COURT FILE NUMBER	2401 05557
COURT	**COURT OF KING'S BENCH OF ALBERTA**
JUDICIAL CENTRE	CALGARY
PLAINTIFF	CARRIE SAKAMOTO
DEFENDANTS	ATTORNEY GENERAL OF CANADA AND HIS MAJESTY THE KING IN RIGHT OF ALBERTA
DOCUMENT	**WRITTEN SUBMISSIONS**
ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT	Attorney General of Canada Department of Justice Canada Prairie Region, Edmonton Office **Per: Christine Ashcroft, Barry Benkendorf, Holly Hargreaves** 300, 10423 – 101 Street NW, Edmonton, AB T5H 0E7 [redacted]

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OVERVIEW

1. The COVID-19 pandemic threatened and disrupted lives in Canada and around the world. As the disease rapidly appeared and evolved, governments acted quickly and responsibly to respond to the crisis. The Courts have almost universally rejected attempts to attack those responses.[1]

2. As the COVID-19 pandemic surged across Canada, with accompanying rising COVID-19 deaths and hospital admissions, Canada streamlined the

[1] Most recently in *Taylor v Newfoundland and Labrador*, 2026 SCC 5, ("*Taylor*").

vaccine approval process, and once vaccines arrived, encouraged vaccination. Canada's highest court recently noted:

> …The COVID-19 pandemic that hit the world in 2020 was an indisputable public health emergency. The virus was infectious and deadly... By September, 2024, when Health Canada discontinued statistical reporting, millions of Canadians had been infected with the virus, and 60,871 Canadians had died of it.[2]

3. In addition to claims against the province of Alberta, this Claim[3] challenges the Canadian government's (**"Canada's"**) actions and policy decisions in response to COVID-19, a response which was in furtherance of its public duties.

4. Canada acknowledges that Ms. Sakamoto's circumstances are unfortunate; nevertheless, she was accepted into the Vaccine Injury Support Program, and the Claim does not disclose any cause of action against Canada.

5. Canada does not owe a private law duty of care to individual recipients of a vaccine. Further, Canada does not owe fiduciary duties to groups or individual members of the public in the circumstances of this case. The pleadings in this action do not disclose a cause of action against Canada on any of the other causes of action pleaded.

6. Addressing the remainder of the certification test, there is no basis in fact that an identifiable class of at least two persons exists with a rational connection to the proposed common issues. Ms. Sakamoto has not provided any basis in fact that a person other than herself received the vaccine as a result of wrongdoing by Canada's officials. The proposed class is overbroad. There is no basis in fact that the proposed common issues exist, can be determined in common, or that a class action is the preferable procedure. This Court should not certify this proposed class action.

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[2] *Taylor* at paras 5, 6.
[3] Amended Amended Amended Amended Amended Statement of Claim, filed July 2, 2025 ("Claim").

PART I - FACTS

A. THE COVID-19 PANDEMIC

7. In early 2020, Canada was faced with the unprecedented challenge of responding to a global pandemic caused by COVID-19, the infectious disease caused by the virus SARS-CoV-2 (**"COVID-19 pandemic"**), resulting in serious illness, deaths, societal disruption, and an extraordinary strain on the Canadian health care system. Canada's primary objective in responding to the COVID-19 pandemic was to minimize serious illness and death while also limiting societal disruptions. Vaccination formed a key component of Canada's efforts to protect Canadians against the impact of the COVID-19 pandemic.

B. CANADA'S PUBLIC HEALTH FRAMEWORK FOR VACCINES

8. Health Canada is a federal department over which the Minister of Health **("the Minister")** presides. The Minister's responsibilities under section 4 of the *Department of Health Act* (***"DHA"***) include the protection of the public against risks to health and the spread of diseases.[4] The Minister's, Health Canada's, and the Public Health Agency of Canada's (**"PHAC"**) powers, duties, and functions in relation to public health are set out in the *DHA, Public Health Agency of Canada Act* (***"PHACA"*****),** and *Food and Drugs Act* (***"FDA"*****).**[5]

9. The PHAC is a statutory federal agency established pursuant to the *PHACA* to assist the Minister in exercising the Minister's powers, duties, and functions in relation to public health, including with respect to health protection, disease prevention, and responses to public health emergencies.[6]

10. The National Advisory Committee on Immunization (**"NACI"**) is a committee that advises PHAC on immunization program recommendations. NACI provides information through PHAC that provinces and territories can consider when deciding what to implement in their own jurisdictions. The advice is provided to

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[4] *Department of Health Act,* SC 1996, c 8, s. 4 ("*DHA*").
[5] *Public Health Agency of Canada Act*, SC 2006, c 5 ("*PHACA*"); *Food and Drugs Act,* RSC 1985, c F-27 ("*FDA*"); *DHA,* s. 4(2)(b).
[6] *PHACA,* s. 3, Preamble.

general health care professionals caring for individual patients, to inform them of evidence-based immunization recommendations. [7]

11. NACI provides recommendations on the use of vaccine products in Canada. These recommendations are shared as public statements posted online and are incorporated into the Canadian Immunization Guide, which are standing recommendations for immunization programs across the country. Immunization programs are determined by provincial governments, which determine eligibility for publicly funded vaccines.

12. In making these decisions, provinces may consider NACI's advice and recommendations; however, the final determinations rest at their own discretion. [8]

13. In determining which vaccines to recommend to the public, in addition to NACI recommendations, Alberta considers several factors: provincial epidemiology (i.e., who is affected by specific diseases in Alberta, and different infection types and strains); scientific evidence-based information used by other organizations such as the U.S. Centers for Disease Control; and in some cases Alberta-specific studies on particular immunization topics, which may be discussed at the Alberta Advisory Committee on Immunization. [9]

14. Dr. Klein, at the time of questioning the Alberta interim deputy chief medical officer of health,[10] is a member of NACI, as an expert in the field of public health and immunization, not as a representative of Alberta.[11]

15. In the event the Minister believes that immediate action is required to deal with a significant direct or indirect risk to health, safety, or the environment, the Minister may make an Interim Order pursuant to section 30.1 of the *FDA*.[12]

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[7] Dr. Kristin Klein ("Klein") cross-examination transcript, November 27, 2025, p. 79, lines 13-25.
[8] Klein cross-examination transcript, November 27, 2025, pp. 80-81, lines 23-27; 1-12.
[9] Klein cross-examination transcript, November 27, 2025, pp.136, lines 10-27.
[10] Klein cross-examination transcript, November 27, 2025, p.5, lines 5-10.
[11] Klein cross-examination transcript, November 27, p. 80, lines 13-18.
[12] *FDA*, s. 30.1.

C. CANADA'S REGULATORY RESPONSE TO THE COVID-19 VACCINES

16. On September 16, 2020, pursuant to s. 30.1 of the *FDA*, the Minister issued the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*.[13] The Explanatory Note to the Interim Order states that 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.[14]

17. The Interim Order created a regulatory pathway for authorization of COVID-19 drugs, including vaccines, with flexibilities which still required the provision of sufficient information to allow the Minister to determine whether to authorize the drug.[15]

18. Section 5 of the Interim Order states that the Minister must issue an authorization for importation or sale if certain requirements are met, including that

> …c) The Minister has sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19.[16]

D. MS. SAKAMOTO

19. In 2021, Ms. Sakamoto (**Ms. Sakamoto or the plaintiff**) was a 41-year-old woman residing in Alberta.[17] She received her first COVID -19 vaccine, the AstraZeneca COVID-19 vaccine, on April 21, 2021, one day after those in her age group were eligible for vaccination. [18] She received the Pfizer-BioNTech COVID-19 (**Pfizer**) vaccine on June 18, 2021.[19]

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[13] Interim Order Respecting the Importation, Sale, and Advertisement of Drugs for Use in Relation to COVID-19, vol 154, no 40, Canada Gazette I, 3 October 2020 (*Food and Drugs Act*), ("Interim Order"), pp. 2542-2565, made by the Minister of Health and approved by OIC September 25, 2020 [**Tab A**].
[14] Interim Order, Explanatory Note, pp. 2556-2557. See also preamble, p. 2542 [**Tab A**].
[15] Interim Order, ss. 3, 4 [**Tab A**].
[16] Interim Order, s. 5 [**Tab A**].
[17] Claim at para 10, 12.
[18] Claim at para 71; Sakamoto Affidavit, para 8, and Sakamoto cross-examination, p. 10, lines 6-11; p. 55, line 21-26.
[19] Claim at para 71.

20. Prior to receiving her first vaccine, Ms. Sakamoto consulted with her doctor about which COVID-19 vaccine she should receive. Her doctor said she couldn't provide a recommendation because she didn't know enough about them and it would have to be a "personal choice."[20] Other than her family doctor, Ms. Sakamoto spoke with no other medical professional.[21] Ms. Sakamoto had no direct contact with Dr. Theresa Tam, Canada's Chief Public Health Officer,[22] or then Prime Minister Trudeau.[23]

21. Ms. Sakamoto was motivated in part to be vaccinated to avoid getting COVID-19, and to avoid infecting friends or family with COVID-19.[24] She had, in other years, received a flu vaccine, and arranged for her children to receive childhood vaccinations.[25]

22. Ms. Sakamoto recalled radio messaging which included constant updates on the number of people in hospital with COVID-19, that hospitals were full, people were getting very sick, and dying, and to take a vaccine to curb the spread. Ms. Sakamoto was homeschooling her children. Government of Alberta messaging included the communication that the sooner persons got the vaccine, the sooner life could go back to normal. [26]

23. Following Ms. Sakamoto's first vaccination, she received a Client Immunization Record and Care After Immunization form,[27] which she reviewed,[28] that set out rare side effects of the vaccine.[29] That document stated "it is rare to have a serious side effect" and described very rare reports of blood clots, low platelet levels and

[20] Sakamoto cross-examination, p. 12, line 26 to p. 13, line 18.
[21] Sakamoto cross-examination, p. 16, line 25 to p. 17 line 6.
[22] Affidavit of Angeline Kunz sworn September 18, 2025 ("Kunz Affidavit"), Exhibit E, p. 1.
[23] Sakamoto cross-examination, p. 79, line 9-16.
[24] Sakamoto cross-examination, p. 68, line 24 to p. 69, line 5.
[25] Sakamoto cross-examination, p. 69 line 6-12, 24-27.
[26] Sakamoto cross-examination, p. 24 lines 7-15, and p. 26, line 3.
[27] Sakamoto cross-examination, p. 13, line 23 to p. 14, line 2.
[28] Sakamoto cross-examination, p. 14, line 23-25.
[29] Sakamoto cross-examination, p. 14, line 16-25 and p. 15, line 7-12.

bleeding.[30] After receiving her first vaccine, Ms. Sakamoto was aware of the risk of side effects listed on that form.[31]

24. Ms. Sakamoto stated that she took the vaccines under "duress", which she said meant she felt pressure from government and peers, and threats from then Prime Minister Justin Trudeau that persons would not be able to travel, grocery shop or attend public events without vaccines.[32] Pursuant to an undertaking, Ms. Sakamoto stated that she could not specifically recall whether grocery stores were mentioned.[33]

E. PUBLICLY AVAILABLE INFORMATION

25. On December 10, 2020, PHAC announced that PHAC was implementing a no-fault vaccine injury support program, the Vaccine Injury Support Program (**"VISP"**). The announcement stated that Canadians would be able to access support "in the rare event that they experience an adverse reaction to a vaccine."[34]

26. The evidence filed on behalf of Ms. Sakamoto does not include all the publicly available statements and documents pertaining to COVID-19 vaccination. For example, on January 8, 2021, CBC News reported that Health Canada identified nine adverse reactions after COVID-19 vaccinations.[35] The same report provided a link taking a reader to "Reported Side Effects Following COVID-19 vaccinations in Canada."[36] This website was continually updated from January 8, 2021 until January 2024.[37]

27. As of January 2024, the website stated that 105,016,456 doses of vaccine had been administered; 11,702 serious adverse events following immunization were

[30] Affidavit of Carrie Sakamoto, sworn September 11, 2024, Exhibit A.
[31] Sakamoto cross-examination, p. 17, line 7-18.
[32] Sakamoto cross-examination, p. 28, line 12-17, line 22 to p. 29, line 5.
[33] Sakamoto cross-examination, Undertaking 3, answer.
[34] Affidavit of Tracey Bradley, affirmed June 9, 2025 ("Bradley Affidavit #2") at Exhibit H.
[35] Kunz Affidavit at para 6, 16-19, and Exhibit E to that affidavit. Exhibit E is Exhibit C for identification to Ms. Sakamoto's cross examination.
[36] Kunz Affidavit at para 6, 16-19, and Exhibits E and O-R.
[37] Kunz Affidavit at Exhibits O-R.

reported (0.011%).[38] Ms. Sakamoto was not aware there was a website that provided weekly reports on vaccine safety.[39]

28. At the time of her vaccinations, Ms. Sakamoto was living in the Lethbridge area.[40] On January 20, 2021, Lethbridge News Now reported that Alberta's Chief Medical Officer of Health, Dr. Hinshaw, stated that 0.019% of COVID-19 vaccines had caused adverse events.[41] Ms. Sakamoto "possibly" looked at the Lethbridge News Now online.[42]

29. Although Ms. Sakamoto stated that she got information from Global TV, CBC and CTV,[43] and that she may have been on the CBC website in the first six months of 2021,[44] her counsel objected to her answering questions respecting whether she had seen the January 8, 2021 CBC report, or the January 20, 2021 Lethbridge News Now article, both of which reported adverse effects from the vaccine.[45] Therefore there is no evidence respecting whether she saw them or not.

30. Although Ms. Sakamoto said she was afraid to take the vaccine, she did not recall whether she visited any Government of Canada websites between January and June of 2021 pertaining to vaccine safety and efficacy. [46]

31. A Canadian government website "Health Product InfoWatch" dated March 2021, stated, among other information provided, that the benefits of the AstraZeneca COVID-19 vaccine outweighed the risks. It further stated that very rare reports of blood clots had been found in Europe, but that the vaccine was not associated with an increase in the overall risk of blood clots.[47]

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[38] Kunz Affidavit at Exhibit R.
[39] Sakamoto cross-examination, pp. 15-18.
[40] Sakamoto cross-examination, p. 37, lines 4-6.
[41] Kunz Affidavit, paragraph 7 and Exhibit G to that affidavit. Exhibit G was also Exhibit B for identification at Sakamoto's cross-examination.
[42] Sakamoto cross-examination, p. 53, lines 21-23.
[43] Sakamoto cross-examination, p. 37, lines 21-26; p. 54, lines 23-26.
[44] Sakamoto cross-examination, p. 62, lines 7 to 13.
[45] Sakamoto cross-examination, p. 60, lines 9 to page 62, line 1; and p. 62, lines 19 to p. 63, line 6.
[46] Sakamoto cross-examination, p. 54, line 26, p. 55, line 4, p. 62, line 2-6.
[47] Kunz Affidavit, para 9, and Exhibit H to that affidavit.

32. On May 4, 2021, Prime Minister Trudeau stated, "the impacts of catching COVID are far greater, and far deadlier, as we've seen across the country, than potential side effects."[48]

33. On May 11, 2021, CBC News posted an article stating both that experts warned of "very rare side effects" of the AstraZeneca vaccine, and that scientists opined that mixing vaccines could boost the immune response.[49]

34. On May 17, 2021, the Minister stated that the Canadian government was "supporting Canadians to make informed COVID-19 vaccine choices."[50]

35. On June 1, 2021, the NACI recommended that the COVID-19 vaccines were interchangeable.[51]

36. On July 13, 2021, CBC reported on new data that concluded that mixing COVID-19 vaccines was safe and effective at preventing COVID-19.[52]

37. On August 6, 2021, Global News reported that Health Canada added a Bell's Palsy warning to Pfizer COVID-19 vaccine labels.[53] On the same date, Health Canada announced that it had updated the Pfizer COVID-19 vaccine label to reflect very rare reports of Bell's Palsy.[54]

38. On October 12, 2021, CBC reported on the "rare, but real" risks of vaccination for COVID-19.[55]

39. Various news reports available on CBC, Global News, and on various Government of Canada websites provided information about rare side effects of myocarditis, pericarditis, and Bell's Palsy associated with some COVID-19 vaccines.[56]

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[48] Claim at para 63(c).
[49] Kunz Affidavit at Exhibit S.
[50] Claim at para 63(d).
[51] Kunz Affidavit, Exhibit X.
[52] Kunz Affidavit, para 24, and Exhibit W. Exhibit W was also Exhibit C for identification at Sakamoto's cross-examination.
[53] Kunz Affidavit, para 11 and Exhibit J.
[54] Kunz Affidavit, para 12 and Exhibit K to that affidavit.
[55] Kunz Affidavit, para 14 and Exhibit M to that affidavit.
[56] Kunz Affidavit, paras 10-13 and Exhibits I-L.

Although these reports were dated after Ms. Sakamoto's vaccinations, this information was accessible to others.

40. The plaintiff has filed no expert evidence in this matter. Dr. Davidson's affidavit does not attach a resume. There is no evidence he has education, expertise or qualifications in epidemiology, immunology, or public health.

41. Dr. Klein, Alberta's Deputy Chief Medical Officer of Health at the time she swore her affidavit, has testified that no vaccine is 100% effective at preventing individuals from being infected with the disease. However, the COVID-19 vaccines authorized for use in Canada have been highly effective in preventing severe illness and death.[57] She has further testified that all vaccines carry a risk of adverse health effects; however, serious side effects of the COVID-19 vaccine are rare. For those recommended to receive a vaccine, the benefits of vaccination far outweigh the risk.[58]

F. NO EVIDENCE RESPECTING OTHER PROPOSED CLASS MEMBERS

42. Ms. Sakamoto does not know what information any other class member might have had prior to receiving the vaccine.[59] She does not know what other class members might have relied on or what access to information they had.[60] She does not know whether other class members spoke to a doctor prior to receiving the vaccine.[61]

G. VACCINE INJURY SUPPORT PROGRAM

43. Ms. Sakamoto was accepted into the VISP program less than two years after applying, on March 3, 2023.[62] There is no evidence that she was not compensated through the program. VISP is a no-fault program that provides financial supports to those injured as a result of receiving a Health Canada approved vaccine administered in Canada after December 8, 2020, including a COVID-19 vaccine.

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[57] Affidavit of Dr. Kristin Klein sworn Sept 18, 2025 (Klein Affidavit), paras 1, 14.
[58] Klein affidavit, para 15.
[59] Sakamoto cross-examination p. 17, line 25 to p. 18, line 3; p. 42, line 22 to p. 43, line 7.
[60] Sakamoto cross-examination p. 39, line 18-23.
[61] Sakamoto cross-examination p. 18, line 9-13.
[62] Sakamoto Affidavit, paras 24-25 and Exhibit D.

A committee of independent medical experts makes decisions on eligibility for compensation and benefits. Financial supports include income replacement, reimbursement for costs and medical expenses, death benefits and funeral expenses. Those compensated are not required to waive their right to pursue litigation.[63] There is an appeal process.[64]

44. Reported statistics from June 1, 2021 to December 1, 2024 showed that 3060 Vaccine Injury claims had been received, and more than $16.5 million paid to claimants.[65]

PART II - ISSUES

45. This proposed class action does not disclose a cause of action in:
    a. Negligent misrepresentation
    b. Negligence
    c. Misfeasance in public office
    d. Breach of fiduciary duty or
    e. Conspiracy.

46. Moreover, there is no basis in fact supporting the proposed class, or the proposed common issues. Finally, the issue of whether a proposed class member relied on misrepresentations, suffered harm, and the amount of their damages cannot be determined in common across the class. These are issues individual to each proposed class member.

PART III - SUBMISSIONS

A. CERTIFICATION TEST

47. The *Class Proceedings Act* sets out the test for certification. Each part of the test must be met:
    a. The pleadings must disclose a cause of action;
    b. There must be an identifiable class of two or more persons;

[63] Gene Smith Affidavit sworn September 19, 2025, paras 30-35.
[64] Bradley Affidavit sworn June 2, 2025, Exhibit F (Bradley Affidavit #1).
[65] Bradley Affidavit #1, Exhibit F.

c. The claims must raise a common issue of law or fact;

d. A class action must be the preferable procedure for the fair and efficient resolution of the common issues; and

e. There is a representative plaintiff who can fairly and adequately represent the claims of the class and has produced a workable plan which will advance the action.[66]

48. The certification motion is intended to be a meaningful screening device. "No evidence is admissible respecting the first criteria; the test is determined based on the pleadings. "Some basis in fact" is required for the remaining criteria.[67] The standard of 'some basis in fact' requires more than "a superficial level of analysis" into the sufficiency of the evidence that "would amount to nothing more than symbolic scrutiny."[68] If the plaintiff fails to meet any one of the five listed criteria, the certification motion must fail.[69]

49. The Claim does not disclose any reasonable cause of action. There is not a properly identifiable class. The proposed common issues either arise from matters which do not disclose a cause of action, or require individual inquiries. This Claim and common issues should not be certified.

