Exibit R25-3 Order in Council dated October 3, 2020, extending the exemption of Covid-19 vaccines from the regular drug approval process, and continuing the substitute process for their approval.

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October 3, 2020

DEPARTMENT OF HEALTH

FOOD AND DRUGS ACT

Order Approving the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19

P.C. 2020-682 September 25, 2020

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to paragraph 30.1(2)(a) [a] of the *Food and Drugs Act* [b], approves the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*, made by the Minister of Health on September 16, 2020.

EXPLANATORY NOTE

(*This note is not part of the Order.*)

Proposal

This Order in Council (the Order) approves the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (the Interim Order), which was signed by the Minister of Health on September 16, 2020. The Interim Order allows for the issuance of an expedited authorization for the importation, sale and advertising of drugs used in relation to COVID-19; this includes both human and veterinary drugs. It allows the Minister to account for urgent public health needs relating to COVID-19 in deciding whether to authorize a COVID-19 drug based on the provided evidence of safety, efficacy, and quality. The Interim Order also allows establishment licences to be issued in relation to COVID-19 drugs in a more agile manner, taking into consideration urgent public health needs, and provides a mechanism for the Minister to allow the Public Health Agency of Canada (PHAC) to import promising COVID-19 drugs for placement (pre-positioning) in Canadian facilities prior to their authorization in Canada.

The Interim Order was made under subsection 30.1(1) of the *Food and Drugs Act* (the Act), which allows the Minister to make temporary interim orders if the Minister believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment.

Without an Order in Council approving it, the Interim Order would, in accordance with paragraph 30.1(2)(a) of the Act, cease to have effect 14 days after it was made. As a result of this Order in Council, the Interim Order will, in accordance with paragraphs 30.1(2)(b) to (d) of the Act, cease to have effect on the earliest of the day on which it is repealed, the day on which regulations having the same effect come into force, or one year after the day on which the Interim Order was made.

Objective

The objective of this Order in Council is to enable the continued effect of the Interim Order, which aims to expedite the authorization for the importation, sale, and advertising of drugs used in relation to COVID-19 while taking into consideration urgent public health needs. It also provides an option for establishment licences to be issued in relation to COVID-19 drugs in a more agile manner. The Interim Order further provides the ability for the Chief Public Health Officer of PHAC to notify the Minister of a need to pre-position a promising COVID-19 drug in Canada. In order for a drug to be pre-positioned, the Government of Canada must have entered into a contract for its procurement and the manufacturer must have filed an application for the drug's authorization in Canada, or abroad with a foreign reference regulator. Together, these measures help ensure Canadians have timely access to COVID-19 drugs.

Background

COVID-19 is a new disease not previously identified in humans. It is an infectious respiratory disease caused by the most recently discovered coronavirus, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). COVID-19 infection has been known to cause respiratory symptoms, fever, cough, shortness of breath, and breathing difficulties. In more severe cases, it may cause pneumonia, severe acute respiratory syndrome, kidney failure, and death. The World Health Organization declared a global pandemic related to COVID-19 on March 11, 2020. There are now more than 26 300 000 cases, in at least 185 countries, and over 860 000 people have lost their lives. [1] The number of confirmed cases in Canada as of September 3, 2020, has exceeded 130 000; [2] however, the situation is changing rapidly.

Many pharmaceutical companies and academic institutions worldwide are developing candidate vaccines and potential treatments and therapies for COVID-19. While these new drugs and vaccines are being developed to specifically address COVID-19, pharmaceutical companies are looking at the potential of using already approved and marketed drugs, such as broad-spectrum antivirals and anti-inflammatory drugs. Expedited authorization of drugs for use in relation to COVID-19 will allow these medically necessary drugs to be made available quickly for Canadians.

Prior to a product being available on the Canadian market, Health Canada reviews product information to confirm the requirements of the *Food and Drugs Act* and its associated regulations are met. Based on the information provided, the Department assesses the risks and benefits of the product to ensure Canadians have access to products that are safe, effective and of high quality. In addition, any person who fabricates, packages, labels, imports, tests, distributes, or wholesales a drug for sale in Canada must hold an establishment licence issued under the *Food and Drug Regulations*.

