consider such measures as posting signs to remind employees to practise these measures and providing better access to handwashing facilities.

Q455. **Did Health Canada see an increase in the number of calls from people reporting health issues related to cleaning products and disinfectants during the COVID-19 pandemic? Have there been more instances of misuse of cleaning products, such as improper use of bleach or improper mixing of products since the COVID-19 outbreak?**

Health Canada and five poison centres across Canada have worked together to analyze the number of calls to poison centres related to exposure to cleaning products. The data are collected by the poison centres and were shared with Health Canada for compilation to provide a Canada-wide overview.

The analysis compared the number of reported exposures in 2019 and 2020. Data for January 2019 were not included because information from one of the poison centres was not available. Also, data for April 2020 are not yet available.

Comparing reports made in February and March 2019 to data from the same months in 2020, poison 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;
- an increase in the amount of cleaning products available in households due to increased purchases as a preparation measure;
- increased availability of products due to increased cleaning and disinfection practices at home and elsewhere.

Health Canada is closely monitoring the situation and has taken steps to inform Canadians about the safe use and storage of cleaning and disinfecting products through regular announcements on social media and its website.

Q456. **Can vaping/smoking/drug use damage the lungs, making a person more vulnerable to COVID-19?**

No direct evidence has been published on vaping or drug use and its association with the evolution of COVID-19.

Studies that have examined the association between smoking and the severity of COVID-19 indicate that smokers may be more susceptible than non-smokers.

Q457. **In the U.S., people under 44 years of age account for a large proportion of hospitalizations. What do we see in 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 have less serious conditions, with only 9% of hospitalizations and 4% of intensive care admissions reported in this age group. (These figures are subject to change as new cases are identified and the situation evolves.)

Q458. **What is your message to youth (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 could harm your health (for example, cause lung damage). It is also important to remember that vaping devices and drug-use equipment should never be used by more than one person. Maintaining a healthy lifestyle is especially important at this time.

Q459. **Until February 22, PHAC still assessed the public health risks associated with COVID-19 in Canada as "low." When did the risk assessment change? What are the current public health risks associated with the coronavirus in Canada?**

The public health risk assessment provided in the Health Portfolio situation reports was based on the risks COVID-19 posed to the Canadian population at that time. As of February 22, 2020, the risks to the population in Canada were low, as there was no evidence that COVID-19 was being transmitted in 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.

The confirmation of community transmission of COVID-19 in the Canadian population led to the establishment of a high risk. The current public health risk assessment for the coronavirus in Canada, effective March 16, shows that the risk is high for the general population.

Q460. **When Dr. Tam was asked about the link between obesity and COVID-19, Minister Hajdu mentioned that there had been research on obesity. Can we access the research? Also, why is obesity not listed as a risk factor on the Public Health Agency of Canada (PHAC) website?**

Current preliminary data published indicate that obesity has been associated with serious results in patients with COVID-19. A rapid review of high-risk populations conducted on April 17 included two studies that found an association between obesity and COVID-19. Qingxian et al. (China) reported that obese patients were more likely to develop severe pneumonia. Petrilli et al. (New York) reported that hospitalized patients were more likely to be male and had significantly more comorbidities than non-hospitalized patients, particularly for cardiovascular disease (44.6% vs. 16.4%), diabetes (31.8% vs. 5.4%) and obesity (39.8% vs. 14.5%). PHAC is reviewing the evidence as it becomes available and is updating its April 17 rapid review to reflect the most recent evidence and to communicate information about the risk factors associated with COVID-19 to the public.

Please contact the Canadian Institutes of Health Research for more information on research associated with COVID-19.