B. DAVIDSON AFFIDAVIT SHOULD BE GIVEN NO WEIGHT AND REPORTS NOT ADMISSIBLE FOR THE TRUTH OF THEIR CONTENTS

50. Dr. Davidson's affidavits are improperly tendered opinion evidence and should be given no weight. The *Mohan* requirements for an expert report apply in certification proceedings.[70] The final *Mohan* requirement for an expert report is a properly qualified expert.[71] Dr. Davidson does not have the qualifications to opine in this matter, because there is no evidence he is an epidemiologist, immunologist, or expert in public health, or has experience in those areas.

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[66] *Class Proceedings Act*, SA 2003, c C-16.5, s. 5 ("*CPA*").
[67] *Hollick v Metropolitan Toronto (City)*, 2001 SCC 68 at para 26; *Spring v Goodyear Canada Inc*., 2021 ABCA 182 at para 40.
[68] *Pro-Sys Consultants Ltd. v Microsoft Corp*., 2013 SCC 57 at para 103 ("*Pro-Sys Consultants Ltd*").
[69] *Kahnapace v Canada (Attorney General)*, 2023 FC 32 at para 95 ("*Kahnapace*").
[70] *O'Connor v Canadian Pacific Railway Limited*, 2023 BCSC 1371 at para 73.
[71] *R v Mohan*, 1994 CanLII 80 (SCC), [1994] 2 SCR 9 at p. 17 (g-i).

51. Furthermore, the report attached to his first affidavit, and the reports attached to his rebuttal affidavit are hearsay documents which should be given no weight.

52. The reports and articles tendered by the plaintiff are not admissible for the truth of their contents as providing "some basis in fact" for certification, as they were not prepared for the purpose of litigation,[72] are unreliable[73] and are being tendered on contentious issues.[74] A certification motion is not an "evidentiary free for all." [75]

53. Where there is primary evidence tendered on the same subject as the report or article,[76] and a report or article is otherwise admissible, the report or article can only be accepted to support the "some basis in fact" standard on non-contentious issues which are common ground between the parties[77] and for putting facts into context.[78] This is not the case here.

54. It is impossible to draw the conclusion that the facts contained in the reports attached to Dr. Davidson's affidavits and the attached reports are not contentious or are common ground among the parties. For example, in response to the Final Report on Alberta's COVID-19 Pandemic Response by the Pandemic Data Review Task Force,[79] the Alberta Medical Association issued a public statement[80] that the report is "anti-science", "anti-evidence", "criticizes proven preventative public health measures while advancing fringe approaches" and "makes recommendations for the future that have real potential to cause harm."[81]

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[72] See *Bigeagle v. Canada*, 2023 FCA 128 at para 46 ("*Bigeagle*"). The Federal Court stated that "[…] commissions of inquiry do not have the same evidentiary standards as those applied by a court, in part because they have a different purpose. Often, the information gathered is not taken under oath and constitutes hearsay. Likewise, the process followed does not automatically provide for due process, including the right to cross-examine during fact gathering".
[73] See *Lam v Flo Health Inc,* 2024 BCSC 391 at para 164.
[74] *Bigeagle* at para 44.
[75] *Johnson v Ontario*, 2016 ONSC 5314 at para 54.
[76] *Canada (Attorney General) v B.W.*, 2025 FCA 199 at para 47.
[77] See *Lockhart v Attorney General of Canada*, 2024 ONSC 6573 at para 191.
[78] *Doan v Canada*, 2023 FC 968 at para 187 ("*Doan*"); *Bigeagle* at para 44.
[79] Exhibit "A", Affidavit of Dr. Gary Davidson, sworn 11 June 2025 ("Davidson Affidavit").
[80] Exhibit "B", Davidson Affidavit.
[81] Exhibit "B", Davidson Affidavit.

55. One obvious example of the frailties of such evidence is the article attached to Dr. Davidson's rebuttal affidavit entitled "Unreliable Evidence: Flawed Vaccinated vs. Unvaccinated Comparisons in Canada's COVID-19 Vaccine Mandates"[82] . It is a peer-reviewed "preprint" taken from the internet. It is authored by a single "independent researcher" with qualifications in mathematics, physics and statistics, who draws conclusions involving alleged Charter violations. Another obvious example is the CNN article attached to Dr. Davidson's rebuttal affidavit, "FDA intends to put its most serious warning on Covid vaccines, sources say",[83] based on information from unnamed sources. The article itself includes a statement from the US Department of Health and Human Services, that "unless the FDA announces it, any claim about what it will do is pure speculation." None of the authors of the articles attached to Dr. Davidson's rebuttal affidavit can be cross-examined.

C. PLEADINGS DO NOT DISCLOSE A CAUSE OF ACTION

56. The test for a reasonable cause of action at certification is the same test used in a motion to strike a claim. The test is well known: a pleading will be permitted to proceed unless it is plain and obvious that the claims in it have no reasonable prospect of success.[84] At certification, the Court is required to consider whether each claim discloses a reasonable cause of action against a defendant.[85] Although the causes of action in this Claim are not novel, even an allegedly novel claim will not succeed if it does not meet this threshold.[86]

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[82] Exhibit "A" to the Rebuttal Affidavit of Dr. Davidson sworn December 31, 2025 ("Davidson Rebuttal Affidavit").
[83] Exhibit "G" to the Rebuttal Affidavit of Dr. Davidson sworn December 31, 2025.
[84] *Nevsun Resources Ltd v Araya*, 2020 SCC 5 at para 64 ("*Nevsun Resources Ltd*"); see also *R v Imperial Tobacco Canada Ltd.*, 2011 SCC 42 ("*Imperial Tabacco")*; *Atlantic Lottery Corp v Babstock*, 2020 SCC 19 at para 19 ("*Atlantic Lottery Corp.*").
[85] *CPA*, s. 5(1); *Atlantic Lottery* at para 14; *Nova Scotia (Health) v Morrison Estate*, 2011 NSCA 68 at paras 19, 22, 23, 25, 40.
[86] *Atlantic Lottery Corp. Inc*.

57. The pleading must plead the essential facts.[87] The facts as pleaded are assumed to be true unless they are "manifestly incapable of being proven."[88] Allegations based on assumptions and speculations need not be taken as true.[89] Bald assertions of misconduct, including allegations of misfeasance in public office, will not be accepted as true without reasonable particulars of the actions.[90]

58. Further, in considering whether a proposed class action meets the first part of the test "the certification jurisprudence has become more stringent and less forgiving, emphasising in more recent times the court's duty to serve as a gatekeeper, scrupulously screening proposed class proceedings to ensure their suitability and conserve finite judicial resources."[91]

59. The material facts pled in the Claim do not disclose a cause of action. This Court's analysis should conclude with the finding that each claim pleaded is bound to fail.[92]

1. No Cause of Action in Negligent Misrepresentation

60. As with all forms of negligence claims, the plaintiff's negligent misrepresentation claim first requires that Canada owe a private law duty of care. It is plain and obvious that Canada does not owe a private law duty of care to the plaintiff or proposed class on the pleaded facts.

61. The existence of a duty of care is determined by the two-part *Anns/Cooper* test. The first stage of the test is to determine whether there is sufficient proximity and foreseeability to raise a *prima facie* duty of care. Proximity is the critical element in assessing whether the government owes a *prima facie* duty of care to members

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[87] *Anglin v Resler*, 2024 ABCA 113 at para 47 ("*Anglin*").
[88] *Imperial Tobacco* at para 22; *Operation Dismantle v. The Queen*, [1985] 1 SCR 441 at p. 455, para 1, 27; *Zbarsky v Canada*, 2022 FC 195 ("*Zbarsky*") at paras 23-24.
[89] *Operation Dismantle* at p. 455, para 27.
[90] *Anglin* at para 45. *G.H. v Alcock,* 2013 ABCA 24 at para 58 ("*G.H.*").
[91] *Canadian Society for the Advancement of Society and Public Policy v British Columbia*, 2025 BCSC 2051 at para 276 ("*Canadian Society*").
[92] *Atlantic Lottery Corp* at para 72.

of the public allegedly injured due to receiving a vaccine. Foreseeability is not contested for the purposes of this motion.

62. The second stage of the test considers whether any considerations negate any *prima facie* duty of care.[93]

63. The plaintiff bears the burden of proving proximity and foreseeability on a balance of probabilities.[94] At the second stage, which addresses policy considerations, the onus shifts to the defendant.[95] Where novel duties of care are alleged, a full analysis is required. [96]

64. These submissions consider the first part of the test (whether Canada owes a *prima facie* duty of care), separately for each of negligent misrepresentation and negligence. Whether other considerations limit the duty of care (the second part of the test), will be considered together, for both negligent misrepresentation and negligence.

a) No Prima Facie Private Law Duty of Care in Negligent Misrepresentation

65. The first step in assessing proximity is to determine whether the matter is analogous to legal precedents that have already recognized or rejected a private law duty of care in similar circumstances.[97] In this case, sufficiently analogous cases establish that Canada owes public, not private law, duties of care.

66. If this Court should proceed past the first step, and an *Anns/Cooper* analysis follows, Stage 1 of that analysis is to determine whether the alleged duty of care arises, explicitly or implicitly, from the statute, from interactions between the claimant and the government, and is not negated by the statute, or both.[98] In this case, the relevant statutes give rise to public duties rather than a private law duty

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[93] *Cooper v Hobart*, 2001 SCC 79 at para 30 ("*Cooper*").
[94] *Childs v Desormeaux*, 2006 SCC 18 at para 13.
[95] *Rausch v Pickering (City)*, 2013 ONCA 740 at para 52.
[96] *Rankin (Rankin's Garage & Sales) v J.J.*, 2018 SCC 19 at para 18.
[97] *Cooper* at paras 35-36.
[98] *Imperial Tobacco* at paras 43-46.

of care, and neither the statutes nor interactions give rise to a private law duty of care.

67. The final step (*Anns/Cooper* stage 2 test) is to determine whether core policy immunity shields the actions alleged, and whether any *prima facie* private law duty of care should nonetheless be negated for residual policy reasons.

Courts have found no Private Law Duty of Care Exists in Analogous Circumstances

68. Courts have found in analogous negligent misrepresentation cases that neither statute nor public representations support proximity between government and individual members of the public, and therefore no *prima facie* duty of care exists. Further, in analogous cases, even if a *prima facie* duty was owed, it would be negated as core policy decisions and for residual policy concerns including conflict between public duties and the proposed private law duty of care, and the potential for the creation of unlimited liability to an indeterminate class.

69. *R v Imperial Tobacco*[99] (*Imperial Tobacco*) is the leading case pertaining to the allegedly negligent misrepresentations of government to the public. Many cases since have relied on *Imperial Tobacco* to find that the relevant statutes support public rather than private law duties, and further, that representations to the public are insufficient to support a proximate relationship.

70. In *Imperial Tobacco*, a proposed class action, the plaintiff sought damages against the defendant tobacco companies to recover the costs of medical treatment for tobacco-related illnesses. The defendants attempted to pursue third party proceedings against Canada on the basis, among other matters, that Canada had negligently misrepresented to the public that low tar cigarettes were less hazardous.[100]

[99] *Imperial Tobacco*.
[100] *Imperial Tobacco* at para 32.

71. The Supreme Court of Canada held that the relevant statutes, including the *DHA*,[101] set out public duties rather than a private law duty to consumers.[102] Canada's statements to the public that low tar cigarettes were less toxic were not specific interactions between Canada and the class members. General representations to the public were not enough to establish a direct relationship.[103] At the second stage of the analysis, the claim was struck on the basis that the representations were based on true policy decisions. A further consideration negating a duty of care was that the claim would expose Canada to indeterminate liability.[104]

72. In the specific context of vaccines, in *Adam v Ledesma-Cadhit,*[105] the Ontario Superior Court of Justice struck a Statement of Claim which alleged that Canada was responsible for the death of the plaintiffs' daughter as the result of an H1N1 influenza vaccination. The H1N1 influenza was a worldwide pandemic health risk. The Court considered the DHA, the PHACA, and the FDA, and an Ontario interim order similar to that in this matter. None of them supported a relationship of proximity to the plaintiff.[106] Representations at issue were representations to the public and were not sufficient to create proximity.[107]

73. Finally, had the claim disclosed a proximate relationship, the Court would have negated the duty of care for policy reasons, and a concern for indeterminate liability.[108]

74. *Hartman v AGC*[109] concerns a COVID-19 vaccination that allegedly resulted in the death of a child, in the context of the COVID-19 pandemic. The Ontario Superior Court determined Canada owed no duty of care in the circumstances.

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[101] *DHA*.
[102] *Imperial Tobacco* at para 50.
[103] *Imperial Tobacco* at para 49.
[104] *Imperial Tobacco* at paras 61, 62.
[105] *Adam, Abudu v Ledesma-Cadhit*, 2014 ONSC 5726 ("*Adam*").
[106] *Adam* at paras 124, 128, 135.
[107] *Adam* at paras 116, 146-151.
[108] *Adam* at paras 160-167.
[109] *Hartman v Attorney General of Canada et al.*, 2025 ONSC 1831 ("*Hartman*"). *Hartman* is currently under appeal (ONCA File No. COA-25-CV-0502).

75. *Hartman,* like this case, focussed on alleged Canadian government misrepresentations to the Canadian public[110] regarding the Pfizer-BioNTech COVID-19 vaccine (**Pfizer Vaccine**) and vaccinations. The representations pertained to the safety, efficacy and quality of the vaccine, and related matters. As in this case, the claim also alleged failures to disclose possible side effects of the COVID-19 vaccine. [111]

76. The Court struck the claim on the basis that it was plain and obvious that the claim could not succeed. There was no proximity grounded in the legislative scheme, and representations to the public were not sufficient to establish proximity. Finally, the decisions made by Canada were core policy decisions addressing a global pandemic and in consideration of the health of the entire Canadian public.[112]

77. Those legal precedents are analogous to the present matter. The claims advanced here are not distinguishable from the claims in the *Imperial Tobacco*, *Adam*, or *Hartman.* The numerous decisions discussed in those decisions also repeatedly find a) no proximity arises from statute and b) public representations are not sufficient to create proximity arising from interactions.

78. Accordingly, this Court can conclude its analysis by determining that sufficiently analogous cases have found no private law duty of care exists in the same circumstances.

79. The negligent misrepresentation cases on which the plaintiff relies[113] are distinguishable. The public duties and lack of individual interactions central to this case are not at issue in those cases. *Hill v Hamilton Wentworth,*[114] on which the plaintiff relies, is a negligent investigation claim, which specifically dealt "only

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[110] *Hartman* at para 52.
[111] *Hartman* at paras 16-20.
[112] *Hartman* at paras 41, 49-50, 53, 68, 73. The court specifically considered the decisions of *Adam, Eliopoulos Estate v Ontario (Minister of Health and Long-Term Care),* 2006 CanLII 37121 (ON CA) ("*Eliopoulos*"), *Abarquez v Ontario*, 2009 ONCA 374 ("*Albarquez*"), *Williams v. Ontario,* 2009 ONCA 378 ("*Williams*"), and *Attis v Canada (Health),* 2008 ONCA 660 ("*Attis*").
[113] Plaintiff's Certification Brief at footnotes 70, 71.
[114] Plaintiff's Certification Brief at paras 109, 110, citing *Hill v Hamilton-Wentworth Regional Police Services Board*, 2007 SCC 41 (CanLII) ("*Hamilton-Wentworth*").

with" the "very particular" relationship between an investigating police officer and a suspect under investigation. The relationship was personal, close and direct. [115] For that reason, *Hill* is distinguishable from this matter.

b) No Private Law Duty of Care through Statute

80. The plaintiff relies on the *DHA,* the *PHACA*, and the *FDA*, stating that they inform the duty of care. Courts have previously found that none of these statutes supports a private law duty of care to an individual or group.

81. Section 4 of the *DHA* provides:

> **4 (1)** The powers, duties and functions of the Minister extend to and include all matters over which Parliament has jurisdiction relating to the promotion and preservation of the health of the people of Canada not by law assigned to any other department, board or agency of the Government of Canada.
>
> **Particulars**
>
> **(2)** Without restricting the generality of subsection (1), the Minister's powers, duties and functions relating to health include the following matters:
>
> - …(a.1) the promotion and preservation of the physical, mental and social well-being of the people of Canada;
> - **(b)** the protection of the people of Canada against risks to health and the spreading of diseases;
> - **(c)** investigation and research into public health, including the monitoring of diseases…

82. As noted, in *Imperial Tobacco,* the Supreme Court of Canada determined that the *DHA* did not give rise to a private law duty of care to the consumers of tobacco products. The general duties to the public set out by the *DHA* did not give rise to a private law duty of care.[116] The Minister's public law discretionary powers, to be

[115] *Hamilton-Wentworth* at paras 27, 33.
[116] *Imperial Tobacco* at paras 50, 60.

exercised in the general public interest, could not be converted to private law duties owed to individuals.[117]

83. The *PHACA* does not give rise to a private law duty of care owed by Canada to the proposed class members. The Ontario Court of Justice considered the *PHACA* in *Adam*, concluding that the *PHACA* establishes a duty to all Canadians, not to individual vaccine recipients.[118]

84. Section 15 of *PHACA* states that the "Governor in Council may" make regulations respecting the collection, analysis, etc. of information relating to public health.[119] The plaintiff's reliance on s. 15[120] to underpin a duty of care is misplaced, because that section describes only a power to make regulations - no duty at all.

85. The Ontario Court of Appeal has concluded that the *FDA* also does not support a private law duty of care. In *Drady v Canada (Minister of Health),*[121] the Court considered the responsibilities of Health Canada and whether it was negligent in allegedly failing to regulate temporomandibular joint implants as medical devices under the *FDA*.[122] In upholding the motions judge's decision to strike the pleading for not disclosing a duty of care, the Court reviewed the legislative scheme of the *FDA*. The Court concluded that Health Canada owed public duties to Canadians. However, the legislation did not envision a relationship between Health Canada and consumers of medical devices and thus could not ground a private law duty of care to any individual.[123] There was no proximity between Canada and the plaintiff stemming from the *FDA*'s regulatory scheme.[124]

86. *Adam* also addressed the *FDA* and considered the Minister of Health and Health Canada's responsibilities stemming from the legislation. In particular, the court

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[117] *Imperial Tobacco* at para 50.
[118] *Adam* at para 128.
[119] *PHACA*, s 15.
[120] Plaintiff's Certification Brief, para 80.
[121] *Drady v Canada (Minister of Health)*, 2008 ONCA 659 ("*Drady*").
[122] *Drady* at para 13.
[123] *Drady* at para 38.
[124] *Drady* at para 58. See also *Attis* at para 59, and *Klein v American Medical Systems Inc.*, 2006 CanLII 42799 at paras 25-31 ("*Klein*").

considered the same interim order provision of s. 30.1 of the *FDA* and *ss.* C.08.002 of the *Food and Drug Regulations*.[125] The *Adam* Interim Order highlighted the policy decision made by the federal government in addressing the H1N1 pandemic.[126] In considering other decisions addressing the *FDA*, including *Drady* and *Attis v Canada (Minister of Health)*,[127] the court concluded that the regulatory powers and functions of Health Canada in relation to licensing vaccines for usage in Canada did not give rise to proximity between Canada and individual users of a vaccine sufficient to create a relationship of proximity.[128] The same analysis applies to the facts in this proposed claim.

c) No Private Law Duty of Care through Interactions

87. Public representations, like those in this case, are insufficient to create a duty of care arising from interactions. The Claim does not allege direct communications between Canada and the alleged class. The jurisprudence is clear that public representations are insufficient to create a direct relationship between Canada and the proposed class.[129]

88. As previously noted, these submissions will consider residual policy considerations for both negligent misrepresentation and negligence following submissions on proximity for negligence.

2. No Cause of Action in Negligence

89. It is plain and obvious that the plaintiff's claim in negligence cannot succeed. As in negligent misrepresentation, a private law duty of care is required. For the same reasons relevant to negligent misrepresentation, Canada owes no duty of care in negligence.

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[125] Claim at paras 22, 25-26, 38, 88, 90, 159, 164, 1.
[126] *Adam* at paras 17, 132-133.
[127] *Attis v Canada (Health),* 2008 ONCA 660
[128] *Adam* at paras 134-135.
[129] *Imperial Tobacco* at para 49; *Hartman* at para 18; *Adam* at para 147.