On March 18, 2020, the Minister of Health published a notice, "Expedited Review of Health Product Submissions and Applications to address COVID-19." This notice outlined Health Canada's intent to expedite the authorization of a vaccine and other therapies for COVID-19 as they become available.

Implications

The Interim Order introduces expedited authorization pathways for the importation, sale and advertising of drugs used in relation to COVID-19. The authorization of a drug under the Interim Order is predicated on the

Minister's determination that the evidence provided supports the conclusion that the benefits outweigh the risks associated with the drug, taking into account the uncertainties related to the benefits and risks, as well as the urgent public health need caused by COVID-19. This includes weighing the risks of modifying certain requirements for information to support the safety and effectiveness of a drug, such as allowing consideration of a foreign regulatory approval, against the benefits of having it available to Canadians quickly.

The Interim Order introduces expedited authorization pathways for drugs with a COVID-19 indication that are not yet authorized in Canada or other jurisdictions, as well as COVID-19 drugs that are authorized for sale by a foreign regulatory authority. In addition, the Interim Order provides a mechanism to permit the sale of a drug that is already authorized in Canada under this Interim Order or the *Food and Drug Regulations*, for indications related to COVID-19 that are not included in the drug's authorization.

Although COVID-19 is understood to be primarily a human disease, COVID-19 is a new disease and its impacts on animal health may not be fully known at this time. To date, there have not been any reports of livestock contracting COVID-19 and early information from a small number of studies suggests pigs, chickens and ducks are not susceptible to the virus. However, there have been several reports of infected humans spreading the virus to their pet dog or cat; therefore, out of an abundance of caution, veterinary drugs were included in the scope of the Interim Order.

Drugs not authorized in Canada or by a foreign regulatory authority

The Interim Order introduces an expedited pathway for the authorization

of a new COVID-19 drug by providing more agile application and administrative requirements than what is offered under division 8 of the *Food and Drug Regulations*.

The Interim Order provides the Minister with the ability to take into consideration the uncertainties and the urgent public health needs in the context of the COVID-19 pandemic while determining if a drug demonstrates that its benefits outweigh its risks. Instead of providing detailed reports of the tests establishing the safety of a new drug and substantial evidence of clinical effectiveness as required by the *Food and Drug Regulations*, the Interim Order requires an applicant to submit the known information with respect to the safety and effectiveness of a COVID-19 drug.

In addition, in order to expedite the review process for drug applications submitted for authorization under the Interim Order, a more agile approach has been included to allow an applicant to file further information throughout the course of the review as it becomes available, also known as a rolling application. If using this rolling application approach, the applicant must submit a plan outlining how and when they will provide the Minister with the required information or data that is outstanding.

Drugs authorized by a foreign regulatory authority

In order for a drug to be eligible to use the expedited pathway for drugs that are authorized by a foreign regulatory authority, the drug must be included on *The List of Foreign Drugs*, which is maintained by the Minister and incorporated by reference in the Interim Order. A drug may be included on this list if it has been shown to provide benefit in the context of the COVID-19 pandemic, and it has received an authorization for sale

in a foreign jurisdiction. The Minister may become aware of such drugs through interactions with international counterparts or environmental scanning, including dialogues with health care providers or potential drug applicants.

In order to be imported, sold, or advertised in Canada, a drug included on the list must still be authorized under the Interim Order; however, the applicant can leverage this foreign regulatory approval and submit a more abbreviated application. The applicant must submit evidence that the drug is authorized for sale in a foreign jurisdiction and sign an attestation that, if requested, all of the information used to authorize the drug by the foreign regulatory authority will be made available to the Minister.

With respect to the foreign drug, the Minister must still determine that all criteria outlined in the Interim Order have been met and, in the context of the COVID-19 pandemic, the benefits of authorizing this drug outweigh the risks.

Expanded indication of drugs authorized in Canada

The Interim Order permits a drug that is already authorized in Canada to be advertised and sold for an expanded indication related to COVID-19. This will be done by the addition of the drug to the incorporated by reference *List of New Drugs for Expanded Indication*. Unlike for an amendment under the *Food and Drug Regulations*, this process can be initiated without an application from the manufacturer.

Additions to this list will be based on environmental scanning by Health Canada, including dialogues with health care providers, as evidence supporting the use of existing drugs in the context of COVID-19 becomes available. However, an external applicant may make the Minister aware

of a drug that may qualify for this process.