5G TECHNOLOGY and COVID-19

Q461. **What is the Government of Canada's role in wireless technology?**

The Government of Canada's approach to the safety of radiofrequency exposure is one of the most rigorous in the world. Health Canada's mandate on the issue of human exposure to radiofrequency electromagnetic energy is to conduct research on potential health effects, analyze relevant scientific literature and develop exposure guidelines commonly referred to as Safety Code 6. We continuously monitor the research and scientific literature on the health effects of radiofrequency exposure to ensure that the limits recommended in Safety Code 6 are consistent with current scientific consensus to prevent potential adverse health effects.

Innovation, Science and Economic Development Canada (ISED) is responsible for the deployment of 5G wireless technology. To help protect Canadians, ISED has adopted the limits in Health Canada's Safety Code 6 for wireless devices and their associated infrastructure.

Safety Code 6 has always maintained an exposure limit below the threshold for the occurrence of all established 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.

Q462. **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) ranging from 3 kHz to 300 GHz. This range includes frequencies used by existing communication devices, as well as those that can be used by devices using 5G technology (i.e. above 6 GHz).

Q463. **How does Safety Code 6 protect the health of Canadians?**

The recommended exposure limits in Safety Code 6 are designed to protect all Canadians from all scientifically established adverse health effects from exposure to radiofrequency electromagnetic fields. These effects are tissue heating (such as heating of 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 any adverse health effects.

Q464. **Is radiofrequency exposure from cell towers and antenna installations safe?**

Yes, radiofrequency exposure from cell towers and antenna installations is safe. There is no scientific basis for the recent suggestion to link the deployment of 5G networks 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 radiofrequency spectrum and requires all antenna systems to comply with the limits of Safety Code 6 to protect the public from overexposure. You can find additional information on antenna towers at www.ic.gc.ca/towers.

Q465. **How does Canada compare to 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 in Safety Code 6.

The exposure limits in Safety Code 6, and Health Canada's conclusions, are similar to those of the International Commission on Non-Ionizing Radiation Protection, the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks, and the World Health Organization.

EMPLOYEE SAFETY

Q466. **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 and occupational health advisory services to departments.

In accordance with standard protocols for such situations, the PSOHP has issued a General Occupational Health Advisory to departments and agencies that provides guidance on the novel coronavirus and recommended precautions for employees, such as frequent hand washing, cough and sneeze hygiene, and monitoring of one's own symptoms.

The advice and information are based on the science and level of risk assessed by the Public Health Agency of Canada and the World Health Organization.

In addition, given the diversity of federal workplaces, PSOHP has developed additional guidance for specific workplaces. The priority was to advise airport employees who interact with travellers, for example, on the personal protective equipment to use when searching luggage or escorting an ill traveller. Health Canada's occupational health nurses also assisted our partner departments by organizing information sessions for airport staff and at 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 information they need on occupational health.

Health Canada's occupational health experts will continue to work closely with departments to ensure the health and safety of federal public service employees.

Q467. **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 isolating himself and following the guidelines of the local public health authority.

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. This was done in collaboration with Statistics Canada as the two departments share a common workspace.

In addition, the local public health authorities contacted the employee to identify any relevant contacts. This involved contacting some co-workers who were advised by the local public health authority to self-isolate.

The Government of Canada calls for the use of telework when and where 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 re-evaluating 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 is working 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.

Q468. **Can you confirm that a number of employees working at Canada's National Microbiology Laboratory 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 isolating and following the guidelines of the local public health authority. Contact tracing is under way by local public health departments who will implement all necessary follow-up procedures to prevent the spread of the virus.

In accordance with standard laboratory protocol, procedures for cleaning and disinfection of work areas and common areas were followed. Our employees continue to practise effective public health measures, including physical distancing, hand washing and respiratory etiquette. It is not surprising that we are seeing cases among our workforce as COVID-19 infection circulates in our community. We are prepared for such circumstances with business continuity plans that ensure that essential NML operations continue under circumstances where employees are ill or absent. For federal employees whose duties allow them to work from home,

this arrangement is supported as part of the Government of Canada's policy during the COVID-19 pandemic. We wish our employees a speedy recovery and are thinking of them and their families during this difficult time.