90. In *Eliopoulos v Ontario*[130] a plaintiff contracted the West Nile Virus and died. His estate sought to hold Ontario liable, based on Ontario's statutory duties under the *Health Protection and Promotion Act,* for not taking reasonable steps to prevent the spread of West Nile Virus. The Court looked to the Act, which, similarly to the *DHA*, stated that the Act's purpose was to prevent the spread of disease and to promote and protect the health of Ontarians.[131] The Court concluded that the Act created discretionary powers incapable of creating a private law duty.[132]

91. Similarly, in *Williams v Canada (AG),*[133] the plaintiff proposed a class action on behalf of those who contracted SARS during an outbreak. The Court found no proximity between the plaintiff, the proposed class, and Ontario.[134] Rather, Ontario was required to address the interests of the public at large rather than the particular interests of the plaintiff or those like her.[135]

92. In the context of informed consent, just as with the other claims of negligence in this action, proximity is required to ground a duty of care. There is no proximity between the Government of Canada and the proposed class, because proximity does not arise from the statute or from direct interactions between the proposed class and the Government of Canada.[136]

93. In *Cardinal v Alberta*, a plaintiff sought to certify a class action against a number of defendants including Alberta, stating she had been sterilized without providing informed consent. The Court refused to certify the action against Alberta, stating that there was no direct relationship, through statute or direct contact, between the proposed class and the government.[137] The Court further found that finding such a

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[130] *Eliopoulos,* 2006 CanLII 37121 (ONCA); see also *Abarquez*, 2009 ONCA 374 ("*Albarquez*").
[131] *Eliopoulos* at para 15.
[132] *Eliopoulos* at paras 15-18, 20. See also *Albarquez* at para 27-29.
[133] *Williams,* 2009 ONCA 378
[134] *Williams* at para 34.
[135] *Williams* at para 31. See also *Wuttunee v Merck Frosst Canada Ltd.*, 2007 SKQB 29 at para 86; *Attis* at para 54.
[136] *Cardinal v Alberta,* 2025 ABKB 270 ("*Cardinal*").
[137] *Cardinal* at para 71.

duty of care would invite government intervention in the physician/patient relationship.[138]

94. The plaintiff alleges Canada was negligent in ending reporting of Canadian Adverse Events Following Immunization and with respect to the VISP program. The plaintiff has cited no case law which would support a claimed duty of care to continue to report adverse events or respecting VISP.

3. Policy Considerations Negate any Private Law Duty of Care in Negligent Misrepresentation or Negligence

95. Even where courts do find that a private law duty of care exists, the second stage of the *Anns/Cooper* test requires an assessment of considerations that may negate that duty of care. Should any novel private law duty of care be found, it should be negated to allow the government to protect the health of Canadians as a whole.[139]

96. The Supreme Court of Canada has recently addressed the shielding of government entities from negligence in relation to core policy decisions. In reiterating the common law position that certain core policy decisions are shielded from negligence, the Court confirmed that "public authorities must be allowed to 'adversely affect the interests of individuals' when making core policy decisions without fear of incurring liability." [140]

97. True policy decisions are "decisions as to a course or principle of action that are based on public policy considerations, such as economic, social and political factors, provided they are neither irrational nor taken in bad faith."[141] These decisions involve weighing competing economic, social and political factors – they require value judgments upon which "reasonable people can and do legitimately disagree."[142]

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[138] *Cardinal* at para 72.
[139] *Hartman* at para 77.
[140] *Laurentide Motels Ltd v Beauport (City)*, 1989 CanLII 81 (SCC) at p. 722, cited with approval in *Nelson (City) v Marchi*, 2021 SCC 41 ("*Nelson (City)*") at para 46.
[141] *Imperial Tobacco* at para 90, quoted with approval in *Nelson (City)* at para 51.
[142] *Nelson (City)* at para 44.

98. The Supreme Court of Canada describes four key factors in assessing the nature of a governmental decision:[143]

a. The level and responsibilities of the decision-maker;

b. The process by which the decision was made;

c. The nature and extent of budgetary considerations; and

d. The extent to which the decision was based on objective criteria.

99. Applying this test results in the conclusion that the representations and actions this Claim challenges were core policy decisions, made in consideration of the health of the entire Canadian public.

a) The level and responsibilities of the decision-maker

100. The higher the level of the decision-maker, or the closer the decision-maker is to an elected official, the more likely the decision is a policy decision.[144] The Minister of Health signed the Interim Order, [145] an Order in Council approved it, and the Minister of Health authorizes COVID-19 drugs.[146] In addition, the Prime Minister's encouragement of vaccination makes clear that the decisions in this matter were made at the highest level of government.

b) The process by which the decision was made

101. The more the process for reaching the government decision was deliberate, required debate, involved input from different levels of authority, and was "intended to have broad application and be prospective in nature, the more the analysis points to a core policy decision.[147] The Interim Order was made pursuant to the *FDA*, by delegated authority, by the Minister of Health. The Governor in Council supported the Interim

[143] *Nelson (City)* at para 56.
[144] *Nelson (City)* at para 62.
[145] Kunz Affidavit, Exhibit Y.
[146] Interim Order, section 5(c) [**Tab A**].
[147] *Nelson (City)* at para 63.

Order by Order in Council, and published it in the Gazette, reflecting a regulatory process.[148]

c) The nature and extent of budgetary considerations

102. This is a neutral factor.

d) The extent to which the decision was based on objective criteria

103. The more a government decision weighs competing interests and requires value judgment, the more likely it is a policy decision. The more a decision is based on technical standards, the less likely it is a policy decision.[149]As noted, the Interim Order states that a COVID-19 drug will be authorized if

> the Minister has sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19.[150]

104. A balancing of risks and benefits in the face of uncertainty and necessity is a clear indication that the decision-making around COVID-19 vaccinations was not a mathematical or technical equation but a consideration of many factors.

105. The application of the *Nelson (City)* test results in the conclusion that the government made policy determinations in this matter, in the context of a global pandemic.

4. Residual Policy Considerations Negate any Private Law Duty

106. The focus in this stage of the *Anns/Cooper* test is the effect of recognizing a duty of care on "other legal obligations, the legal system and society more generally."[151] This

[148] Interim Order [**Tab A**].
[149] *Nelson (City)* at para 65.
[150] Interim Order, s. 5 [**Tab A**].
[151] *Cooper* at para 37.

Court must consider the policy concerns involved with this potential duty, including whether such a duty would conflict with public duties, create indeterminate liability, or cause a chilling effect on the efforts of the impugned person to pursue public interests.[152]

107. There is no doubt that imposing a private law duty of care would conflict with Canada's public law duties to protect the health of all Canadians, including through preventing the spread of disease.

108. In *Syl Apps*, the Supreme Court of Canada refused to recognize a duty of care to an apprehended child's family, stating that imposing such a duty could result in a "chilling effect" on social workers, who may be hesitant to act in a child's best interest due to concerns of litigation or criticism by the family.[153]

109. In both *Eliopoulos* and *Williams*, the Ontario Court of Appeal found that had a *prima facie* duty of care been found, policy considerations would negate it, since imposing such a duty of care would "create an unreasonable and undesirable burden on Ontario that would interfere with sound decision-making in the realm of public health."[154]

110. Here, too, imposing a private law duty of care to the class could impact Canada's ability to act in the best interests of the Canadian public.

111. Finally, imposition of a duty of care in this matter could result in indeterminate liability. Health Canada authorizes vaccines and drugs. If Canada has a duty of care due to recommendations or encouragement to vaccinate or medicate, this duty would lead to unlimited liability to an indeterminate class.[155] The spectre of

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[152] *Cooper* at paras 44, 55; *Syl Apps Secure Treatment Centre v BD*, 2007 SCC 38 at para 50 ("*Syl Apps*"). *Klein* at para 37: "public health involves placing considerations of collective risk and benefit to a population above consideration as to the possible effects on individuals."
[153] *Syl Apps* at para 50.
[154] *Eliopoulos* at para 33, cited with approval in *Williams* at para 35.
[155] *Adam* at para 165; *Hartman* at para 78.

potential litigation and liability would negatively impact Canada's ability to respond to healthcare issues.

112. Based on all of the foregoing, there is no reasonable prospect of success related to the negligence and negligent misrepresentation claims. Although the proposed class alleges intention at some points, the negligence and negligent misrepresentation portions of the claim do not disclose a cause of action as required under the first arm of the certification test. There is no proximity and private law duty of care.

5. Canada Owes No Fiduciary Duty to the Class

113. The Supreme Court of Canada has stated that the requirements to establish a fiduciary duty must be rigorously applied at the pleadings stage.[156] It is plain and obvious that the Claim does not meet the requirements in this case. The paragraphs of the Claim that allege fiduciary duty and breach of that fiduciary duty do not disclose a reasonable cause of action.

114. Public duties, such as those the Crown owes in this case, are owed not to individuals, but to society as a whole. The Crown is not normally viewed as a fiduciary in the exercise of its administrative function,[157] and "[n]o fiduciary duty is owed to the public as a whole."[158]

115. *Alberta v Elder Advocates of Alberta Society* is the leading case on fiduciary duties in the government context. It supersedes the cases on which the plaintiff relies.[159] In *Elder Advocates*, the Supreme Court of Canada stated the Crown's responsibility to act in the public interest means that a duty of loyalty to a particular group will be "rare."[160] There are three requirements to establish a fiduciary duty, including a fiduciary duty the government is alleged to owe.[161] The

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[156] *Alberta v Elder Advocates of Alberta Society*, 2011 SCC 24 ("*Elder Advocates*") at para 54.
[157] *Elder Advocates* at para 37, quoting with approval from *Guerin v The Queen,* [1984] 2 SCR 335 at p. 385.
[158] *Elder Advocates* at para 50.
[159] Plaintiff's Certification Brief at para 170.
[160] *Elder Advocates* at para 44.
[161] *Elder Advocates* at para 37.

first requirement is that the alleged fiduciary must have given an undertaking of responsibility to act in the best interests of a beneficiary, which includes a forsaking by the fiduciary of the interests of all others in favour of the beneficiary.[162]

116. The plaintiff has not pleaded that Canada gave an undertaking to the plaintiff or other potential members of the proposed class to put their best interests above the interests of all other Canadians. Furthermore, the essential requirement that the fiduciary put the best interests of the beneficiary above all other interests is at odds with the Crown's duty to act in the best interests of society as a whole.[163] Exercises of government discretionary power are not typically undertakings to act in a beneficiary's best interests or in some particular manner.[164] Further, "a general obligation to the public or sectors of the public cannot meet the requirement of an undertaking."[165] On this basis alone, the Claim does not disclose a reasonable cause of action for breach of fiduciary duty.

117. The second requirement to establish a fiduciary duty is that there must be a defined person or class of persons vulnerable to the fiduciary's exercise of discretionary power.[166] A person alleging a fiduciary duty must bring themselves within a class to whom a duty is owed, such as adults or children in need of a guardian.[167] No such class exists here.

118. Finally, a third requirement to establish a fiduciary duty is a showing that the government power attacked affects a legal or significant practical interest – it is not enough that a fiduciary's acts impact generally on a person's well-being, property or security.[168] Rather, the interest affected must be a specific private law

[162] *Elder Advocates* at paras 30, 31.
[163] *Elder Advocates* at para 44.
[164] *Elder Advocates* at para 42.
[165] *Elder Advocates* at para 48.
[166] *Elder Advocates* at para 49.
[167] *Elder Advocates* at para 50.
[168] *Elder Advocates* at para 51.

interest to which the person has a pre-existing distinct and complete legal entitlement.[169] No such private law interest exists here.

6. No Misfeasance in Public Office

119. The leading case on the tort of misfeasance in public office is *Odhavji Estate v Woodhouse.*[170] There are two elements to the tort. First, a "public officer must have engaged in deliberate and unlawful conduct in his or her capacity as a public officer."[171] This has been described as the "*actus reus*."[172] Second, "the public officer must have been aware both that his or her conduct was unlawful and that it was likely to harm the plaintiff",[173] the "*mens rea*."[174]

120. The Supreme Court of Canada stated that there are two categories of the tort-Category A and Category B:

> Category A involves conduct that is specifically intended to injure a person or class of persons. Category B involves a public officer who acts with knowledge both that she or he has no power to do the act complained of and that the act is likely to injure the plaintiff.[175]

121. To prove Category B misfeasance in public office a plaintiff must prove these two elements (*actus reus* and *mens rea*) of the "tort independently of one another."[176] However, in Category A "the fact that the public officer has acted for the express purpose of harming the plaintiff is sufficient to establish each element of the tort."[177]

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[169] *Elder Advocates* at para 51.
[170] *Odhavji Estate v Woodhouse*, 2003 SCC 69 ("*Odhavji Estate*").
[171] *Odhavji Estate* at para 23.
[172] *J.P. v British Columbia*, 2017 BCCA 308 at para 324 ("*J.P.*").
[173] *Odhavji Estate* at para 23.
[174] *J.P.* at para 324.
[175] *Odhavji Estate* at para 22.
[176] *Odhavji Estate* at para 23.
[177] Ibid.

122. In addition, as with any tort, a plaintiff needs to "prove that the tortious conduct was the legal cause of his or her injuries, and that the injuries are compensable in tort law."[178]

123. The British Columbia Court of Appeal recently stated that misfeasance in public office is "an unusual tort" as it requires "proof of specific intent" and "is exclusive to public officers."[179] It went on to say that it is "among the most egregious of tortious misconduct", that its ambit "has always been narrow", and the court "must take a cautious approach to finding liability."[180] It noted that "[g]overnment representatives … will rarely be confined to considering the plaintiff's interests alone. Instead, they will often be required to simultaneously account for and balance public policy considerations such as "economic, social and political factors.""[181]

124. The Manitoba Court of Appeal recently overturned a trial level decision that found misfeasance in public office.[182] It noted that the judge failed to consider the relevant statutory, by-law or policy framework to determine the nature and extent of the breach of an obligation owed by the public officers."[183] Questions not properly addressed included "what statutory authority was the trial judge referencing? In what manner was this statutory authority breached?"[184] Further, the court did not assess whether there was "cogent evidence that demonstrates a conscious disregard for the interests of those affected by the misconduct".[185]

125. Misfeasance in public office "has a narrow ambit that requires an element of bad faith or dishonesty."[186]

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[178] *Odhavji Estate* at para 32; *GH* at para 58.
[179] *British Columbia v Greengen Holdings Ltd.,* 2025 BCCA 115 at para 47 ("*Greengen*"); also note leave to appeal refused by Glen L. Resler, in his capacity as *Chief Electoral Officer v Joseph V. Anglin,* 2024 CanLII 111481 (SCC).
[180] *Greengen* at para 49.
[181] *Greengen* at para 51.
[182] *6165347 Manitoba Inc v Robinson*, 2025 MBCA 33 ("*6165347 Manitoba*"), leave to appeal refused, *6165347 Manitoba Inc., et al. v City of Winnipeg, et al.*, 2026 CanLII 7572 (SCC).
[183] *6165347 Manitoba* at para 323.
[184] *6165347 Manitoba* at para 324.
[185] *6165347 Manitoba* at para 329.
[186] *Madadi v Nichols*, 2021 BCCA 10 at para 63.

> [3] The appeal raises issues of procedural fairness, limitations and the requirements of proof of serious allegations of wrongdoing against public officers in the discharge of their duties. Primarily fact-driven, it serves to remind all concerned that claims for damages for the misuse of public power by dissatisfied citizens must be advanced, scrutinized and resolved with caution and restraint. As Justice Newbury explained in *Powder Mountain Resorts Ltd. v. British Columbia*, 2001 BCCA 619, the tort of misfeasance in public office provides redress for egregious intentional misconduct, not for what may be, at worst, maladministration, official incompetence or bad judgment in the execution of public duties. For this reason, when addressing claims of misfeasance in public office, the courts strike a careful balance between curbing unlawful behaviour by governmental officials, on the one hand, and, on the other, protecting those charged with making decisions for the public good from unmeritorious claims by those adversely affected by their decisions.

126. This approach has also been adopted in Alberta. In *Forsyth* the Alberta Court of Appeal recently stated that:

> [31] It is to be remembered that the personal intentional tort of misfeasance in public office involves knowingly and deliberately engaging in unlawful conduct by a public office holder abusing or exceeding authority and aware that it would likely harm the claimant. "[L]iability does not attach to maladministration, incompetence, bad judgment or mere disregard for an official duty". It only attaches "to a public officer who, in addition, demonstrates a conscious disregard for the interests of those who will be affected by the misconduct in question".

127. Misfeasance in public office allegations must be particularized.[187] The "allegations must be as detailed and as facts-specific as is possible at the pleading stage."[188] A plaintiff must either name the individual who is alleged to have engaged in misfeasance or, at the very least, identify a particular group of individuals who were dealing with the matter, one or more of whom was allegedly responsible. The requirements of pleadings should not be relaxed in the context of a class action, nor can a department be directly liable for misfeasance.[189]

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[187] *Merchant Law Group v Canada Revenue Agency*, 2010 FCA 184 at para 35 ("*Merchant Law Group*"); *Gay v Alberta (Worker's Compensation Board)*, 2023 ABCA 351 ("*Gay*") at para 12; *GH* at para 58.
[188] *M.M. v British Columbia,* 2021 BCSC 588 at para 48.
[189] *Merchant Law Group* at paras 39-40.

128. In this matter the plaintiff has not relied on the *Odhavji* test. Her reliance on *Ingram*[190] is misplaced. In that decision, which is under appeal, the Court relied heavily upon *Alberta (Minister of Infrastructure) v Nilsson*[191] (*Nilsson*), even going so far as to describe it as "the leading Alberta case on misfeasance in public office."[192] With respect, that is not correct.

129. *Nilsson* was decided before *Odhavji*. While some aspects of the test in both overlap to a degree, they are different. The *Nilsson* test conflates the *actus reas* with the *mens rea* at each of its two stages. Further, the use of the phrase "statutory authority for an improper purpose"[193] rather than "unlawful" would seems to lead to the interpretation that would allow a wider range of activities that could be captured by the tort, thereby creating a separate basis for liability. Moreover, the use of the terms "willful blindness" and "reckless indifference" from *Nilsson* is different terminology with respect to actual knowledge. The Supreme Court of Canada more recently described actual knowledge as, at a minimum, ""subjective recklessness" or "conscious disregard.""[194]

130. In any event, the Alberta Court of Appeal has consistently used *Odhavji* as the test in all its recent decisions in relation to the tort of misfeasance in public office.[195]

131. In this case the plaintiff has fallen well short of meeting the high onus to properly plead misfeasance in public office. The plaintiff instead improperly seeks to have this court scrutinize policy decisions and "become the arbiters of the personal thought process of public officials."[196]

132. It is unclear as to whether the plaintiff seeks to establish Category A or Category B misfeasance in public office, or both. To establish Category A she needs to establish that a government actor expressly intended to injure the plaintiff (or

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[190] Plaintiffs Brief at paras 154 and 163.
[191] *Alberta (Minister of Infrastructure) v Nilsson*, 2002 ABCA 283 ("*Nilsson*").
[192] *Ingram v Alberta (Chief Medical Officer of Health)*, 2023 ABKB 453 at para 53, see also para 57.
[193] *Nilsson* at para 95.
[194] *Ontario (Attorney General) v Clark,* 2021 SCC 18 at para 23.
[195] *Gay* at para 40; *Forsyth v LC*, 2024 ABCA 14 at para 31; *Anglin* at paras 63-70;
[196] *Powder Mountain Resorts Ltd. v British Columbia*, 2001 BCCA 619 at para 2.

class). There is nothing pleaded in the Claim that anyone intended to harm the plaintiff. Further, the logical extension of the plaintiff's argument is that the because the defendants intended to cause everyone to be vaccinated, they thereby intended to hurt every single Canadian. This type of reasoning is antithetical to the rationale underpinning the intentional tort of misfeasance of public office, which is designed to deter the targeted abuse of certain individuals.

133. If the plaintiff is attempting to plead Category B misfeasance in public office, she has also fallen short. For the reasons set out previously, there was nothing unlawful about interpreting and reporting clinical data,[197] recommending vaccines for approval,[198] regulating data from manufacturers[199], or not revoking vaccine approvals.[200] The allegations made are essentially claims of negligence. These allegations do not constitute claims of unlawfulness. Further, the plaintiff has not pleaded that these actions were known by certain individuals to be unlawful.