As a drug qualifying for this process will already hold an authorization through the Interim Order or the *Food and Drug Regulations*, there will already be known evidence to support its safety, efficacy (for other indications) and quality. In addition, the inclusion of a drug to this list will allow the Minister to request any information the authorization holder may have pertaining to the COVID-19 indication. Any additional information provided on the COVID-19-related indication is also included on the incorporated by reference list.

Drug establishment licences and good manufacturing practices

The Interim Order introduces an option for drug establishment licences to be issued or amended to include the conduct of activities in relation to COVID-19 drugs. This balances the need for flexibilities, such as the modification of certain good manufacturing practices requirements, while still protecting the health and safety of Canadians who will use these COVID-19 drugs. All drug establishment licence applications submitted in relation to the Interim Order will be processed in an expedited manner. Licensing decisions will consider both the material submitted in the application and the necessity of the drug in addressing urgent COVID-19-related health needs.

Labelling, advertising, and reporting requirements

In order to maintain bilingual labelling requirements in accordance with the *Official Languages Act*, the Interim Order ensures the appropriate sections of the *Food and Drug Regulations* will still apply to COVID-19 drugs. These drugs are also subject to similar advertising prohibitions, as well as adverse drug reaction reporting and recall and shortages reporting requirements, as drugs authorized under the *Food and Drug*

Regulations.

Terms and conditions

The Interim Order allows the Minister to impose or amend terms and conditions, and request additional information, in relation to a COVID-19 drug submission, authorization, or establishment licence, at any time while it is in effect. In light of the severity of the COVID-19 pandemic, this allows the Minister to act quickly to gather important safety information or mitigate risk in a timely manner.

Suspension or cancellation

When expediting the authorization of a drug in relation to COVID-19 through the Interim Order, with the goal of enabling timely access to drugs in relation to COVID-19, Health Canada will continue to ensure that these products are supported by sufficient evidence of safety, efficacy and quality. Health Canada will monitor the safety and effectiveness of these drugs and will take immediate action, including the suspension or cancellation of authorizations or establishment licences, if required, to protect the health and safety of Canadians.

Intellectual property

The Interim Order does not include explicit intellectual property protections for innovative drugs submitted for authorization through this process. However, Health Canada will ensure that an innovative drug is able to receive data protection, if and when an authorization is issued under the *Food and Drug Regulations* or another transitional mechanism, by ensuring an authorization for a drug and its medicinal ingredients issued under the Interim Order is not considered a previous approval for the purposes of defining an innovative drug under section C.08.004.1 of

the *Food and Drug Regulations*; and stipulating that a submission cannot be made under the *Food and Drug Regulations* for a new drug, in respect of a COVID-19 claim, based on a direct or indirect comparison to a COVID-19 drug authorized under the Interim Order.

In addition, to maintain incentives for manufacturers of COVID-19 drugs and to ensure the accessibility of these drugs, an application for an authorization based on the direct or indirect comparison to another COVID-19 drug will only be accepted if that other drug is not available on the Canadian market in sufficient quantities to address urgent public health needs related to COVID-19. Prior to a person submitting an application based on a direct or indirect comparison to another drug, they must notify the Minister of their intent to file and provide information demonstrating that the drug being compared to has been issued an authorization under the Interim Order or a Notice of Compliance and is not available in sufficient quantities. The Minister is then required to notify the manufacturer of the drug it is being compared to so the manufacturer can make representations to the Minister as to whether or not it is available in sufficient quantities. If the Minister determines that the drug being compared to is not available in sufficient quantities, the application can be submitted.

Authorization period and fees

Authorizations issued under, and drug establishment licences issued in relation to, the Interim Order are only valid while the Interim Order is in effect. The review of drug applications submitted under the Interim Order will not be subject to cost recovery fees, nor will fees be charged for establishment licence applications submitted in relation to the Interim Order if the application meets the conditions specified in the

Establishment Licence Fees Remission Order (Indication of an activity in respect of a COVID-19 Drug). In addition, the annual fee to sell a product on the Canadian market will not apply to COVID-19 drugs.

Release of clinical information

Health Canada will make publicly available the safety and efficacy evidence relied upon to issue an authorization under the Interim Order. Clinical information will be released for non-commercial purposes and will have all personal information and confidential business information protected prior to publication on Health Canada's Clinical Information Portal.

Pre-positioning

In order to facilitate timely access to promising COVID-19 drugs, the Interim Order introduces a mechanism for the Minister to allow the importation of promising COVID-19 drugs for placement in Canadian facilities prior to their market authorization in Canada, referred to as pre-positioning. This mechanism may be used to import a promising COVID-19 drug into Canada if the Chief Public Health Officer of Canada has notified the Minister of a need to pre-position a COVID-19 drug and the Government of Canada has a procurement agreement for the purchase of the drug. In addition, the manufacturer of the drug must have filed an application for market authorization with Health Canada under the Interim Order or the *Food and Drug Regulations*, or filed an application for market authorization with a foreign regulatory authority.

The Chief Public Health Officer of Canada must also provide a description of the drug to be pre-positioned, which includes the quantity of the drug to be imported into Canada, information regarding the drug's manufacturer, the proposed Canadian drug establishment licence holder

that will import and pre-position the drug, and the facilities where the drug is to be stored. This establishment licence holder could be PHAC, which operates the National Emergency Stockpile System (NESS); the manufacturer itself, which has the contractual agreement with the Government of Canada; or an establishment licence holder identified by the Chief Public Health Officer of Canada.

Guidance and resources

The guidance document entitled "Information and Application Requirements for Drugs Authorized Under the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19" outlines the regulatory requirements and other important information for manufacturers wishing to submit an application for authorization through the Interim Order. In addition, Health Canada will publish a list of COVID-19 drug applications received and a list of COVID-19 drugs authorized under the Interim Order. These lists, along with the *List of Foreign Drugs* and the *List of New Drugs for Expanded Indication,* will be made publicly available on the Government of Canada website.

Consultation

Canadians have been informed of the expedited review of COVID-19 drug submissions and applications through the Notice entitled "Expedited Review of Health Product Submissions and Applications to address COVID-19," published on March 18, 2020. Through various other communications, members of the federal health portfolio, provincial and territorial governments, industry associations, and other stakeholders have been made aware, and are supportive of this action to expedite the authorization of COVID-19 drugs.

Three engagement sessions with health care system partners took place between April 30 and May 15, 2020. Stakeholders invited included hospital associations, national advisory committees, the Pan-Canadian Pharmaceutical Alliance, and provincial and territorial drug plan managers, among others. An information session with industry and industry association stakeholders was held on June 25, 2020, with over 80 participants attending, including BIOTECanada and Innovative Medicines Canada. Additional targeted sessions were held on July 2, 2020, to engage the Canadian Animal Health Institute, and July 24 and August 11, 2020, to engage innovative drug manufacturers. The intent of these sessions was to inform these key stakeholders about the details of the Interim Order, to identify measures to ensure its efficient implementation, to discuss future transition measures under consideration for when the Interim Order ceases to have effect, and to provide stakeholders with an opportunity to ask questions.

Participants of all sessions were generally supportive of the Interim Order and the proposed measures. Innovative drug manufacturers, however, raised concerns regarding the absence of protections for innovative products and intellectual property and proposed changes to alleviate these concerns. Health Canada subsequently modified the Interim Order based on these suggestions.

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PUBLIC HEALTH AGENCY OF CANADA

QUARANTINE ACT

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

P.C. 2020-672 September 20, 2020

Whereas the Governor in Council is of the opinion that

(a) based on the declaration of a pandemic by the World Health Organization, there is an outbreak of a communicable disease, namely coronavirus disease 2019 (COVID-19), in the majority of foreign countries;

(b) the introduction or spread of the disease would pose an imminent and severe risk to public health in Canada;

(c) the entry of persons into Canada who have recently been in a foreign country may introduce or contribute to the spread of the disease in Canada; and

(d) no reasonable alternatives to prevent the introduction or spread of the disease are available;

Therefore, Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to section 58 of the *Quarantine Act* [c] makes the annexed *Minimizing the Risk of Exposure to COVID-19 in Canada Order (Prohibition of Entry into Canada from the United States)*.