134. Similarly, the allegation that the "federal Minister of Health" did not properly "discharge its responsibilities of approval, oversight, direction, and control over the vaccine approval process"[201] does not constitute an allegation of subjective unlawfulness or an intent to hurt anyone. Moreover, the allegation that the defendants could be liable for misfeasance in public office for creating "fear" or "coercing compliance" due to messaging is also untenable. There was nothing unlawful about this behaviour. The suggestion that this was intended to harm Canadians flies in the face of the obvious reality that urging Canadians to become vaccinated was intended to protect them and their fellow Canadians.

135. A good example of the problems with the Claim is para 144 of the Claim. The plaintiff pleads that the Minister of Health failed to report "vaccine outcomes as required under the *Department of Health Act*." This apparently "undermined public trust, prevented informed decision making," and exposed the class to "risk

[197] Claim at para 137(a).
[198] Claim at para 137(b).
[199] Claim at para 137(c).
[200] Claim at para 137(d).
[201] Claim at para 140.

and injuries." This "was in bad faith or with deliberate indifference to the harm caused to Canadians".

136. However, section 4 of the *Department of Health Act*[202] grants general powers and public duties to the Minister of Health. This includes "**(h)** subject to the *Statistics Act*, the collection, analysis, interpretation, publication and distribution of information relating to public health."[203] It does not prescribe or proscribe how, when, or where this is to occur. Nor does the Claim provide particulars of how the Minister failed in this regard. Therefore, it is impossible to guess as to how any failure may have been unlawful. Further, there are no particulars pleaded as to how the Minister acted in "bad faith or with deliberate indifference." A failure to provide this information could have been done negligently for example. Making a bald allegation of this sort is not only contrary to the Rules,[204] it is also insufficient to ground a claim in an intentional tort such as misfeasance in public office.

137. It should be noted that the few particulars plead in the Claim with respect to misfeasance in public office are of little assistance to the plaintiff. For example, the Claim alleges that the defendants did not accept recommendations from a provincial task force report which came out in January 2025.[205] This certainly could not have influenced their behaviour in 2021 with respect to the plaintiff. Further, whether to accept recommendations falls within the realm of policy decisions, not illegality.

138. The establishment of the Vaccine Injury Support Program[206] is not evidence of the defendants intending to hurt anyone but instead a policy decision offering support for those few people injured by vaccines. The attempts to facilitate vaccine uptake is similarly a policy decision, which like almost all difficult policy decisions may result in some injury to some people. There can be no question that Canada's

[202] *DHA*, s. 4.
[203] *DHA*, s. 4(2)(h).
[204] *Alberta Rules of Court,* Alta Reg 124/2010, r. 13.7.
[205] Claim at para 147.
[206] Claim at para 153.

vaccine policy was an attempt to help Canadians. All the bald allegations to the contrary cannot change this.

139. Moreover, as noted in *Hartman*, there has to be some consideration of a duty to the plaintiff. As noted above, Canada did not owe a private law duty to the plaintiff or class. If there is no private law duty there cannot be "subjective awareness that harm to the plaintiff was a likely consequence."[207]

140. In sum, the plaintiff's allegations of misfeasance in public office, like the Claim as a whole, is really an attack on policy decisions designed to help Canadians at a time of vast peril and uncertainty for Canadians and the population of the world. The plaintiff has not and cannot establish that this Claim is one of the narrow situations giving rise to a valid action for misfeasance in public office.

7. This Claim Does Not Meet the Legal Requirements of Conspiracy

141. It is plain and obvious that the conspiracy claim cannot succeed and discloses no cause of action against Canada. The plaintiff has failed to plead the required elements. Instead, the claim consists of bald, vague, and speculative allegations.

142. The leading case on civil conspiracy is *Canada Cement and LaFarge v BC Lightweight Aggregate*[208] in which the Supreme Court of Canada set out the requirements for the two types of civil conspiracy: predominant purpose and unlawful conduct conspiracy.[209] Unlawful conduct conspiracy, as is alleged here, requires conspirators partake in some sort of unlawful conduct, where the conspirators know or ought to have known harm would befall the plaintiff(s).[210]

143. The elements of a claim of unlawful conduct conspiracy are: (1) an agreement between two or more persons; (2) concerted action taken pursuant to the agreement; (3) that the conspirators knew or ought to have known their actions would injure the plaintiff (constructive intent); and (4) actual damage suffered by

[207] *Hartman* at paras 84, 85.
[208] *Canada Cement LaFarge Ltd v B.C. Lightweight Aggregate*, 1983 CanLII 23 (SCC) ("*Cement LaFarge*").
[209] *Cement LaFarge* at para 33.
[210] *Cement LaFarge* at para 34.

the plaintiff.[211] Conspiracy is an intentional tort and a serious allegation, as such the material facts must be pleaded with heightened particularity.[212] If the plaintiff does not, at the time of the pleading, have knowledge of the facts necessary to support the cause of action, then it is inappropriate to make the allegations in the statement of claim.[213]

144. The jurisprudence requires the pleading of particulars regarding the identities of parties to the alleged agreement and their relationships to one another.[214] Under the *Crown Liability and Proceedings Act*,[215] the federal Crown can be held liable not on its own account, but solely for the fault of its servants.[216] Although conspiracy is a tort committed by two or more persons, the liability of each defendant arises because they individually participated as a member of the group: a conspirator is not liable simply vicariously for what somebody else did; he or she is liable for having participated and contributed to the conspiracy. [217] It is not sufficient to simply "lump some or all of the defendants together into a general allegation that they conspired".[218]

145. Here, Canada cannot be liable for conspiracy. No individual alleged conspirator is identified. The plaintiff has not pleaded material facts on the identities of the conspirators and relies on only vague and bald assertions of combination, and coordination between the defendants purportedly "acting through senior officials, departments, agencies, and coordinated intergovernmental mechanisms"[219] and "with international governing bodies and pharmaceutical companies"[220] to create, maintain and enforce a coercive framework in promoting, enforcing and

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[211] *Mraiche Investment Corporation v McLennan Ross LLP*, 2012 ABCA 95 at para 40; *D'Agnone v D'Agnone*, 2017 ABCA 35 at paras 19-24.
[212] *Ontario Consumers Home Services v Enercare Inc*., 2014 ONSC 4154 at para 25 ("*Enercare Inc.*").
[213] *Balanyk v University of Toronto*, 1999 CanLII 14918 at para 29.
[214] *Normart* at para 21; *Khan v Canada (Attorney General)*, 2009 CanLII 7090 ("*Khan*") at para 31, case affirmed in 2009 ONCA 737, leave to appeal to the SCC refused in 2009 CarswellOnt 8387.
[215] *Crown Liability and Proceedings Act*, RSC, 1985, c C-50 ("*CLPA*"); *Hinse v Canada (Attorney General)*, 2015 SCC 35 (CanLII), [2015] 2 SCR 621 at para 58.
[216] *CLPA*, s. 3(b)(i).
[217] *EnerWorks Inc. v Glenbarra Energy Solutions Inc*., 2012 ONSC 414 at paras 74-79.
[218] *Enercare Inc.* at para 26.
[219] Plaintiff's Certification Brief at para 192.
[220] Claim at para 172.

maintaining COVID-19 vaccination policies where informed consent was vitiated.[221] This is not sufficient: vague and/or generalized allegations will not suffice.[222]

146. In *Sivak v Canada*, the Federal Court struck the paragraphs of a statement of claim alleging conspiracy after finding, among other things, that bald allegations of a conspiracy involving undefined Ministers, the Immigration and Refugee Board, and unidentified defendants' officials, without reference to the elements of the tort, to be "entirely deficient."[223]

147. The jurisprudence requires the pleading of material facts concerning the alleged agreement between the defendants to conspire, including the date, object and purpose of the alleged conspiracy between the parties, as well as the overt acts, including the times and dates of such overt acts, which are alleged to have been done by each of the alleged conspirators in furtherance of the conspiracy.[224]

148. No material facts are pleaded on the actual agreement between the parties, such as particulars as to the time, place, or mode of agreement amongst the alleged co-conspirators.[225] Rather, the Plaintiff alleges "such coordination supports the inference of an agreement".[226] No materials facts are pleaded that each conspirator knew or ought to have known that their actions would injure the plaintiff or the proposed class. Particulars of the overt acts alleged to have been committed by each of the alleged conspirators, including dates and times, are lacking; rather all defendants are lumped together. Material facts must be pleaded "with precision and clarity",[227] which the plaintiff has failed to do in this case.

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[221] Plaintiff's Certification Brief at paras 187-188.
[222] *Khan* at para 19.
[223] *Sivak v Canada,* 2012 FC 272 at paras 54-57 ("*Sivak*"), citing *Normart Management Ltd. v West Hill Redevelopment Co*., 1998 CanLII 2447 (ON CA) at paras 21-22 ("*Normart*").
[224] *Normart* at para 21; *Sivak* at para 54; *Khan* at para 31; *Dorceus v. Ontario et al*., 2024 ONSC 7087 at para 67 ("*Dorceus*").
[225] *Enercare Inc.* at para 24.
[226] Plaintiff's Certification Brief at para 192.
[227] *Enercare Inc.* at para 24.

149. In *Dorceus v Ontario et al*, the ONSC struck the plaintiffs' claim, which included a conspiracy claim against the Premier of Ontario, a number of cabinet ministers, and 54 non-government defendants alleging they conspired to declare a false pandemic for the predominant purpose of harming the plaintiffs. In striking the claim, the Court noted that the claim did not describe the relationship of the alleged conspirators to each other, did not refer to any alleged agreement between the parties, did not refer to the acts that led to such an agreement, and did not refer to the acts of each alleged conspirator in furtherance of the conspiracy.[228]

150. In *Khan v Canada (Attorney General)*,[229] the Ontario Superior Court of Justice struck an alleged claim for conspiracy for failure to plead the facts required, including particulars as to the identities of the several parties and their relationship to each other, the agreement between the alleged conspirators, the purpose of the alleged conspiracy, details of the acts which each alleged conspirator was alleged to have done and particulars of the damage suffered. [230]

151. It is plain and obvious that the Claim does not meet the requirements in this case as it does not identify and plead key pieces of information required to meet the legal requirements of conspiracy.

152. Given that the Claim fails to disclose a cause of action as required under the first arm of the certification test, this Court should dismiss the Claim on this basis.[231] Canada will deal with the remaining arms of the certification test briefly.

D. NO IDENTIFIABLE CLASS OF TWO OR MORE PERSONS

153. The proposed class includes:

> all individuals who received COVID-19 vaccines (the "**Covid Vaccine**" or "**Covid Vaccines**") marketed or manufactured by Pfizer-BioNTech, AstraZeneca PLC, Moderna Inc., Janssen Inc., and Novavax Inc. (the "**Vaccine Manufacturers**") in the Province of Alberta between December 9, 2020 and the date of certification

[228] *Dorceus* at para 67.
[229] *Khan* at para 31.
[230] *Khan* at para 31; *Al Omani v. Canada*, 2017 FC 786 at para 88.
[231] *Atlantic Lottery* at para 68.

> of this action as a class proceeding, or such other date determined to be appropriate by the Court (the "**Class Period**"), and who suffered injury (the "**Class**" or "**Class Members**").[232]

154. The evidence does not reveal two or more individuals with viable common issues and does not establish an identifiable class. Further, the plaintiff's proposed class – those who received COVID-19 vaccines and "suffered injury" – is vague and overbroad.

155. A clear class definition will create certainty as to who is bound by final judgment and who is entitled to notice.[233] The class must be capable of clear definition, and the definition should rely on clear criteria with a rational relationship to the common issues, but not dependant on the outcome of the litigation.[234] It is not necessary that every class member be named or known, but their status must be objectively determinable.[235]

1. No basis in fact for a class of two or more

156. There must be an evidentiary basis to support an assertion of an identifiable class.[236] There must be more than one person in the proposed class with a complaint.[237] Crucially, the plaintiff has not presented evidence aimed to demonstrate that anyone other than Ms. Sakamoto received a vaccine due to Canada's alleged negligent misrepresentations or other wrongful conduct.[238]

157. Here, only Ms. Sakamoto has provided affidavit evidence of her own personal experience following her COVID-19 vaccinations; the remaining plaintiff affidavits consist only of publicly available documents including various articles,

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[232] Plaintiff's Certification Brief at paras 12-13.
[233] *Bywater v Toronto Transit Commission*, 1998 CarswellOnt 4645, [1998] O.J. No. 4913 at para 10.
[234] *Western Canadian Shopping Centres Inc. v Dutton*, 2001 SCC 46 at para 38 ("*Western Canadian*").
[235] *Western Canadian*.
[236] *Harrison v Afexa Life Sciences Inc.*, 2016 BCSC 2123 at para 47 ("*Harrison*"); aff'd 2018 BCCA 165, leave to appeal to the SCC refused in 2018 CarswellBC 2409.
[237] *Lee v Georgia Properties Partnership*, 2012 BCSC 1484 at para 43.
[238] *Harrison* at paras 47-51.

and reports on COVID-19. The evidence is insufficient to establish an identifiable class of two or more persons as the *Class Proceedings Act* requires.[239]

2. Class is Vague and Overbroad

158. The representative plaintiff is obligated to articulate a sufficiently narrow class definition.[240] In this case, the proposed class definition is vague and overbroad. "Injury" has no legal definition, and the plaintiff has not provided any definition in her pleading.[241] As defined, it could include temporary or minor injury such as bruising, pain, soreness, swelling, redness, and/or headaches.

159. The proposed definition is overbroad. This is so because the definition captures individuals who did not rely on public representations set out in the plaintiff's claims, who obtained the COVID-19 vaccine for reasons unconnected to the plaintiff's claim, and who would have been vaccinated in any event.[242] Many Canadians consciously chose to be vaccinated to protect themselves, their families and communities, and Canada's health care system capacity, without any consideration of government representations.

160. In *Harrison,* the Court held that a class of all persons who purchased Cold-Fx, supplied, offered for sale, advertised or promoted by the defendants was overbroad. The claim alleged that the defendants made several specific misrepresentations on the packaging of their product and in their advertising. The certification judge considered that the class included people who were not exposed to the alleged misrepresentations, and people who purchased the product for purposes other than "immediate relief" of cold and flu symptoms. Because of those issues, she found, and the British Columbia Court of Appeal agreed, that the

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[239] *CPA*, ss. 1, 5(1).
[240] *Hollick* at para 21.
[241] Sakamoto Undertaking #1: "Advise what "injury" in paragraph 14 of the Statement of Claim is intended to cover" as requested by Counsel for the AGC was refused by the plaintiff following the July 22, 2025 questioning of Carrie Sakamoto on her affidavit sworn September 11, 2024.
[242] See *Harrison* at paras 51-60.

class description was "overbroad" and therefore failed to meet the identifiable class requirement of the British Columbia *Class Proceedings Act*.[243]

161. In *Clark v Energy Brands Inc.*[244] the plaintiff alleged that CocaCola marketed and labelled beverages sold under the trade name "Vitaminwater" misleadingly, that had the effect of making consumers think they were drinking a healthy product, with a minimal amount of sugar, when that was not true. The representative plaintiff proposed a class composed of persons who had purchased Vitaminwater for consumption.

162. The British Columbia Supreme Court rejected this class definition, determining that the proposed class at certification was overbroad and did not meet the identifiable class requirement under the provincial class proceedings legislation.[245] This was so because the class would include persons who did not rely on the impugned representations, who purchased Vitaminwater for other reasons than the representations, or who would have purchased it in any event.[246]

163. Where the class can be more narrowly stated, the Court indicated that certification should be disallowed or allowed on the condition that the definition of the class be amended.[247] Applying that principle, the Claim should not be certified, given the other shortcomings in this motion for certification.

E. NO COMMON ISSUES

164. The principles applying to the "commonality" question on a motion for certification are well known. A common issue is an essential element of each class member's claim; its resolution will avoid duplication of fact-finding or legal analysis; its resolution will meaningfully advance the claim.[248] Certification should be refused where numerous individual issues overwhelm common issues and

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[243] *Harrison* at para 37-44, CPA, s. 5(1)(b).
[244] *Clark v Energy Brands Inc.*, 2014 BCSC 1891 ("*Clark*").
[245] *Clark* at para 145; *Harrison* at paras 54, 57.
[246] *Clark* at para 145.
[247] *Hollick* at para 21.
[248] *Pioneer Corp. v Godfrey*, 2019 SCC 42 at paras 104–105, citing *Canadian Shopping Centres Inc. v Dutton,* 2001 SCC 46 and *Vivendi Canada Inc. v Dell'Aniello,* 2014 SCC 1.

where the issues are intrinsically individualistic. A common issue cannot be dependent upon findings of fact with respect to each individual claimant.[249]

165. The "some basis in fact" standard for commonality has a dual component: (1) that the proposed common issue exists and (2) that resolution of the common issue is necessary to the resolution of each class member's claim.[250] Failure to lead evidence may result in wasted judicial and other resources caused by an unworkable class action.[251]

166. The plaintiff has proposed approximately 29 common issues.[252] The following pertain to matters which do not disclose a cause of action. They are obviously not common issues and need not be considered further. Those include the proposed common issues relating to:

a. negligent misrepresentation;[253]

b. negligence;[254]

c. misfeasance in public office;[255]

d. breach of fiduciary duty;[256]

e. conspiracy;[257]

f. lack of informed consent.[258]

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[249] *Kenney v Canada (AG)*, 2016 FC 367 at para 37; *Kahnapace* at para 177.
[250] *Jensen v Samsung Electronics Co. Ltd.*, 2023 FCA 89 at paras 78-79. *Fulawka v Bank of Nova Scotia*, 2012 ONCA 443 at para 79.
[251] *McCracken v Canadian National Railway*, 2012 ONCA 445 at para 83; *Rumley v BC (Province of)*, 2003 BCSC 234 at paras 30-31.
[252] Plaintiff's Certification Brief, pp. 4 to 7, para 15 with subheadings.
[253] Plaintiff's Certification Brief, p. 4, para 15(a).
[254] Plaintiff's Certification Brief, p. 5, para 15(b).
[255] Plaintiff's Certification Brief, p. 7, para 15 (c).
[256] Plaintiff's Certification Brief, p. 7, para 15(d).
[257] Plaintiff's Certification Brief, p. 7, para 15(e).
[258] Plaintiff's Certification Brief, p. 7, para 15(f).

1. No basis in Fact for Conspiracy

167. In addition to disclosing no cause of action, there is no basis in fact for the conspiracy claim. The only evidence before the Court is that Canada and Alberta both encouraged vaccination, and that NACI provides evidence-based recommendations on the use of vaccine products.[259] However, provinces have many sources of information. Provinces may consider NACI's advice and recommendations. In addition to these, Alberta considers provincial epidemiology, scientific evidence-based information used by other organizations such as the US Centers for Disease Control, and in some cases, Alberta specific studies on particular immunization topics.[260] Provinces use their own discretion to make final decisions on what vaccines will be available and recommended in their jurisdictions.[261]

2. Class member reliance on representations cannot be determined in common

168. Reliance on the defendants' representations, proposed common issue 15 (g), cannot be determined in common. Whether any member of the class relied on representations is typically an individual issue, unless reliance can be inferred.[262]

169. An individual's reasons for vaccination against COVID-19 cannot be inferred and cannot be determined across the class. Reliance contains a subjective component (did the individual rely on the representation?) and an objective component (was the individual's reliance reasonable?)[263]

170. An individual may choose to be vaccinated for many reasons, including the desire to avoid becoming ill with a serious disease like COVID-19, the desire to avoid infecting vulnerable persons in their family or community, based on a

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[259] Klein cross-examination transcript, November 27, 2025, p. 79, lines 13-25.
[260] Klein cross-examination transcript, November 27, 2025, p. 136, lines 10-27.
[261] Klein cross-examination transcript, November 27, 2025, pp. 80-81, lines 23-27; 1-12. Klein affidavit, para 48.
[262] *Green v. Canadian Imperial Bank of Commerce*, 2014 ONCA 90 at para 103, affirmed on this point, 2015 SCC 60 at paras 125, 129; *Musicians' Pension Fund of Canada (Trustee of) v Kinross Gold Corp,* 2014 ONCA 901 at paras 117, 120; *Fantl v Transamerica Life Canada*, 2016 ONCA 633 at paras 19-21, 24 (individual issues trials necessary on the issues of reliance and damages); See also *Da Silva v River Run Vistas Corp*, 2018 ABQB 869 at paras 116-133 (*in obiter*).
[263] *Queen v Cognos,* 1993 CanLII 146 (SCC) at p. 110.

recommendation from a family or other doctor, a desire to reduce the strain on hospital resources, a desire to assist in communities returning to normal, to meet an employment requirement, and so on. Similarly, whether a class member's reliance is reasonable is also an individual issue. These issues cannot be determined on a common basis.

3. Aggregate Damages cannot be determined in Common

171. Proposed common issue 15(h) asks whether the Court can assess aggregate damages. Aggregate damages may not be certified as common issues where the plaintiff proposes no methodology to assess damages in aggregate.[264] The plaintiff has not done so in this case, and in any event, there is no such methodology. This issue cannot be certified as a common issue.

172. Proposed common issue 15(i) is whether the defendants should pay punitive, exemplary, or aggravated damages. Since none of the proposed causes of action disclose a reasonable cause of action, such damages should not be certified as common issues. In any event, conduct meriting punitive (exemplary) damages must be "harsh, vindictive, reprehensible and malicious" as well as "extreme in its nature and such that by any reasonable standard it is deserving of full condemnation and punishment."[265] Aggravated and punitive damages are available to punish misconduct that is "so malicious, oppressive and highhanded that it offends the court's sense of decency."[266] There is no basis in fact that Canada's actions merit punitive damages on a class basis.

F. A CLASS ACTION IS NOT THE PREFERABLE PROCEDURE

173. The plaintiff has the onus of demonstrating that a class action is preferable to VISP applications or individual actions. The plaintiff has not met that onus. Most importantly, VISP claims are preferable because compensation does not require a

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[264] *Pro-Sys Consultants Ltd.* at para 118; *Virani v Uber Portier Canada Inc*., 2023 ABKB 240 at para 62 (*in obiter*) ("*Virani*").
[265] *Honda Canada Inc. v Keays*, 2008 SCC 39 (CanLII) at para 68, quoting with approval from *Vorvis v ICBC*, 1989 CanLII 93 (SCC); *Virani* at para 62 (*in obiter*).
[266] *Hill v Church of Scientology of Toronto*, 1995 CanLII 59 (SCC) at para 196.

finding of legal wrong-doing – the program is no-fault. There is no requirement to undergo the lengthy litigation process, and uncertain recovery following that process. An independent medical panel determines eligibility, rather than a court determining causation at the conclusion of litigation, potentially following the evidence of competing medical experts.

174. While Ms. Sakamoto has complained of her interactions with VISP representatives, the VISP program accepted that she had been injured as a result of her COVID-19 vaccination more than two years ago, while this action is only now reaching the very first stage of a class action – certification. A common issues trial, should this action be certified, is years away.

175. Even if successful at a common issues trial, any claimant would have to show that the COVID-19 vaccine caused the claimant's injury. Determining a causal relationship between COVID-19 vaccination and vaccine injury can be difficult. For example, myocarditis can be caused by infections from viruses, bacteria, fungi or parasites. It can result from COVID-19 infection.[267] Bell's Palsy and pericarditis were illnesses Canadians suffered before COVID-19. That such illnesses followed COVID-19 vaccination does not necessarily mean that they were caused by the vaccination.

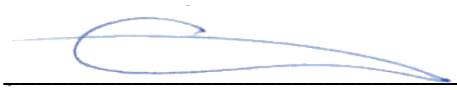
G. REMAINDER OF THE CERTIFICATION TEST

176. Canada makes no submissions respecting whether the plaintiff is an appropriate representative plaintiff.

[267] Klein affidavit, para 102-103.

PART IV - ORDER REQUESTED

177. Canada respectfully asks that this certification motion be dismissed, with costs.



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PART V – LIST OF AUTHORITIES

Statutes and Regulations

1. *Alberta Rules of Court,* Alta Reg 124/2010
2. *Class Proceedings Act*, SA 2003, c C-16.5
3. *Crown Liability and Proceedings Act*, RSC, 1985, c C-50
4. *Department of Health Act,* SC 1996, c 8
5. *Food and Drugs Act,* RSC 1985, c F-27
6. *Public Health Agency of Canada Act*, SC 2006, c 5

Jurisprudence

7. *6165347 Manitoba Inc., et al. v City of Winnipeg, et al.*, 2026 CanLII 7572 (SCC)
8. *6165347 Manitoba Inc v Robinson*, 2025 MBCA 33
9. *Abarquez v Ontario*, 2009 ONCA 374
10. *Adam, Abudu v Ledesma-Cadhit*, 2014 ONSC 5726
11. *Alberta v Elder Advocates of Alberta Society*, 2011 SCC 24
12. *Alberta (Minister of Infrastructure) v Nilsson*, 2002 ABCA 283
13. *Al Omani v. Canada*, 2017 FC 786
14. *Anglin v Resler*, 2024 ABCA 113
15. *Atlantic Lottery Corp v Babstock*, 2020 SCC 19
16. *Attis v Canada (Health),* 2008 ONCA 660
17. *Balanyk v University of Toronto*, 1999 CanLII 14918
18. *Bigeagle v. Canada*, 2023 FCA 128
19. *British Columbia v Greengen Holdings Ltd.,* 2025 BCCA 115
20. *Bywater v Toronto Transit Commission*, 1998 CarswellOnt 4645, [1998] O.J. No. 4913
21. *Canada (Attorney General) v B.W.*, 2025 FCA 199
22. *Canada Cement LaFarge Ltd v B.C. Lightweight Aggregate*, 1983 CanLII 23 (SCC)
23. *Canadian Imperial Bank of Commerce v Green*, 2015 SCC 60
24. *Canadian Shopping Centres Inc. v Dutton,* 2001 SCC 46
25. *Canadian Society for the Advancement of Society and Public Policy v British Columbia*, 2025 BCSC 2051
26. *Cardinal v Alberta,* 2025 ABKB 270
27. *Chief Electoral Officer v Joseph V. Anglin,* 2024 CanLII 111481 (SCC).
28. *Childs v Desormeaux*, 2006 SCC 18
29. *Clark v Energy Brands Inc.*, 2014 BCSC 1891
30. *Cooper v Hobart*, 2001 SCC 79
31. *D'Agnone v D'Agnone*, 2017 ABCA 35
32. *Da Silva v River Run Vistas Corp*, 2018 ABQB 869
33. *Doan v Canada*, 2023 FC 968

34. *Dorceus v. Ontario et al.*, 2024 ONSC 7087
35. *Drady v Canada (Minister of Health)*, 2008 ONCA 659
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Secondary Sources

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Part I

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DEPARTMENT OF HEALTH

FOOD AND DRUGS ACT

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

Whereas the Minister of Health believes that immediate action is required to deal with a significant risk, direct or indirect, to health, safety or the environment;

Therefore, the Minister of Health, pursuant to subsection 30.1(1)[a] of the *Food and Drugs Act*[b], makes the annexed *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19*.

Ottawa, September 16, 2020

Patricia Hajdu
Minister of Health

MINISTÈRE DE LA SANTÉ

LOI SUR LES ALIMENTS ET DROGUES

Arrêté d'urgence concernant l'importation, la vente et la publicité de drogues à utiliser relativement à la COVID-19

Attendu que la ministre de la Santé estime qu'une intervention immédiate est nécessaire afin de parer à un risque appréciable — direct ou indirect — pour la santé, la sécurité ou l'environnement,

À ces causes, la ministre de la Santé, en vertu du paragraphe 30.1(1)[a] de la *Loi sur les aliments et drogues*[b], prend l'*Arrêté d'urgence concernant l'importation, la vente et la publicité de drogues à utiliser relativement à la COVID-19*, ci-après.

Ottawa, le 16 septembre 2020

La ministre de la Santé
Patricia Hajdu

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

Interpretation

Definitions

1 (1) The following definitions apply in this Interim Order.

authorization means an authorization issued under section 5. (*autorisation*)

Chief Public Health Officer means the Chief Public Health Officer appointed under subsection 6(1) of the *Public Health Agency of Canada Act*. (*administrateur en chef de la santé publique*)

COVID-19 means the coronavirus disease 2019. (*COVID-19*)

COVID-19 drug means a drug that is manufactured, sold or represented for use in relation to COVID-19. (*drogue contre la COVID-19*)

drug means a drug other than

(a) a veterinary health product; or

[a] S.C. 2004, c. 15, s. 66
[b] R.S., c. F-27

Arrêté d'urgence concernant l'importation, la vente et la publicité de drogues à utiliser relativement à la COVID-19

Définitions et interprétation

Définitions

1 (1) Les définitions qui suivent s'appliquent au présent arrêté d'urgence.

administrateur en chef de la santé publique L'administrateur en chef de la santé publique nommé en vertu du paragraphe 6(1) de la *Loi sur l'Agence de la santé publique du Canada*. (*Chief Public Health Officer*)

autorisation Autorisation délivrée en application de l'article 5. (*authorization*)

autorité réglementaire étrangère Organisme gouvernemental ou toute autre entité, ailleurs qu'au Canada, qui est habilité à contrôler la fabrication, l'utilisation ou la vente de drogues dans le territoire relevant de sa compétence et qui peut prendre des mesures d'exécution pour veiller à ce que les drogues qui y sont commercialisées satisfassent aux exigences légales qui s'appliquent. (*foreign regulatory authority*)

[a] L.C. 2004, ch. 15, art. 66
[b] L.R., ch. F-27

(b) a *natural health product* as defined in subsection 1(1) of the *Natural Health Products Regulations*. (*drogue*)

foreign drug means a drug that is set out in the *List of Foreign Drugs*. (*drogue étrangère*)

foreign regulatory authority means a government agency or other entity outside Canada that has a legal right to control the manufacturing, use or sale of drugs within its jurisdiction and that may take enforcement action to ensure that drugs marketed within its jurisdiction comply with the applicable legal requirements. (*autorité réglementaire étrangère*)

List of Foreign Drugs means the *List of Foreign Drugs in Relation to the COVID-19 Pandemic* that is published on a Government of Canada website, as amended from time to time. (*Liste des drogues étrangères*)

List of New Drugs for Expanded Indication means the *List of New Drugs for Expanded Indication in Relation to the COVID-19 Pandemic* that is published on a Government of Canada website, as amended from time to time. (*Liste des drogues nouvelles à indication supplémentaire*)

notice of compliance means a notice of compliance issued under section C.08.004 or C.08.004.01 of the Regulations. (*avis de conformité*)

Regulations means the *Food and Drug Regulations*. (*Règlement*)

submission means any of the following:

(a) a new drug submission that is filed under section C.08.002 of the Regulations;

(b) an extraordinary use new drug submission that is filed under section C.08.002.01 of the Regulations;

(c) an abbreviated new drug submission that is filed under section C.08.002.1 of the Regulations; or

(d) an abbreviated extraordinary use new drug submission that is filed under section C.08.002.1 of the Regulations. (*présentation*)

supplement means a supplement to a submission that is filed under section C.08.003 of the Regulations. (*supplément*)

avis de conformité Avis de conformité délivré au titre des articles C.08.004 ou C.08.004.01 du Règlement. (*notice of compliance*)

COVID-19 La maladie à coronavirus 2019. (*COVID-19*)

drogue Drogue autre que l'une des drogues suivantes :

a) un produit de santé animale;

b) un *produit de santé naturel*, au sens du paragraphe 1(1) du *Règlement sur les produits de santé naturels*. (*drug*)

drogue contre la COVID-19 Drogue fabriquée ou vendue en vue d'être utilisée relativement à la COVID-19 ou présentée comme tel. (*COVID-19 drug*)

drogue étrangère Drogue qui figure dans la *Liste des drogues étrangères*. (*foreign drug*)

Liste des drogues nouvelles à indication supplémentaire La *Liste des drogues nouvelles à indication supplémentaire relativement à la pandémie de la COVID-19*, publiée sur un site Web du gouvernement du Canada, avec ses modifications successives. (*List of New Drugs for Expanded Indication*)

Liste des drogues étrangères La *Liste des drogues étrangères relativement à la pandémie de la COVID-19*, publiée sur un site Web du gouvernement du Canada, avec ses modifications successives. (*List of Foreign Drugs*)

présentation S'entend de l'une des présentations suivantes :

a) toute présentation de drogue nouvelle déposée en application de l'article C.08.002 du Règlement;

b) toute présentation de drogue nouvelle pour usage exceptionnel déposée en application de l'article C.08.002.01 de ce règlement;

c) toute présentation abrégée de drogue nouvelle déposée en application de l'article C.08.002.1 du même règlement;

d) toute présentation abrégée de drogue nouvelle pour usage exceptionnel déposée en application de l'article C.08.002.1 du même règlement. (*submission*)

Règlement Le *Règlement sur les aliments et drogues*. (*Regulations*)

supplément Supplément à une présentation déposé en application de l'article C.08.003 du Règlement. (*supplement*)

Other words and expressions

(2) Unless the context otherwise requires, words and expressions used in this Interim Order have the meanings assigned by the Regulations.

Interpretation

(3) For the purposes of the definition *innovative drug* in subsection C.08.004.1(1) of the Regulations, a medicinal ingredient in a COVID-19 drug is not considered to be approved in a drug by the Minister by reason of the Minister having issued or amended an authorization in respect of the COVID-19 drug.

Authorizations

Non-application

2 (1) The provisions of the Regulations — other than the following provisions — do not apply to a COVID-19 drug if an authorization is issued in respect of the drug and the authorization is not suspended or revoked:

(a) sections A.01.014, A.01.015, A.01.022 to A.01.043, A.01.050, A.01.051 and A.01.060.1 to A.01.068;

(b) sections C.01.004 to C.01.011, C.01.014.9, C.01.014.10, C.01.017 and C.01.019, subsection C.01.020(1), sections C.01.020.1, C.01.040.3 to C.01.053, C.01.064 to C.01.069 and C.01.401;

(c) the provisions of Division 1A of Part C;

(d) the provisions of Division 2 of Part C with the exception of section C.02.019;

(e) sections C.03.202, C.03.203 and C.03.206 to C.03.209; and

(f) sections C.04.013 to C.04.016, C.04.019 and C.04.020.

Clarification

(2) For greater certainty, an authorization issued in respect of a COVID-19 drug authorizes the sale and advertising of the drug in accordance with this Interim Order.

Application for authorization

3 (1) Subject to section 4, an application for an authorization in respect of a COVID-19 drug must be in a form established by the Minister and contain sufficient information and material to enable the Minister to determine whether to issue the authorization, including

(a) the applicant's name and contact information and, in the case of a foreign applicant, the name and contact information of their representative in Canada;

(b) a description of the drug and a statement of its proper name or its common name if there is no proper name;

Terminologie

(2) Sauf indication contraire du contexte, les termes utilisés dans le présent arrêté d'urgence s'entendent au sens du Règlement.

Interprétation

(3) Pour l'application de la définition de *drogue innovante* au paragraphe C.08.004.1(1) du Règlement, la délivrance ou la modification par le ministre d'une autorisation à l'égard d'une drogue contre la COVID-19 n'a pas pour effet d'approuver tout ingrédient médicinal que contient cette drogue contre la COVID-19.

Autorisations

Non-application

2 (1) Les dispositions du Règlement — autres que les dispositions ci-après — ne s'appliquent pas à la drogue contre la COVID-19 qui fait l'objet d'une autorisation qui n'est pas suspendue ou révoquée :

a) les articles A.01.014, A.01.015, A.01.022 à A.01.043, A.01.050, A.01.051 et A.01.060.1 à A.01.068;

b) les articles C.01.004 à C.01.011, C.01.014.9, C.01.014.10, C.01.017 et C.01.019, le paragraphe C.01.020(1) et les articles C.01.020.1, C.01.040.3 à C.01.053, C.01.064 à C.01.069 et C.01.401;

c) les dispositions du titre 1A de la partie C;

d) les dispositions du titre 2 de la partie C, à l'exception de l'article C.02.019;

e) les articles C.03.202, C.03.203 et C.03.206 à C.03.209;

f) les articles C.04.013 à C.04.016, C.04.019 et C.04.020.

Précision

(2) Il est entendu que toute autorisation délivrée à l'égard d'une drogue contre la COVID-19 permet la vente et la publicité de la drogue en conformité avec le présent arrêté d'urgence.

Demande d'autorisation

3 (1) Sous réserve de l'article 4, la demande d'autorisation à l'égard d'une drogue contre la COVID-19 respecte la forme établie par le ministre et contient suffisamment de renseignements et de matériel pour permettre à ce dernier de déterminer s'il doit délivrer l'autorisation, notamment :

a) les nom et coordonnées du demandeur, et, s'il s'agit d'un demandeur étranger, ceux de son représentant au Canada;

b) une description de la drogue et la mention de son nom propre ou, à défaut, de son nom usuel;

(c) a statement of the brand name of the drug or the identifying name or code proposed for the drug;

(d) a list of the ingredients of the drug, stated quantitatively;

(e) the specifications for each of the drug's ingredients;

(f) a description of the facilities and equipment to be used in the manufacture, preparation and packaging of the drug;

(g) details of the method of manufacture and the controls to be used in the manufacture, preparation and packaging of the drug;

(h) details of the tests to be applied to control the potency, purity, stability and safety of the drug;

(i) the names and qualifications of all the investigators to whom the drug has been sold;

(j) a draft of every label to be used in connection with the drug, including any package insert and any document that is provided on request and that sets out supplementary information on the use of the drug;

(k) a statement of all the representations to be made for the promotion of the drug respecting

(i) the recommended route of administration of the drug,

(ii) the proposed dosage of the drug,

(iii) the drug's indications, and

(iv) the contra-indications and side effects of the drug;

(l) a description of the dosage form that is proposed for the sale of the drug;

(m) evidence that all test batches of the drug used in any studies conducted in connection with the application were manufactured and controlled in a manner that is representative of market production;

(n) in the case of a drug intended for administration to food-producing animals, the withdrawal period of the drug; and

(o) the known information in relation to the quality, safety and effectiveness of the drug.

c) la mention de la marque nominative de la drogue ou du nom ou code d'identification projeté pour celle-ci;

d) la liste quantitative des ingrédients de la drogue;

e) les spécifications relatives à chaque ingrédient de la drogue;

f) la description des installations et de l'équipement à utiliser pour la fabrication, la préparation et l'emballage de la drogue;

g) des précisions sur la méthode de fabrication et les mécanismes de contrôle à appliquer pour la fabrication, la préparation et l'emballage de la drogue;

h) le détail des épreuves qui doivent être effectuées pour contrôler l'activité, la pureté, la stabilité et la sûreté de la drogue;

i) les noms et titres professionnels des chercheurs à qui la drogue a été vendue;

j) une esquisse de toute étiquette à utiliser relativement à la drogue, y compris toute notice d'accompagnement et toute documentation supplémentaire sur l'emploi de la drogue qui est fournie sur demande;

k) la déclaration de toutes les recommandations qui doivent être faites dans la réclame pour la drogue au sujet de ce qui suit :

(i) la voie d'administration recommandée pour la drogue,

(ii) la posologie proposée pour la drogue,

(iii) les indications de la drogue,

(iv) les contre-indications et les effets secondaires de la drogue;

l) la description de la forme posologique proposée pour la vente de la drogue;

m) les éléments de preuve établissant que les lots d'essai de la drogue ayant servi aux études menées dans le cadre de la demande ont été fabriqués et contrôlés d'une manière représentative de la production destinée au commerce;

n) dans le cas d'une drogue destinée à être administrée à des animaux producteurs de denrées alimentaires, le délai d'attente applicable;

o) les renseignements connus relativement à la qualité, à la sûreté et à l'efficacité de la drogue.

Incomplete application — plan

(2) If, at the time an application is initially submitted to the Minister, the applicant is unable to provide information or material referred to in any of paragraphs (1)(g) to (k) and (m) to (o) or that information or material is incomplete, the applicant must include in the initial part of the application a plan as to how and when they will provide the Minister with the missing information or material.

Application based on comparison

(3) A person may submit an application for an authorization in respect of a COVID-19 drug under this section on the basis of a direct or indirect comparison to another drug only if

(a) the person notifies the Minister of their intention to submit the application and provides information to the Minister to establish that the following requirements are met:

(i) a notice of compliance or authorization is issued in respect of the other drug, and

(ii) the other drug is not offered for sale in Canada or is offered for sale in Canada but not in sufficient quantities to address the urgent public health need related to COVID-19;

(b) the Minister, after receiving the notification and information referred to in paragraph (a), provides the manufacturer of the other drug with, having regard to the urgent public health need related to COVID-19, an opportunity to make representations to the Minister as to whether the requirement set out in subparagraph (a)(ii) is met; and

(c) the Minister determines that the requirements set out in subparagraphs (a)(i) and (ii) are met and notifies the person in writing of that determination.

Application for authorization — foreign drug

4 (1) An application for an authorization in respect of a COVID-19 drug may be based on a comparison to a foreign drug if the sale of the foreign drug is authorized by a foreign regulatory authority on the basis of information submitted to the authority in relation to the quality, safety and effectiveness of that drug.