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

Definitions

1 The following definitions apply in this Order.

common-law partner has the same meaning as in subsection 1(1) of the *Immigration and Refugee Protection Regulations*. (*conjoint de fait*)

foreign national has the same meaning as in subsection 2(1) of the *Immigration and Refugee Protection Act*. (*étranger*)

immediate family member with respect to a person means,

(a) the spouse or common-law partner of the person;

(b) a *dependent child*, as defined in section 2 of the *Immigration and Refugee Protection Regulations*, of the person or of the person's spouse or common-law partner;

(c) a *dependent child*, as defined in section 2 of the *Immigration and Refugee Protection Regulations*, of a dependent child referred to in paragraph (b);

(d) the parent or step-parent of the person or of the person's spouse or common-law partner; or

(e) the guardian or tutor of the person. (*membre de la famille immédiate*)

Prohibition — signs and symptoms

2 (1) A foreign national is prohibited from entering Canada from the United States if they have COVID-19 or have signs and symptoms of COVID-19 or have reasonable grounds to suspect they have such signs and symptoms, including

(a) a fever and cough; or

(b) a fever and breathing difficulties.

Non-application — certain persons

(2) Subsection (1) does not apply to persons referred to in subsection 5(1) or (2) who seek to enter Canada from the United States for the purpose of making a claim for refugee protection.

Prohibition — optional or discretionary purpose

3 (1) A foreign national is prohibited from entering Canada from the United States if they seek to enter for an optional or discretionary purpose, such as tourism, recreation or entertainment.

Non-application — immediate family member

(2) Subsection (1) does not apply to a foreign national who is an immediate family member of a Canadian citizen or a *permanent resident*, as defined in subsection 2(1) of the *Immigration and Refugee Protection Act*, if the foreign national intends to enter Canada to be with their immediate family member who is a Canadian citizen or a permanent resident and can demonstrate the intent to stay in Canada for a period of at least 15 days.

Prohibition — unable to meet quarantine requirement

4 (1) A foreign national is prohibited from entering Canada from the United States if, based on the purpose of entry and the length of their stay, the requirement to quarantine under any order made under section 58 of the *Quarantine Act* with respect to mandatory isolation or quarantine cannot be complied with.

Non-application — certain persons

(2) Subsection (1) does not apply to persons referred to in subsections 5(1) or (2) who seek to enter Canada from the United States for the purpose of making a claim for refugee protection.

Prohibition — claim for refugee protection

5 (1) A foreign national is prohibited from entering Canada from the United States for the purpose of making a claim for refugee protection unless the person

(a) seeks to enter Canada at a land port of entry designated by the Minister of Public Safety and Emergency Preparedness under section 26 of the *Immigration and Refugee Protection Regulations* and

(i) is a person referred to in section 159.2, 159.5 or 159.6 of the *Immigration and Refugee Protection Regulations*; or

(ii) is a citizen of the United States; or

(b) is a person whose presence in Canada is determined by the Minister of Public Safety and Emergency Preparedness or the Minister of Citizenship and Immigration to be in the national or public interest, while recognizing the paramount public health interests of Canada and Canadians.

Non-application — certain persons

(2) Subsection (1) does not apply to the following persons who seek to enter Canada at any place referred to in paragraph 159.4(1)(a), (b) or (c) of the *Immigration and Refugee Protection Regulations*:

(a) a citizen of the United States;

(b) a stateless habitual resident of the United States; or

(c) a person who

(i) has not attained the age of 18 years and is not accompanied by their mother, father or legal guardian within the meaning of the *Immigration and Refugee Protection Regulations*,

(ii) has neither a spouse nor a common-law partner within the meaning of those Regulations, and

(iii) has neither a mother or father nor a legal guardian within the meaning of those Regulations in the United States.

Non-application — Order

6 This Order does not apply to

(a) a person registered as an Indian under the *Indian Act*;

(b) a person who, as determined by the Chief Public Health Officer appointed under subsection 6(1) of the *Public Health Agency of Canada Act*, does not pose a risk of significant harm to public health;

(c) a protected person within the meaning of subsection 95(2) of the *Immigration and Refugee Protection Act*; or

(d) a person who enters Canadian waters, including the inland waters, or the airspace over Canada on board a conveyance while proceeding

directly from one place outside Canada and leaves Canada to another place outside Canada on board the conveyance, as long as the person was continuously on board that conveyance while in Canada and, in the case of a conveyance other than an aircraft, the person did not land in Canada and the conveyance did not make contact with another conveyance, moor or anchor while in Canadian waters, including the inland waters, other than anchoring carried out in accordance with the right of innocent passage under international law and, in the case of an aircraft, the conveyance did not land while in Canada.

Powers and obligations

7 For greater certainty, this Order does not affect any of the powers and obligations set out in the *Quarantine Act*.

Repeal of P.C. 2020-565

8 The *Minimizing the Risk of Exposure to COVID-19 in Canada Order (Prohibition of Entry into Canada from the United States)* [3] is repealed.

Effective period

9 This Order has effect for the period beginning at 23:59:59 p.m. Eastern Daylight Time on the day on which it is made and ending at 23:59:59 p.m. Eastern Daylight Time on October 21, 2020.

EXPLANATORY NOTE

(*This note is not part of the Order*.)

Proposal

This Order in Council, entitled *Minimizing the Risk of Exposure to COVID-19*

in Canada Order (Prohibition of Entry into Canada from the United States), is made pursuant to section 58 of the *Quarantine Act*.

The Order repeals and replaces Order in Council P.C. 2020-565 of the same name, which came into force on August 20, 2020.

The new Order complements any Order made under the *Quarantine Act* imposing isolation or quarantine requirements upon entry.

This Order will be in effect from 23:59:59 p.m., Eastern Daylight Time, on the date it is made until 23:59:59 p.m., Eastern Daylight Time, October 21, 2020.

Objective

This Order extends the effective date of the previous Order restricting entry into Canada from the United States.

It furthers Canada's continued focus on reducing the introduction and spread of COVID-19 by decreasing the risk of importing cases from outside the country. The Order continues to prohibit entry into Canada of foreign nationals arriving from the United States for an optional or discretionary purpose, with some limited exceptions. Even those who are exempted from the prohibition may not enter if they have COVID-19 or they exhibit signs and symptoms of COVID-19.

Background

COVID-19

COVID-19 is caused by a novel coronavirus capable of causing severe illness, named the Severe Acute Respiratory Syndrome coronavirus 2 (SARS-CoV-2). It is part of a family of viruses that includes Middle East

Respiratory Syndrome coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome coronavirus (SARS-CoV).

COVID-19 was first detected in Wuhan, China, in December 2019. The disease is caused by a new strain of coronavirus never before seen in humans. Therefore, information about the virus, how it causes disease, whom it affects, and how to appropriately treat or prevent illness has been limited and based on best practices approaches to coronaviruses at large. Originally seen to be a local outbreak, COVID-19 has now affected the majority of countries around the globe. The science surrounding the virus is still evolving.

Coronaviruses are spread among humans primarily through the inhalation of infectious respiratory droplets (e.g. when an infected individual coughs or sneezes) or through contact with objects or surfaces contaminated by infectious droplets. Human-to-human transmission is the main driving force of the current COVID-19 outbreak and is exacerbated by a lack of immunity in the general population.

COVID-19 has been clearly demonstrated to be a severe, life-threatening respiratory disease. Patients with COVID-19 present with symptoms that may include fever, malaise, dry cough, shortness of breath, and damage to the lungs. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure and death. Older individuals and those with a weakened immune system or an underlying medical condition have been seen to be at a higher risk of severe disease. The time from exposure to onset of symptoms is currently estimated to be up to 14 days, with an average of 5 days. No vaccine is available to protect Canadians from COVID-19. Current treatment is supportive, aimed at relief of symptoms and treatment of associated medical complications.

The World Health Organization (WHO) declared an outbreak of what is now known as COVID-19 to be a Public Health Emergency of International Concern (PHEIC) on January 30, 2020, and a pandemic on March 11, 2020. COVID-19 has demonstrated that it can cause widespread illness if not properly contained. Global efforts are focused on identification of cases and the prevention of further spread. If widespread disease occurs in Canada, the health system could be overwhelmed, further increasing negative health impacts.