Content

(2) The application must be in a form established by the Minister and contain the following information and material:

(a) the information and material described in paragraphs 3(1)(a) to (d), (f), (j) to (l) and, if applicable, (n);

Demande incomplète – plan

(2) Si, au moment de présenter sa demande initiale au ministre, le demandeur ne peut fournir les renseignements ou le matériel visés à l'un des alinéas (1)g) à k) et m) à o) ou qu'il fournit de tels renseignements ou matériel mais que ceux-ci sont incomplets, il fournit dans la partie de sa demande initiale un plan précisant les modalités selon lesquelles il fournira au ministre les renseignements ou le matériel manquants.

Demande fondée sur une comparaison

(3) Toute personne peut présenter une demande d'autorisation à l'égard d'une drogue contre la COVID-19 conformément au présent article sur la base d'une comparaison directe ou indirecte entre cette drogue et une autre drogue, uniquement si les conditions ci-après sont réunies :

a) elle avise le ministre de son intention de présenter la demande et lui fournit des renseignements visant à établir que les exigences suivantes sont respectées :

(i) l'autre drogue fait l'objet d'une autorisation ou d'un avis de conformité,

(ii) l'autre drogue n'est pas mise en vente au Canada ou elle l'est, mais en quantité insuffisante pour combler le besoin urgent en matière de santé publique relatif à la COVID-19;

b) le ministre, sur réception de l'avis et des renseignements visés à l'alinéa a), fournit au fabricant de l'autre drogue l'occasion de lui présenter, compte tenu du besoin urgent en matière de santé publique relatif à la COVID-19, des observations quant au respect de l'exigence prévue au sous-alinéa a)(ii);

c) le ministre établit que les exigences prévues aux sous-alinéas a)(i) et (ii) sont respectées et en avise par écrit la personne.

Demande d'autorisation – drogue étrangère

4 (1) Toute demande d'autorisation à l'égard d'une drogue contre la COVID-19 peut être fondée sur une comparaison de la drogue avec une drogue étrangère, dont la vente est autorisée par une autorité réglementaire étrangère sur le fondement de renseignements fournis à cette autorité relativement à la qualité, à la sûreté et à l'efficacité de cette drogue.

Contenu

(2) La demande respecte la forme établie par le ministre et contient les renseignements et le matériel suivants :

a) les renseignements et le matériel visés aux alinéas 3(1)a) à d), f), j) à l) et, s'il y a lieu, n);

(b) an attestation, signed and dated by an individual who has authority to bind the applicant in Canada, certifying that the applicant has access to the information referred to in paragraph 3(1)(o) that was submitted to the relevant foreign regulatory authority in order for the foreign drug to be authorized to be sold;

(c) information that demonstrates that the drug is identical to, and is manufactured, prepared and packaged in the same manner as, the foreign drug;

(d) information that demonstrates that the sale of the foreign drug is authorized by the foreign regulatory authority referred to in paragraph (b); and

(e) any labels that are approved by the foreign regulatory authority referred to in paragraph (b) for use in connection with the foreign drug.

b) une attestation, signée et datée par un individu qui a le pouvoir de lier le demandeur au Canada, portant que le demandeur dispose des renseignements visés à l'alinéa 3(1)o) qui ont été fournis à l'autorité réglementaire étrangère compétente afin que la vente de la drogue étrangère soit autorisée;

c) des renseignements établissant que la drogue est identique à la drogue étrangère et qu'elle est fabriquée, préparée et emballée de la même façon que cette dernière;

d) des renseignements établissant que la vente de la drogue étrangère est autorisée par l'autorité réglementaire étrangère visée à l'alinéa b);

e) toute étiquette approuvée par l'autorité réglementaire étrangère visée à l'alinéa b) à utiliser relativement à la drogue étrangère.

Issuance

5 The Minister must issue an authorization in respect of a COVID-19 drug if the following requirements are met:

(a) the applicant has submitted an application to the Minister that meets the requirements set out in subsection 3(1) or 4(2);

(b) the applicant has provided the Minister with all information or material, including samples, requested under subsection 13(1) in the time, form and manner specified under subsection 13(2); and

(c) the Minister has sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19.

Délivrance

5 Le ministre délivre une autorisation à l'égard d'une drogue contre la COVID-19 si les exigences suivantes sont respectées :

a) le demandeur lui a présenté une demande conforme aux exigences des paragraphes 3(1) ou 4(2);

b) le demandeur lui a fourni les renseignements ou le matériel, y compris les échantillons, qu'il a demandés en vertu du paragraphe 13(1), selon les modalités qu'il a fixées en application du paragraphe 13(2);

c) le ministre dispose de preuves suffisantes pour conclure que les avantages associés à la drogue l'emportent sur les risques associés à cette dernière, compte tenu des incertitudes à l'égard de ces avantages et de ces risques et de la nécessité de combler le besoin urgent en matière de santé publique relatif à la COVID-19.

Prohibition — significant difference

6 (1) It is prohibited to sell a COVID-19 drug to which an authorization relates if any of the matters referred to in subsection 3(1) or subsection 4(2) — other than in paragraph 3(1)(i) or 4(2)(e), as the case may be — are significantly different from the information or material contained in the application, unless the Minister amends the authorization.

Interdiction — différence appréciable

6 (1) Il est interdit de vendre une drogue contre la COVID-19 qui fait l'objet d'une autorisation si l'un des éléments visés aux paragraphes 3(1) ou 4(2) — à l'exception des alinéas 3(1)i) ou 4(2)e), selon le cas — diffère sensiblement des renseignements ou du matériel contenus dans la demande d'autorisation, à moins que le ministre ne modifie l'autorisation.

Amendment

(2) The Minister must amend the authorization if the following requirements are met:

(a) the holder of the authorization has submitted an application to the Minister to amend it;

(b) the holder has provided the Minister with all information or material, including samples, requested

Modification

(2) Le ministre modifie l'autorisation si les exigences suivantes sont remplies :

a) le titulaire de l'autorisation lui a présenté une demande de modification de celle-ci;

b) le titulaire de l'autorisation lui a fourni les renseignements ou le matériel, y compris les échantillons,

under subsection 13(1) in the time, form and manner specified under subsection 13(2); and

(c) the Minister has sufficient evidence to support the conclusion that the benefits associated with the drug outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19.

qu'il a demandés en vertu du paragraphe 13(1), selon les modalités qu'il a fixées en application du paragraphe 13(2);

c) le ministre dispose de preuves suffisantes pour conclure que les avantages associés à la drogue l'emportent sur les risques associés à cette dernière, compte tenu des incertitudes à l'égard de ces avantages et de ces risques et de la nécessité de combler le besoin urgent en matière de santé publique relatif à la COVID-19.

Drug identification number

7 (1) When the Minister issues or amends an authorization, he or she must assign a drug identification number for each distinct combination of dosage form, strength and route of administration for the COVID-19 drug to which the authorization relates.

Identification numérique

7 (1) Lorsqu'il délivre ou modifie une autorisation, le ministre attribue une identification numérique à chaque combinaison distincte de forme posologique, de concentration et de voie d'administration de la drogue contre la COVID-19 qui fait l'objet de l'autorisation.

Deeming — holder

(2) Any reference to a person that holds a drug identification number in sections C.01.050, C.01.052, C.01.053 and C.01A.003 of the Regulations is deemed to include a reference to the holder of an authorization.

Fiction — titulaire

(2) Le renvoi au titulaire d'une identification numérique aux articles C.01.050, C.01.052, C.01.053 et C.01A.003 du Règlement vaut renvoi au titulaire d'une autorisation.

Deeming — drug identification number

(3) Any reference to a drug identification number in the provisions of Divisions 1 and 1A of Part C of the Regulations — other than in sections C.01.050, C.01.052, C.01.053 and C.01A.003 — is deemed to include a reference to a drug identification number assigned under subsection (1).

Fiction — identification numérique

(3) Le renvoi à une identification numérique dans les dispositions des titres 1 et 1A de la partie C du Règlement — à l'exception des articles C.01.050, C.01.052, C.01.053 et C.01A.003 — vaut renvoi à une identification numérique attribuée en application du paragraphe (1).

Notification of first sale

8 The holder of an authorization must, within 15 days after the day on which the COVID-19 drug to which the authorization relates is first sold in Canada, notify the Minister, in writing, of the date of that first sale.

Notification – première vente

8 Le titulaire d'une autorisation doit, dans les quinze jours suivant la date de la première vente au Canada de la drogue contre la COVID-19 qui fait l'objet de l'autorisation, notifier par écrit cette date au ministre.

Notification of discontinuance

9 The holder of an authorization must, within 15 days after the day on which they permanently discontinue the sale in Canada of the COVID-19 drug to which the authorization relates, notify the Minister, in writing, of the date on which the sale was permanently discontinued.

Notification – cessation de vente

9 Le titulaire d'une autorisation doit, dans les quinze jours suivant la date à laquelle il cesse définitivement de vendre au Canada la drogue contre la COVID-19 qui fait l'objet de l'autorisation, notifier par écrit cette date au ministre.

Terms and conditions

10 The Minister may, at any time, impose terms and conditions on an authorization or amend those terms and conditions.

Conditions

10 Le ministre peut, en tout temps, assortir l'autorisation de conditions ou modifier de telles conditions.

Suspension

11 (1) The Minister may suspend an authorization, in whole or in part, giving reasons, if

(a) the Minister determines that the requirement set out in paragraph 5(c) is no longer met;

Suspension

11 (1) Le ministre peut, par avis motivé, suspendre une autorisation, en partie ou en totalité, dans les cas suivants :

a) il conclut que l'exigence prévue à l'alinéa 5c) n'est plus respectée;

(b) the Minister has reasonable grounds to believe that the holder of the authorization has contravened, in relation to the COVID-19 drug to which the authorization relates, any provision of this Interim Order, the Regulations or the *Food and Drugs Act* or any order made under that Act; or

(c) in the case of an authorization that was issued on the basis of an application submitted under section 4, the Minister becomes aware that the foreign regulatory authority has revoked or suspended the authorization to sell the foreign drug.

b) il a des motifs raisonnables de croire que le titulaire de l'autorisation a contrevenu, à l'égard de la drogue contre la COVID-19 qui fait l'objet de l'autorisation, à toute disposition du présent arrêté d'urgence, du Règlement, ou de la *Loi sur les aliments et drogues*, ou à tout ordre qui lui est donné en vertu de cette loi;

c) dans le cas où l'autorisation a été délivrée en réponse à une demande visée à l'article 4, il apprend que l'autorité réglementaire étrangère a révoqué ou suspendu l'autorisation de vendre la drogue étrangère.

Reinstatement

(2) The Minister must reinstate a suspended authorization if the holder provides to the Minister, in the time, form and manner specified by the Minister, information or material that demonstrates that the situation giving rise to the suspension did not exist or has been corrected.

Rétablissement

(2) Le ministre rétablit l'autorisation suspendue si le titulaire de celle-ci lui fournit, selon les modalités fixées par le ministre, des renseignements ou du matériel démontrant que la situation ayant donné lieu à la suspension n'a jamais existé ou qu'elle a été corrigée.

Discretionary revocation

12 (1) The Minister may revoke an authorization, in whole or in part, giving reasons, if the holder of the authorization has not provided to the Minister, in the time, form and manner specified by the Minister, the information or material referred to in subsection 11(2).

Révocation facultative

12 (1) Le ministre peut, par avis motivé, révoquer une autorisation, en partie ou en totalité, si le titulaire de celle-ci ne lui a pas fourni, selon les modalités qu'il a fixées, les renseignements ou le matériel visés au paragraphe 11(2).

Mandatory revocation

(2) The Minister must revoke an authorization if the holder of the authorization requests it.

Révocation obligatoire

(2) Le ministre révoque l'autorisation si le titulaire de celle-ci lui en fait la demande.

Request for information or material

13 (1) The Minister may request that a person that has submitted an application for an authorization in respect of a COVID-19 drug or the holder of such an authorization provide any information or material, including samples, that is necessary to enable the Minister to determine whether to issue, amend or suspend the authorization.

Demande de renseignements ou de matériel

13 (1) Le ministre peut demander à la personne qui a présenté une demande d'autorisation à l'égard d'une drogue contre la COVID-19 ou au titulaire d'une telle autorisation de lui fournir des renseignements ou du matériel, y compris les échantillons, qui lui sont nécessaires pour déterminer s'il convient de délivrer, de modifier ou de suspendre l'autorisation.

Time, form and manner

(2) The person or holder, as the case may be, must provide the information, material or samples in the time, form and manner specified by the Minister.

Modalités

(2) La personne qui a présenté la demande ou le titulaire de l'autorisation, selon le cas, fournit les renseignements ou le matériel, y compris les échantillons, au ministre selon les modalités fixées par ce dernier.

Comparison — submission or supplement

14 (1) Despite sections C.08.002, C.08.002.01, C.08.002.1 and C.08.003 of the Regulations and subject to subsection (2), a manufacturer of a new drug is not permitted to file a submission or supplement for the new drug on the basis of a direct or indirect comparison to a COVID-19 drug in respect of which an authorization is issued.

Comparaison — présentation ou supplément

14 (1) Malgré les articles C.08.002, C.08.002.01, C.08.002.1 et C.08.003 du Règlement et sous réserve du paragraphe (2), le fabricant d'une drogue nouvelle ne peut déposer une présentation ou un supplément à l'égard de la drogue nouvelle sur la base d'une comparaison directe ou indirecte entre la drogue nouvelle et une drogue contre la COVID-19 qui fait l'objet d'une autorisation.

Clarification

(2) In the case where both a notice of compliance and an authorization are issued in respect of a COVID-19 drug, subsection (1) does not prevent a manufacturer of a new drug from filing a submission or supplement for the new drug in respect of the matters that are approved under the notice of compliance.

Expanded indication

15 Section C.08.003 of the Regulations does not apply to the sale of a new drug — in respect of which a notice of compliance is issued and that is set out in the *List of New Drugs for Expanded Indication* — in relation to the expanded indication that is set out in the List in respect of the new drug if the Minister

(a) determines that the expanded indication of the new drug is necessary to address the urgent public health need related to COVID-19; and

(b) has evidence to support the conclusion that the benefits associated with the expanded indication outweigh the risks, having regard to the uncertainties relating to the benefits and risks and the necessity of addressing the urgent public health need related to COVID-19.

Supplementary information

16 The Minister must publish on a Government of Canada website supplementary information pertaining to the expanded indication of a new drug that is set out in the *List of New Drugs for Expanded Indication*, including

(a) a statement of the expanded indication;

(b) a statement of the known and potential benefits and the known and potential risks; and

(c) any supplement to the directions for use, unless a supplement is not required for the new drug to be used safely and effectively.

Information request

17 (1) If a new drug for which a notice of compliance is issued is set out in the *List of New Drugs for Expanded Indication*, the Minister may request the manufacturer to which the notice of compliance is issued to provide any information that it possesses or has reasonable access to in relation to the expanded indication that is set out in the List in respect of the drug.

Time, form and manner

(2) The manufacturer must provide the information in the time, form and manner specified by the Minister.

Précision

(2) S'agissant d'une drogue contre la COVID-19 qui fait l'objet d'un avis de conformité et d'une autorisation, le paragraphe (1) n'empêche pas le fabricant d'une drogue nouvelle de déposer une présentation ou un supplément à l'égard de la drogue nouvelle relativement aux éléments approuvés par le biais de cet avis de conformité.

Indication supplémentaire

15 L'article C.08.003 du Règlement ne s'applique pas à la vente d'une drogue nouvelle — qui fait l'objet d'un avis de conformité et qui figure dans la *Liste des drogues nouvelles à indication supplémentaire* — relativement à l'indication supplémentaire mentionnée dans cette liste à l'égard de la drogue nouvelle si le ministre, à la fois :

a) conclut que l'indication supplémentaire de la drogue nouvelle est nécessaire pour combler le besoin urgent en matière de santé publique relatif à la COVID-19;

b) dispose d'éléments de preuve lui permettant de conclure que les avantages associés à l'indication supplémentaire l'emportent sur les risques associés à cette indication, compte tenu des incertitudes à l'égard de ces avantages et de ces risques et de la nécessité de combler le besoin urgent en matière de santé publique relatif à la COVID-19.

Renseignements additionnels

16 Le ministre publie sur un site Web du gouvernement du Canada des renseignements additionnels relativement à l'indication supplémentaire de chaque drogue nouvelle qui figure dans la *Liste des drogues nouvelles à indication supplémentaire*, notamment :

a) la mention de l'indication supplémentaire;

b) la mention des avantages connus et possibles et des risques connus et possibles;

c) tout supplément au mode d'emploi, sauf lorsque la drogue nouvelle peut être utilisée de façon efficace et en toute sécurité sans un tel supplément.

Demande de renseignements

17 (1) S'agissant d'une drogue nouvelle qui fait l'objet d'un avis de conformité et qui figure dans la *Liste des drogues nouvelles à indication supplémentaire*, le ministre peut demander au fabricant à qui l'avis de conformité a été délivré de lui fournir les renseignements dont il dispose ou qu'il peut raisonnablement obtenir relativement à l'indication supplémentaire mentionnée dans cette liste à l'égard de la drogue.

Modalités

(2) Le fabricant fournit les renseignements au ministre selon les modalités fixées par ce dernier.

Shortages or discontinuation of sale

18 Despite the definition *drug* in section C.01.014.8 of the Regulations, sections C.01.014.9 and C.01.014.10 of the Regulations apply, with any modifications that may be necessary, to the holder of an authorization in respect of the COVID-19 drug to which the authorization relates.

Records

19 (1) The holder of an authorization must maintain records of the following in relation to the COVID-19 drug to which the authorization relates:

(a) any substitution of another substance for the drug or any mixing of another substance with the drug;

(b) any error in the labelling of the drug or in the use of the labels designed for the drug;

(c) any bacteriological or any significant chemical or physical or other change or deterioration in any lot of the drug;

(d) any failure of one or more distributed lots of the drug to meet the specifications established for the drug; and

(e) any unusual failure in efficacy of the drug.

Provision to Minister

(2) The holder of the authorization must provide to the Minister

(a) a summary of a record respecting any information referred to in paragraphs (1)(a) to (c), immediately after the holder establishes the record; or

(b) a summary of a record respecting any information referred to in paragraph (1)(d) or (e), within 15 days after the day on which the holder establishes the record.

Establishment Licences

Application for establishment licence

20 (1) A person that submits an application for an establishment licence under section C.01A.005 of the Regulations that relates solely to one or more activities set out in Table I of section C.01A.008 of the Regulations in respect of a COVID-19 drug may include a statement to that effect in the application.

Application for amendment

(2) A person that submits an application for the amendment of their establishment licence under section C.01A.006 of the Regulations that relates solely to one

Pénurie ou cessation de vente

18 Malgré la définition de *drogue* à l'article C.01.014.8 du Règlement, les articles C.01.014.9 et C.01.014.10 de ce règlement s'appliquent au titulaire d'une autorisation à l'égard de la drogue contre la COVID-19 qui fait l'objet de l'autorisation, avec les adaptations nécessaires.

Dossiers

19 (1) Le titulaire d'une autorisation tient des dossiers au sujet des éléments ci-après relativement à la drogue contre la COVID-19 qui fait l'objet de l'autorisation :

a) toute substitution d'une autre substance à la drogue ou tout mélange d'une autre substance avec cette dernière;

b) toute erreur dans l'étiquetage de la drogue ou dans l'utilisation des étiquettes destinées à la drogue;

c) tout changement ou toute détérioration bactériologiques, ou tout changement ou toute détérioration importants de nature physique, chimique ou autre, dans n'importe quel lot de la drogue;

d) toute occasion où l'un ou plusieurs des lots de la drogue qui ont été distribués n'étaient pas conformes aux spécifications établies relativement à celle-ci;

e) tout cas inhabituel où la drogue n'a pas produit l'effet prévu.

Fourniture au ministre

(2) Il fournit au ministre :

a) le résumé du dossier relatif à tout renseignement visé à l'un des alinéas (1)a) à c) immédiatement après l'établissement de ce dossier;

b) le résumé du dossier relatif à tout renseignement visé aux alinéas (1)d) ou e) dans les quinze jours suivant la date d'établissement du dossier.

Licences d'établissement

Demande de licence d'établissement

20 (1) La personne qui présente, en application de l'article C.01A.005 du Règlement, une demande de licence d'établissement qui vise seulement l'une ou plusieurs des activités mentionnées au tableau I de l'article C.01A.008 de ce règlement à l'égard d'une drogue contre la COVID-19 peut inclure dans la demande une mention à cet égard.

Demande de modification

(2) La personne qui présente, en application de l'article C.01A.006 du Règlement, une demande de modification d'une licence d'établissement qui vise seulement l'une

or more activities set out in Table I of section C.01A.008 of the Regulations in respect of a COVID-19 drug may include a statement to that effect in the application.

Deeming

(3) In the case of an application referred to in subsection (1) or (2) that includes the relevant statement, any reference to information and documents in sections C.01A.006 and C.01A.008 of the Regulations is deemed to include that statement.

Information and material

21 For the purposes of section C.01A.008 of the Regulations, the Minister must, in determining whether he or she has received the information and material required by sections C.01A.005 to C.01A.007 of the Regulations in relation to an application referred to in subsection 20(1) or (2) that includes the statement referred to in the applicable subsection, also take into consideration the necessity of addressing the urgent public health need related to COVID-19.

Terms and conditions

22 (1) Despite subsection C.01A.008(4) of the Regulations and subject to subsection (2), the Minister may, at any time, including when issuing an establishment licence, impose terms and conditions on an establishment licence that is issued or amended under section C.01A.008 of the Regulations on the basis of an application referred to in subsection 20(1) or (2) that includes the statement referred to in the applicable subsection.

Duration

(2) Any terms and conditions that the Minister imposes on an establishment licence under subsection (1) cease to apply to the licence immediately before this Interim Order ceases to have effect.

Scope

(3) For greater certainty, terms and conditions that may be imposed under subsection (1) are not limited to those described in paragraphs C.01A.008(4)(a) and (b) of the Regulations.

Amending terms and conditions

23 Despite section C.01A.012 of the Regulations, the Minister may, at any time, amend any terms and conditions that are imposed on an establishment licence under section 22.

Verification — holder or importer

24 (1) If the holder of an authorization receives a lot or batch of the COVID-19 drug to which the authorization relates — or an importer receives a lot or batch of such a COVID-19 drug — on their premises in Canada the useful

ou plusieurs des activités mentionnées au tableau I de l'article C.01A.008 de ce règlement à l'égard d'une drogue contre la COVID-19 peut inclure dans la demande une mention à cet égard.

Fiction

(3) S'agissant d'une demande visée aux paragraphes (1) ou (2) qui contient la mention visée à celui de ces paragraphes qui s'applique, le renvoi à des renseignements et documents, aux articles C.01A.006 et C.01A.008 du Règlement, vaut renvoi à cette mention.

Renseignements et matériel

21 Pour l'application de l'article C.01A.008 du Règlement, lorsqu'il détermine s'il a reçu les renseignements et le matériel visés aux articles C.01A.005 à C.01A.007 de ce règlement à l'égard de la demande visée aux paragraphes 20(1) ou (2) qui contient la mention visée à celui de ces paragraphes qui s'applique, le ministre prend également en considération la nécessité de combler le besoin urgent en matière de santé publique relatif à la COVID-19.

Conditions

22 (1) Malgré le paragraphe C.01A.008(4) du Règlement et sous réserve du paragraphe (2), le ministre peut, à tout moment, y compris lorsqu'il délivre une licence d'établissement, assortir de conditions la licence d'établissement qu'il délivre ou modifie en application de l'article C.01A.008 de ce règlement en réponse à la demande visée aux paragraphes 20(1) ou (2) qui contient la mention visée à celui de ces paragraphes qui s'applique.

Durée

(2) Les conditions dont le ministre assortit une licence d'établissement en vertu du paragraphe (1) cessent de s'appliquer à la licence immédiatement avant que le présent arrêté d'urgence cesse d'avoir effet.

Portée

(3) Il est entendu que les conditions dont le ministre peut assortir toute licence d'établissement en vertu du paragraphe (1) ne se limitent pas à celles visées aux alinéas C.01A.008(4)a) et b) du Règlement.

Modification de conditions

23 Malgré l'article C.01A.012 du Règlement, le ministre peut, à tout moment, modifier les conditions dont il assortit une licence d'établissement en vertu de l'article 22.

Vérification — titulaire ou importateur

24 (1) Lorsqu'il reçoit, dans ses locaux au Canada, un lot ou lot de fabrication d'une drogue contre la COVID-19 qui fait l'objet d'une autorisation et dont la période de vie utile est de plus de trente jours, le titulaire de l' autorisation ou

life of which is more than 30 days, the holder or importer must visually inspect the lot or batch to confirm its identity.

Verification — packager/labeller

(2) If a packager/labeller receives a lot or batch of a COVID-19 drug on their premises in Canada the useful life of which is more than 30 days, the packager/labeller must test the lot or batch for identity and must confirm the identity of the lot or batch after it is packaged/labelled.

Exception — holder

(3) Subsection (1) does not apply to the holder of the authorization if the COVID-19 drug is fabricated, packaged/labelled and tested in Canada by a person that holds an establishment licence that authorizes those activities in respect of that drug.

Exception — holder or importer

(4) Subsection (1) does not apply to the holder of the authorization or the importer if the following requirements are met:

(a) the COVID-19 drug is fabricated, packaged/labelled and tested in an MRA country at a recognized building;

(b) the address of the building is set out in their establishment licence; and

(c) they retain a copy of the batch certificate for each lot or batch of the drug that they receive.

Non-application — records

25 (1) Paragraphs C.02.020(1)(a), (b) and (d) of the Regulations do not apply to an importer in respect of a COVID-19 drug to which an authorization relates.

Deeming — holder

(2) Any reference in section C.02.020 of the Regulations to a distributor referred to in paragraph C.01A.003(b) of the Regulations is deemed to include a reference to the holder of an authorization.

Cancellation

26 (1) Any establishment licence that the Minister has issued under section C.01A.008 of the Regulations on the basis of an application referred to in subsection 20(1) that includes the statement referred to in that subsection is cancelled immediately before this Interim Order ceases to have effect.

Amendment ceasing to have effect

(2) Any amendment that the Minister has made to an establishment licence that was issued under section C.01A.008 of the Regulations before this Interim

l'importateur en fait une inspection visuelle afin d'en confirmer l'identité.

Vérification — emballeur-étiqueteur

(2) Lorsqu'il reçoit, dans ses locaux au Canada, un lot ou lot de fabrication d'une drogue contre la COVID-19 dont la période de vie utile est de plus de trente jours, l'emballeur-étiqueteur soumet le lot ou lot de fabrication à une analyse d'identité et en confirme l'identité après son emballage-étiquetage.

Exception — titulaire

(3) Le paragraphe (1) ne s'applique pas au titulaire de l'autorisation si la drogue contre la COVID-19 est manufacturée, emballée-étiquetée et analysée au Canada par le titulaire d'une licence d'établissement autorisant ces activités à l'égard de cette drogue.

Exception — titulaire ou importateur

(4) Le paragraphe (1) ne s'applique pas au titulaire de l'autorisation ou à l'importateur si les exigences suivantes sont réunies :

a) la drogue contre la COVID-19 est manufacturée, emballée-étiquetée et analysée dans un bâtiment reconnu d'un pays participant;

b) l'adresse du bâtiment est indiquée dans sa licence d'établissement;

c) il conserve une copie du certificat de lot pour chaque lot ou lot de fabrication de la drogue qu'il reçoit.

Non-application — dossiers

25 (1) Les alinéas C.02.020(1)a), b) et d) du Règlement ne s'appliquent pas à l'importateur d'une drogue contre la COVID-19 qui fait l'objet d'une autorisation.

Fiction — titulaire

(2) Le renvoi, à l'article C.02.020 du Règlement, au distributeur visé à l'alinéa C.01A.003b) de ce règlement vaut renvoi au titulaire d'une autorisation.

Annulation

26 (1) La licence d'établissement que le ministre a délivrée en application de l'article C.01A.008 du Règlement en réponse à une demande visée au paragraphe 20(1) contenant la mention visée à ce paragraphe est annulée immédiatement avant que le présent arrêté d'urgence cesse d'avoir effet.

Modification cessant d'avoir effet

(2) Toute modification que le ministre a apportée à une licence d'établissement qu'il a délivrée en application de l'article C.01A.008 du Règlement avant de prendre le

Order is made ceases to have effect immediately before this Interim Order ceases to have effect if the Minister made the amendment on the basis of an application referred to in subsection 20(2) that included the statement referred to in that subsection.

Pre-positioning of COVID-19 Drugs

Application

27 Sections 28 to 30 apply in respect of a COVID-19 drug if the following conditions are met:

(a) a notice of compliance has not been issued in respect of the drug;

(b) an authorization has not been issued in respect of the drug; and

(c) Her Majesty in right of Canada has entered into a contract for the procurement of the drug.

Importation

28 (1) The holder of an establishment licence may import a COVID-19 drug if the following conditions are met:

(a) the Chief Public Health Officer provides the Minister with

(i) information indicating that

(A) the drug is the subject of an application submitted under section 3 or 4,

(B) the drug is the subject of a submission, or

(C) an application has been submitted to a foreign regulatory authority to authorize the sale of a foreign drug that is identical to, and is manufactured in the same manner as, the drug,

(ii) the name of the drug and a description of it,

(iii) the name and contact information of the drug's manufacturer,

(iv) information specifying the quantity of the drug to be imported,

(v) the name and contact information of the holder of an establishment licence who is proposed to import the drug, and

(vi) the civic address of the place where the drug will be stored after importation;

présent arrêté d'urgence cesse d'avoir effet immédiatement avant que l'arrêté cesse d'avoir effet si le ministre a apporté la modification en réponse à une demande visée au paragraphe 20(2) contenant la mention visée à ce paragraphe.

Prépositionnement de drogues contre la COVID-19

Application

27 Les articles 28 à 30 s'appliquent à l'égard de la drogue contre la COVID-19 si les conditions suivantes sont réunies :

a) aucun avis de conformité n'a été délivré à l'égard de la drogue;

b) aucune autorisation n'a été délivrée à l'égard de la drogue;

c) Sa Majesté du chef du Canada a conclu un contrat en vue de l'acquisition de la drogue.

Importation

28 (1) Le titulaire d'une licence d'établissement peut importer une drogue contre la COVID-19 si les conditions suivantes sont réunies :

a) l'administrateur en chef de la santé publique fournit au ministre :

(i) l'information selon laquelle :

(A) ou bien la drogue fait l'objet d'une demande présentée conformément aux articles 3 ou 4,

(B) ou bien la drogue fait l'objet d'une présentation,

(C) ou bien une demande d'autorisation de vente a été présentée à une autorité réglementaire étrangère à l'égard d'une drogue étrangère identique à la drogue et fabriquée de la même manière que celle-ci,

(ii) le nom et la description de la drogue,

(iii) les nom et coordonnées du fabricant de la drogue,

(iv) l'information quant à la quantité de la drogue à importer,

(v) les nom et coordonnées du titulaire d'une licence d'établissement envisagé pour l'importation de la drogue,

(vi) l'adresse municipale du lieu où la drogue sera entreposée après l'importation;

(b) the holder provides the Minister with

(i) the name and contact information of each fabricator, packager/labeller and tester of the drug and the civic address of each building at which the drug will be fabricated, packaged/labelled or tested, specifying for each building

(A) the activities referred to in Table I to section C.01A.008 of the Regulations that apply to the drug,

(B) the categories referred to in Table II to that section that apply to the drug, and

(C) for each category, the dosage form classes, if any, and whether the drug will be in a sterile form, and

(ii) a certificate from an inspector indicating that each fabricator's, packager/labeller's and tester's buildings, equipment, practices and procedures meet the applicable requirements of the provisions of Divisions 2 to 4 of Part C of the Regulations or, alternatively, other evidence establishing that those requirements are met; and

(c) the holder is specified in the information that the Chief Public Health Officer provides under subparagraph (a)(v).

b) le titulaire de licence fournit au ministre :

(i) les nom et coordonnées de chaque manufacturier, emballeur-étiqueteur et analyste de la drogue et l'adresse municipale de chaque bâtiment où celle-ci sera manufacturée, emballée-étiquetée ou analysée, avec une mention, pour chaque bâtiment, de ce qui suit :

(A) les activités mentionnées au tableau I de l'article C.01A.008 du Règlement qui s'appliquent à la drogue,

(B) les catégories mentionnées au tableau II de cet article qui s'appliquent à la drogue,

(C) pour chacune de ces catégories, la classe de forme posologique, le cas échéant, et une mention indiquant s'il s'agit d'une drogue stérile,

(ii) le certificat d'un inspecteur indiquant que les bâtiments, l'équipement et les méthodes et pratiques de chaque manufacturier, emballeur-étiqueteur et analyste satisfont aux exigences applicables des dispositions des titres 2 à 4 de la partie C du Règlement ou, à défaut, toute autre preuve établissant que ces exigences sont satisfaites.

c) le titulaire de licence est celui que l'administrateur en chef de la santé publique a mentionné dans les renseignements fournis en application du sous-alinéa a)(v).

Exception

(2) Paragraph (1)(b) does not apply to the holder of an establishment licence in respect of a building referred to in subparagraph (1)(b)(i) if

(a) the building is listed in the licence; and

(b) the information referred to in clauses (1)(b)(i)(A) to (C) that the holder submitted in respect of the building in their application for the licence under section C.01A.005 of the Regulations, or in an application for an amendment to the licence under section C.01A.006 of the Regulations, as the case may be, has not changed.

Exception

(2) L'alinéa (1)b) ne s'applique pas au titulaire de licence d'établissement à l'égard de tout bâtiment visé au sous-alinéa (1)b)(i) si les conditions suivantes sont réunies :

a) le bâtiment figure sur sa licence;

b) les renseignements visés aux divisions (1)b)(i)(A) à (C) qu'il a fournis à l'égard du bâtiment dans la demande qu'il a présentée conformément à l'article C.01A.005 du Règlement en vue d'obtenir la licence ou dans toute demande de modification de cette dernière qu'il a présentée conformément à l'article C.01A.006 de ce règlement, le cas échéant, demeurent inchangés.

Letter

(3) If the conditions set out in subsection (1) are met, the Minister must send a letter to the Chief Public Health Officer to that effect.

Lettre

(3) Lorsque les conditions prévues au paragraphe (1) sont remplies, le ministre fait parvenir à l'administrateur en chef de la santé publique une lettre à cet égard.

Non-application — importation

29 Sections A.01.040 and C.01.004.1, subsection C.01A.004(1) and section C.01A.006 of the Regulations and the provisions of Divisions 2 to 4 of Part C of the Regulations, except for the following provisions, do not

Non-application — importation

29 Les articles A.01.040 et C.01.004.1, le paragraphe C.01A.004(1), l'article C.01A.006 et, à l'exception des dispositions ci-après, les dispositions des titres 2 à 4 de la partie C du Règlement ne s'appliquent pas à l'égard de

apply in respect of the importation of a COVID-19 drug by the holder of an establishment licence under section 28:

(a) sections C.02.003.1, C.02.004 and C.02.006, as they apply to the storage of the drug by the holder;

(b) subsection C.02.012(1);

(c) sections C.02.013 and C.02.014;

(d) section C.02.015, as it applies to the storage and transportation of the drug by the holder;

(e) subsection C.02.021(1), as it applies to the storage of the drug by the holder;

(f) subsection C.02.022(1);

(g) section C.02.023;

(h) subsection C.02.024(1);

(i) section C.03.013; and

(j) section C.04.001.1, as it applies to the storage of the drug by the holder.

Distribution of imported drug

30 Despite anything in the Regulations, the holder of an establishment licence may distribute a COVID-19 drug that they have imported under section 28 if the following conditions are met:

(a) the Chief Public Health Officer provides the Minister with the name of the drug and the civic address of the place where the drug will be stored after the distribution; and

(b) the drug is distributed to a person who will store it at the place.

EXPLANATORY NOTE

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

Proposal

The *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (the Interim Order) 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

l'importation, en vertu de l'article 28, d'une drogue contre la COVID-19 par le titulaire d'une licence d'établissement :

a) les articles C.02.003.1, C.02.004 et C.02.006, en ce qui a trait à l'entreposage de la drogue par le titulaire de licence;

b) le paragraphe C.02.012(1);

c) les articles C.02.013 et C.02.014;

d) l'article C.02.015, en ce qui a trait à l'entreposage et au transport de la drogue par le titulaire de licence;

e) le paragraphe C.02.021(1), en ce qui a trait à l'entreposage de la drogue par le titulaire de licence;

f) le paragraphe C.02.022(1);

g) l'article C.02.023;

h) le paragraphe C.02.024(1);

i) l'article C.03.013;

j) l'article C.04.001.1, en ce qui a trait à l'entreposage de la drogue par le titulaire de licence.

Distribution de drogue importée

30 Malgré toute disposition du Règlement, le titulaire d'une licence d'établissement peut distribuer une drogue contre la COVID-19 qu'il a importée en vertu de l'article 28 si les conditions suivantes sont réunies :

a) l'administrateur en chef de la santé publique fournit au ministre le nom de la drogue et l'adresse municipale du lieu où la drogue sera entreposée suivant la distribution;

b) la drogue est distribuée à une personne qui l'entreposera dans ce lieu.

NOTE EXPLICATIVE

(*Cette note ne fait pas partie de l'Arrêté d'urgence.*)

Proposition

L'*Arrêté d'urgence concernant l'importation, la vente et la publicité de drogues à utiliser relativement à la COVID-19* (l'« arrêté d'urgence ») a été signé par la ministre de la Santé le 16 septembre 2020. L'arrêté d'urgence permet d'accélérer l'obtention d'une autorisation pour l'importation, la vente et la publicité de drogues utilisées relativement à la COVID-19, ce qui comprend à la fois les drogues destinées aux humains et celles destinées aux animaux. Il permet à la ministre de tenir compte des besoins urgents en matière de santé publique liés à la COVID-19 dans sa décision d'autoriser ou non une drogue

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. An Order in Council would enable the operation of the Interim Order, allowing it to remain in effect for up to one year after it is made.

Objective

The objective of the Interim Order is 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

contre la COVID-19 sur la base des données d'innocuité, d'efficacité et de qualité qui sont fournies. L'arrêté d'urgence offre aussi une plus grande souplesse dans la délivrance des licences d'établissement en lien avec les drogues contre la COVID-19, en tenant compte des besoins urgents en matière de santé publique, et offre à la ministre un mécanisme pour permettre à l'Agence de la santé publique du Canada (ASPC) d'importer des drogues prometteuses contre la COVID-19 en vue de leur stockage (mise en place) dans des installations canadiennes avant leur autorisation au Canada.

L'arrêté d'urgence a été pris en vertu du paragraphe 30.1(1) de la *Loi sur les aliments et drogues* (la « Loi »), qui permet à la ministre de prendre des arrêtés d'urgence si elle estime qu'une intervention immédiate est nécessaire afin de parer à un risque appréciable — direct ou indirect — pour la santé, la sécurité ou l'environnement.

Sans un décret qui l'approuve, l'arrêté d'urgence, conformément à l'alinéa 30.1(2)a) de la Loi, cesserait d'avoir effet 14 jours après sa prise. Un décret permettra à l'arrêté d'urgence d'avoir effet jusqu'à un an après sa prise.

Objectif

L'arrêté d'urgence a pour but d'accélérer l'autorisation de l'importation, de la vente et de la publicité de drogues utilisées relativement à la COVID-19 tout en tenant compte des besoins urgents en matière de santé publique. Il offre aussi une plus grande souplesse dans la délivrance des licences d'établissement en lien avec les drogues contre la COVID-19. L'arrêté d'urgence permet en outre à l'administrateur en chef de la santé publique de l'ASPC d'aviser la ministre de la nécessité de mettre en place une drogue prometteuse contre la COVID-19 au Canada. Pour qu'une drogue puisse être mise en place, le gouvernement du Canada doit avoir conclu un marché pour en faire l'acquisition, et le fabricant doit avoir rempli une demande d'autorisation de la drogue auprès de Santé Canada ou d'un organisme de réglementation étranger. Ces mesures visent à s'assurer que les Canadiens aient accès aux drogues contre la COVID-19 en temps opportun.

Contexte

La COVID-19 est une nouvelle maladie qui n'avait encore jamais été diagnostiquée chez l'humain. Il s'agit d'une maladie respiratoire infectieuse causée par le coronavirus du syndrome respiratoire aigu sévère 2 (SRAS-CoV-2), un coronavirus récemment découvert. On sait que l'infection à la COVID-19 provoque des symptômes respiratoires, de la fièvre, de la toux, un essoufflement et des difficultés respiratoires. Dans des cas graves, elle peut entraîner une pneumonie, un syndrome respiratoire aigu sévère, une insuffisance rénale et la mort. L'Organisation mondiale de la Santé a déclaré une pandémie mondiale

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 entitled "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.