Government of Canada response to COVID-19 pandemic

The Government of Canada's top priority is the health and safety of Canadians. To limit the introduction and spread of COVID-19 in Canada, the Government of Canada has taken unprecedented action to implement a comprehensive strategy with layers of precautionary measures. Measures include, for example, the establishment of a more than $1 billion COVID-19 Response Fund, restrictions on entry into Canada for optional or discretionary travel, restrictions on cruise ship travel in Canada, and mandatory quarantine and isolation measures to prevent further spread of the virus.

Together, these measures have been effective. For instance, by limiting incoming travel to Canada and requiring mandatory isolation and quarantine, the Government of Canada has reduced travel-related infections to low numbers. While these measures cannot prevent COVID-19 from crossing the borders, they are effective at reducing the risk that community transmission will occur due to international travel.

As the COVID-19 pandemic evolves, the Government of Canada is continuing to evaluate the latest science and situational assessments of what is occurring in various jurisdictions across Canada and

internationally when considering any changes to border restrictions or border measures. All changes to international travel restrictions and advice are based on national and international evidence-based risk assessments. At this time, travel continues to present a risk of imported cases and increases the potential for onward community transmission of COVID-19. This is because, while some countries are starting to see confirmed cases and deaths fall following strict lockdown restrictions, others are still seeing figures rise.

The global number of cases of COVID-19 is rising at an accelerated pace, with sharp increases in cases in Latin America, Africa, Asia and the Middle East. Cases of COVID-19 in the United States also remain high.

The WHO has also warned countries to prepare for new outbreaks, especially in areas where lockdowns have been eased. As of September 18, 2020, there were 6 674 458 detected cases in the United States, 5 214 677 detected cases in India, and 4 455 386 detected cases in Brazil. In August 2020, of the travel-related cases identified in Canada for which a country of origin is identified, 20% of cases were attributed to travellers from the United States.

There remains significant potential for a resurgence of travel-related cases in Canada if the border restrictions between the United States and Canada were to be lifted at this time. Adequate scientific support for the role of laboratory testing as part of a multilayered approach to reduce the risk of importation or to ease quarantine measures is not yet available. Opportunities to develop this necessary evidence are actively being explored.

Entry prohibitions coupled with mandatory isolation and quarantine remain the most effective means of limiting the introduction of new

cases of COVID-19 into Canada. With some countries easing COVID-19 protection measures and the risk of new cases increasing in those countries as a result, the Government of Canada continues to take a precautionary approach to maintain the current border restrictions at this time in an effort to preserve the fragile recovery in Canada.

Implications

Key impacts for travellers

By limiting the number of incoming foreign nationals, Canada has taken strict border measures to limit the risk of the introduction or spread of COVID-19 transmitted via travellers from foreign countries, while maintaining critical services and support necessary for Canada.

This Order will continue to generally prohibit foreign nationals from entering Canada from the United States, unless they are entering for non-optional or non-discretionary purposes or are immediate family members of a Canadian citizen or permanent resident and entering Canada to be with that person for at least 15 days.

Foreign nationals travelling for any purpose will be denied entry into Canada if they have COVID-19, or are exhibiting signs and symptoms of COVID-19, subject to certain narrow exemptions. The enforcement of the prohibition on entry for foreign nationals who arrive exhibiting COVID-19 symptoms, despite having appeared healthy prior to boarding an aircraft or vessel, may be deferred to the extent required to maintain public health and ensure the safety of the commercial transportation system.

The Government of Canada recognizes that the prohibition on entry to Canada has significantly impacted the Canadian economy. However, the measures taken by the Government of Canada continue to be necessary

to address the serious health threat posed by COVID-19.

Penalties

Failure to comply with this Order and other related measures under the *Quarantine Act* are offences under the Act. The maximum penalties are a fine of up to $1,000,000 or imprisonment for three years, or both.

Consultation

The Government of Canada has engaged provinces and territories to coordinate efforts and implementation plans. In addition, there has been consultation across multiple government departments, including the Canada Border Services Agency; Immigration, Refugees and Citizenship Canada; Transport Canada; Public Safety Canada; and Global Affairs Canada, given linkages to other statutory instruments.

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Footnotes

a S.C. 2004, c. 15, s. 66

b R.S., c. F-27

c S.C. 2005, c. 20

1 COVID-19 Dashboard by the Center for Systems Science and Engineering at Johns Hopkins University

2 Coronavirus disease (COVID-19): Outbreak update

3 P.C. 2020-565, August 20, 2020