[1] COVID-19 Dashboard by the Center for Systems Science and Engineering at Johns Hopkins University
[2] Coronavirus disease (COVID-19): Outbreak update

liée à la COVID-19 le 11 mars 2020. Il a y eu un total de 26 300 000 cas jusqu'à présent, dans au moins 185 pays, et plus de 860 000 personnes ont perdu leur vie[1]. Au 3 septembre 2020, le Canada dénombrait plus de 130 000 cas[2]; cependant, la situation évolue rapidement.

Un grand nombre de sociétés pharmaceutiques et d'établissements universitaires développent actuellement des vaccins candidats et des thérapies et traitements potentiels contre la COVID-19. Bien que ces nouveaux vaccins et drogues soient développés expressément pour lutter contre la COVID-19, des sociétés pharmaceutiques envisagent la possibilité d'utiliser des drogues déjà approuvées et commercialisées, comme des antiviraux à large spectre et des anti-inflammatoires. L'autorisation accélérée de drogues destinées à lutter contre la COVID-19 permettra à ces drogues médicalement nécessaires d'être mis rapidement à la disposition des Canadiens.

Avant qu'un produit puisse être commercialisé au Canada, Santé Canada examine les renseignements sur le produit pour s'assurer du respect des exigences de la *Loi sur les aliments et drogues* et de ses règlements d'application. En se fondant sur les renseignements fournis, le ministère évalue les risques et les avantages du produit pour veiller à ce que la population canadienne ait accès à des produits sûrs, efficaces et de grande qualité. De plus, toute personne qui fabrique, emballe, étiquette, importe, teste, distribue ou vend en gros une drogue destinée à être vendue au Canada doit détenir une licence d'établissement délivrée en vertu de la *Loi sur les aliments et drogues*.

Le 18 mars 2020, la ministre de la Santé a publié un avis intitulé « Examen accéléré des présentations et demandes de produits de santé liées au COVID-19 ». Cet avis précisait l'intention de Santé Canada d'accélérer l'autorisation d'un vaccin et d'autres thérapies contre la COVID-19 à mesure qu'ils sont disponibles.

Répercussions

L'arrêté d'urgence introduit des processus d'autorisation accélérés pour l'importation, la vente et la publicité de drogues utilisées relativement à la COVID-19. Pour qu'une drogue soit autorisée en vertu de l'arrêté d'urgence, la ministre doit conclure, à la lumière des renseignements fournis, que les avantages l'emportent sur les risques associés à la drogue en tenant compte des incertitudes entourant les avantages et les risques ainsi que des besoins urgents en matière de santé publique engendrés par la COVID-19. Cela nécessite de soupeser les risques qu'entraîne la modification de certaines exigences afin que les renseignements appuient l'innocuité et l'efficacité d'une drogue, comme de permettre la prise en compte d'une approbation fournie par un organisme de réglementation étranger, par rapport aux avantages de la mettre plus rapidement à la disposition de la population canadienne.

[1] COVID-19 Dashboard by the Center for Systems Science and Engineering at Johns Hopkins University (en anglais seulement)
[2] Maladie à coronavirus (COVID-19) : Mise à jour sur l'éclosion

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.

L'arrêté d'urgence introduit des processus d'autorisation accélérés pour les drogues à indication en lien avec la COVID-19 qui ne sont pas encore autorisées au Canada ou dans d'autres administrations, ainsi que les drogues contre la COVID-19 dont la vente est autorisée par un organisme de réglementation étranger. De plus, l'arrêté d'urgence offre un mécanisme pour autoriser la vente d'une drogue qui est déjà autorisée au Canada en vertu de cet arrêté d'urgence ou du *Règlement sur les aliments et drogues*, pour des fins liées à la COVID-19 qui ne sont pas incluses dans l'autorisation de la drogue.

Bien que la COVID-19 soit principalement considérée comme une maladie humaine, il s'agit d'une nouvelle maladie, et ses répercussions sur la santé des animaux ne sont pas encore entièrement connues. À l'heure actuelle, aucun cas d'infection à la COVID-19 n'a été signalé chez les animaux d'élevage, et les renseignements préliminaires tirés de quelques études indiquent que les porcs, les poulets et les canards ne sont pas susceptibles de contracter le virus. Toutefois, quelques rapports discutent de situations où les humains infectés ont transmis le virus à leur chat ou leur chien domestique. Ainsi, par excès de prudence, les médicaments vétérinaires ont été inclus dans la portée de l'arrêté d'urgence.

Drogues non autorisées au Canada ou par un organisme de réglementation étranger

L'arrêté d'urgence introduit un processus accéléré pour l'autorisation d'une nouvelle drogue contre la COVID-19 en prescrivant des exigences de présentation et des formalités administratives plus souples que ce que prévoit le titre 8 du *Règlement sur les aliments et drogues*.

L'arrêté d'urgence permet à la ministre de tenir compte des incertitudes et des besoins urgents en matière de santé publique dans le contexte de la pandémie de COVID-19 lorsqu'elle doit déterminer si les avantages d'une drogue l'emportent sur les risques qui y sont associés. Plutôt que des rapports détaillés des tests établissant l'innocuité d'une nouvelle drogue et des preuves substantielles de son efficacité clinique, comme l'exige le *Règlement sur les aliments et drogues*, l'arrêté d'urgence exige que le demandeur présente les renseignements connus en ce qui concerne l'innocuité et l'efficacité d'une drogue contre la COVID-19.

De plus, afin d'accélérer le processus d'examen des présentations de drogues soumises aux fins d'autorisation en vertu de l'arrêté d'urgence, une approche plus souple a été prévue afin de permettre au demandeur de présenter d'autres renseignements tout au long de l'examen à mesure qu'ils sont disponibles, dans le cadre de ce qu'on appelle une « demande progressive ». Dans le cadre d'une demande progressive, le demandeur doit présenter un plan précisant comment et quand il fournira à la ministre les données ou les renseignements requis qui n'ont pas encore été fournis.

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.

Drogues autorisées par un organisme de réglementation étranger

Pour être admissible au processus d'autorisation accéléré prévu pour les drogues autorisées par un organisme de réglementation étranger, une drogue doit figurer dans la *Liste des drogues étrangères* tenue par la ministre et incorporée par renvoi à l'arrêté d'urgence. Une drogue peut être ajoutée à la liste s'il a été démontré qu'elle procure des avantages dans le contexte de la pandémie de COVID-19 et si elle a reçu une autorisation de vente dans une administration étrangère. La ministre peut prendre connaissance de ces drogues dans le cadre d'interactions avec des homologues internationaux ou d'une analyse de l'environnement, y compris dans le cadre de discussions avec des fournisseurs de soins de santé ou des demandeurs potentiels.

Avant de pouvoir être importée, vendue ou annoncée au Canada, une drogue figurant sur la liste doit être autorisée en vertu de l'arrêté d'urgence; toutefois, le demandeur peut se servir de l'autorisation fournie par un organisme de réglementation étranger et présenter une demande plus abrégée. Le demandeur doit fournir la preuve que la drogue est autorisée à la vente dans une administration étrangère et, sur demande, signer une attestation indiquant que tous les renseignements utilisés par l'organisme de réglementation étranger pour autoriser la drogue seront mis à la disposition de la ministre.

La ministre doit tout de même conclure, en ce qui concerne la drogue étrangère, que tous les critères énoncés dans l'arrêté d'urgence ont été remplis et que, dans le contexte de la pandémie de COVID-19, les avantages qu'entraîne l'autorisation de cette drogue l'emportent sur les risques qui y sont associés.

Indication supplémentaire des drogues autorisées au Canada

L'arrêté d'urgence permet d'annoncer et de vendre une drogue qui est déjà autorisée au Canada pour une indication supplémentaire liée à la COVID-19. Pour ce faire, la drogue sera ajoutée à la *Liste des drogues nouvelles à indication supplémentaire* qui est incorporée par renvoi. Contrairement à lorsqu'on apporte une modification au titre du *Règlement sur les aliments et drogues*, ce processus peut être engagé sans qu'il soit nécessaire pour le fabricant de présenter une demande.

Les ajouts à cette liste se fonderont sur l'analyse de l'environnement réalisée par Santé Canada, y compris des discussions avec les fournisseurs de soins de santé, à mesure que les données appuyant l'utilisation de drogues existantes dans le contexte de la COVID-19 seront disponibles. Toutefois, un demandeur externe peut aviser la ministre de l'existence d'une drogue pouvant être admissible à ce processus.

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.

Étant donné qu'une drogue admissible à ce processus sera déjà autorisée en vertu de l'arrêté d'urgence ou du *Règlement sur les aliments et drogues*, il y a aura déjà des données faisant état de son innocuité, de son efficacité (pour d'autres indications) et de sa qualité. De plus, l'ajout d'une drogue à cette liste permettra à la ministre de demander tout renseignement que détient le titulaire de l'autorisation au sujet de son indication en lien avec la COVID-19. Tout renseignement supplémentaire fourni sur l'indication en lien avec la COVID-19 sera également inclus dans la liste incorporée par renvoi.

Licences d'établissement de produits pharmaceutiques et bonnes pratiques de fabrication

L'arrêté d'urgence introduit la possibilité de délivrer ou de modifier des licences d'établissement de produits pharmaceutiques pour y inclure la conduite d'activités en lien avec des drogues contre la COVID-19. Cela permet d'offrir plus de souplesse, notamment en modifiant certaines exigences relatives aux bonnes pratiques de fabrication, tout en continuant de protéger la santé et la sécurité des Canadiens qui utiliseront ces drogues contre la COVID-19. Le traitement de toutes les demandes de licence d'établissement de produits pharmaceutiques présentées en lien avec l'arrêté d'urgence sera accéléré. Les décisions relatives à la délivrance des licences tiendront compte des renseignements fournis dans la demande et du caractère impératif de la drogue pour répondre aux besoins de santé urgents liés à la COVID-19.

Exigences en matière d'étiquetage, de publicité et de déclaration

Afin de maintenir les exigences en matière d'étiquetage bilingue en application de la *Loi sur les langues officielles*, l'arrêté d'urgence s'assure que les sections appropriées du *Règlement sur les aliments et drogues* continueront de s'appliquer aux drogues contre la COVID-19. Ces drogues sont également assujetties à des interdictions similaires en matière de publicité ainsi qu'aux mêmes exigences de déclaration des effets indésirables et de déclaration des rappels et des pénuries que les drogues autorisées en vertu du *Règlement sur les aliments et drogues*.

Conditions

L'arrêté d'urgence permet à la ministre d'imposer ou de modifier des conditions et de demander des renseignements supplémentaires en lien avec une présentation de drogue contre la COVID-19, une autorisation ou une licence d'établissement à tout moment pendant que l'arrêté est en vigueur. Compte tenu de la gravité de la pandémie de COVID-19, cela permet à la ministre d'agir rapidement pour recueillir des renseignements importants liés à la sécurité ou de réduire les risques en temps opportun.

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.

Suspension ou annulation

Lorsque Santé Canada accélérera le processus d'autorisation des drogues liées à la COVID-19 en vertu de l'arrêté d'urgence, dans le but d'assurer l'accès en temps opportun à ces drogues, le ministère continuera de veiller à ce que l'innocuité, l'efficacité et la qualité de ces produits s'appuient sur des données suffisantes. Santé Canada fera le suivi de l'innocuité et de l'efficacité de ces drogues et prendra des mesures immédiates, y compris la suspension ou l'annulation d'autorisations ou de licences d'établissement, au besoin, pour protéger la santé et la sécurité des Canadiens.

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.

Propriété intellectuelle

L'arrêté d'urgence ne prévoit pas des mesures de protection explicites de la propriété intellectuelle pour les drogues innovantes faisant l'objet d'une demande d'autorisation dans le cadre de ce processus. Toutefois, pour s'assurer qu'une drogue innovante puisse bénéficier d'une protection des données lorsqu'une autorisation est accordée en vertu du *Règlement sur les aliments et drogues* ou d'un autre mécanisme transitoire, Santé Canada veillera à ce que l'autorisation accordée pour une drogue et ses ingrédients médicinaux en vertu de l'arrêté d'urgence ne soit pas considérée comme une approbation préalable aux fins de la définition d'une drogue innovante en application de l'article C.08.004.1 du *Règlement sur les aliments et drogues*, et stipulera qu'une demande ne peut être présentée en vertu du *Règlement sur les aliments et drogues* pour une nouvelle drogue, à l'égard d'une allégation relative à la COVID-19, sur la base d'une comparaison directe ou indirecte avec une drogue contre la COVID-19 autorisée en vertu de l'arrêté d'urgence.

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.

De plus, afin de maintenir les incitatifs pour les fabricants de drogues contre la COVID-19 et de garantir l'accès à ces drogues, une demande d'autorisation fondée sur une comparaison directe ou indirecte avec une autre drogue contre la COVID-19 ne sera acceptée que si cette autre drogue n'est pas disponible en quantité suffisante sur le marché canadien pour répondre aux besoins en matière de santé publique liés à la COVID-19. Avant de présenter une demande fondée sur une comparaison directe ou indirecte avec une autre drogue, une personne doit aviser la ministre de son intention de présenter la demande et fournir des renseignements démontrant que la drogue utilisée aux fins de comparaison a reçu une autorisation en vertu de l'arrêté d'urgence et qu'elle n'est pas disponible en quantité suffisante. La ministre est ensuite tenue d'aviser le fabricant de la drogue utilisée aux fins de comparaison afin que ce dernier puisse présenter des observations à la ministre sur la question de savoir si la drogue est disponible en quantité suffisante. Si la ministre juge que la drogue utilisée aux fins de comparaison n'est pas disponible en quantité suffisante, la demande d'autorisation peut être présentée.

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

Période d'autorisation et frais

Les autorisations accordées en vertu de l'arrêté d'urgence et les licences d'établissement de produits pharmaceutiques délivrées en lien avec l'arrêté d'urgence ne sont valides que durant la période où l'arrêté d'urgence est en vigueur. L'examen des présentations de drogues soumises en vertu de l'arrêté d'urgence ne sera pas assujetti à des frais pour le recouvrement des coûts, et il n'y aura pas de frais facturés pour les demandes de licences d'établissement présentées en lien avec l'arrêté d'urgence si la demande satisfait aux conditions prescrites dans le *Décret de remise visant les frais de licence d'établissement (indication d'une activité en lien avec une drogue contre la COVID-19)*. De plus, les frais annuels pour la vente d'un produit sur le marché canadien ne s'appliqueront pas aux drogues contre la COVID-19.

Publication des renseignements cliniques

Santé Canada diffusera les données d'innocuité et d'efficacité sur lesquelles le ministère s'est fondé pour accorder une autorisation en vertu de l'arrêté d'urgence. Les renseignements cliniques seront publiés à des fins non commerciales seulement, et tous les renseignements personnels et les renseignements commerciaux confidentiels seront protégés avant la publication sur le portail de renseignements cliniques de Santé Canada.

Mise en place

Afin de faciliter l'accès en temps opportun aux drogues prometteuses contre la COVID-19, l'arrêté d'urgence prévoit un mécanisme permettant à la ministre d'autoriser l'importation de drogues prometteuses contre la COVID-19 en vue de leur stockage dans des installations canadiennes avant leur autorisation de mise en marché au Canada, un processus appelé « mise en place ». Ce mécanisme peut être utilisé pour importer une drogue prometteuse contre la COVID-19 au Canada si l'administrateur en chef de la santé publique du Canada a avisé la ministre de la nécessité de mettre en place une drogue contre la COVID-19 et que le gouvernement a conclu une entente d'approvisionnement pour l'achat de la drogue. De plus, le fabricant de la drogue doit avoir présenté une demande d'autorisation de mise en marché auprès de Santé Canada en vertu de l'arrêté d'urgence ou du *Règlement sur les aliments et drogues* ou avoir présenté une demande d'autorisation de mise en marché auprès d'un organisme de réglementation étranger.

L'administrateur en chef de la santé publique du Canada doit également fournir une description de la drogue qui sera mise en place, y compris la quantité qui sera importée au Canada, des renseignements sur le fabricant de la drogue, le titulaire canadien de licence d'établissement de produits pharmaceutiques qui se chargera de l'importation et de la mise en place de la drogue ainsi que les installations où la drogue sera stockée. Ce titulaire de licence

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.

d'établissement peut être l'ASPC, qui gère la Réserve nationale stratégique d'urgence (RNSU), le fabricant lui-même, qui a conclu l'entente contractuelle avec le gouvernement du Canada, ou un titulaire de licence d'établissement désigné par l'administrateur en chef de la santé publique du Canada.

Orientation et ressources

Le document d'orientation intitulé « Renseignements et exigences en matière de demande pour les drogues autorisées en vertu de l'Arrêté d'urgence concernant l'importation, la vente et la publicité de drogues à utiliser relativement à la COVID-19 » présente les exigences réglementaires et d'autres renseignements importants à l'intention des fabricants qui souhaitent présenter une demande d'autorisation en vertu de l'arrêté d'urgence. De plus, Santé Canada publiera une liste des présentations de drogues reçues et une liste des drogues contre la COVID-19 autorisées en vertu de l'arrêté d'urgence. Ces listes, de même que la *Liste des drogues étrangères* et la *Liste des drogues nouvelles à indication supplémentaire,* seront publiées sur le site Web du gouvernement du Canada.

Consultation

La population canadienne a été informée du processus accéléré d'examen des présentations de drogues et des demandes d'autorisation par le biais d'un avis intitulé « Examen accéléré des présentations et demandes de produits de santé liées au COVID-19 », publié le 18 mars 2020. Dans le cadre de diverses autres communications, les membres du portefeuille fédéral de la Santé, les gouvernements provinciaux et territoriaux, les associations de l'industrie et les autres intervenants ont été avisés de cette mesure visant à accélérer l'autorisation des drogues contre la COVID-19 et l'appuient.

Trois séances de mobilisation avec les partenaires du système de soins de santé ont eu lieu entre le 30 avril et le 15 mai 2020. Les intervenants invités comprenaient entre autres des associations d'hôpitaux, des comités consultatifs nationaux, l'Alliance pancanadienne pharmaceutique et des gestionnaires de régimes provinciaux et territoriaux d'assurance-médicaments. Une séance d'information auprès des intervenants de l'industrie et des associations industrielles a eu lieu le 25 juin 2020, et plus de 80 participants y ont assisté, y compris BIOTECanada et Médicaments novateurs Canada. Une séance ciblée a été présentée le 2 juillet 2020 afin de mobiliser l'Institut canadien de la santé animale, et d'autres séances ont lieu les 24 juillet et 11 août 2020 pour mobiliser les fabricants de drogues innovantes. Ces séances avaient pour but d'informer ces intervenants clés des modalités de l'arrêté d'urgence, de cerner les mesures à prendre pour assurer sa mise en œuvre efficace, de discuter des futures mesures de transition envisagées lorsque l'arrêté d'urgence cessera d'avoir effet et d'offrir aux intervenants l'occasion de poser des 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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Les participants à toutes les séances étaient généralement favorables à l'arrêté d'urgence et aux mesures proposées. Les fabricants de drogues innovantes, toutefois, ont formulé des réserves quant à l'absence de mesures de protection pour les produits novateurs et la propriété intellectuelle et ont suggéré des modifications afin d'atténuer ces préoccupations. Santé Canada a par la suite modifié l'arrêté d'urgence en se fondant sur ces suggestions.

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DEPARTMENT OF PUBLIC SAFETY AND EMERGENCY PREPAREDNESS

TIME LIMITS AND OTHER PERIODS ACT (COVID-19)

Order Respecting Periods Established by the Firearms Act (COVID-19)

The Minister of Public Safety and Emergency Preparedness, pursuant to subsection 7(1) of the *Time Limits and Other Periods Act (COVID-19)*[a], makes the annexed *Order Respecting Periods Established by the Firearms Act (COVID-19)*.

Ottawa, September 14, 2020

William Sterling Blair
Minister of Public Safety and Emergency Preparedness

[a] S.C. 2020, c. 11, s. 11

MINISTÈRE DE LA SÉCURITÉ PUBLIQUE ET DE LA PROTECTION CIVILE

LOI SUR LES DÉLAIS ET AUTRES PÉRIODES (COVID-19)

Arrêté sur les périodes prévues par la Loi sur les armes à feu (COVID-19)

En vertu du paragraphe 7(1) de la *Loi sur les délais et autres périodes (COVID-19)*[a], le ministre de la Sécurité publique et de la Protection civile prend l'*Arrêté sur les périodes prévues par la Loi sur les armes à feu (COVID-19)*, ci-après.

Ottawa, le 14 septembre 2020

Le ministre de la Sécurité publique et de la Protection civile
William Sterling Blair

[a] L.C. 2020, ch. 11, art. 11