RULE 25

REQUEST FOR ADMISSION TO INQUIRY RECORD

DRUG TEST FOR COVID-19 VACCINES

Date: July 16, 2026

To: Dean Allison, Inquiry Chairperson

From: Shawn Buckley, Inquiry Counsel

Inquiry Rule 25 permits the Chairperson and Inquiry Counsel to jointly agree to admit materials to the Inquiry Record.

This is a request under Inquiry Rule 25 to admit evidence into the Inquiry Record.

Primary Points

The Covid-19 Vaccines were first approved without the need for safety or efficacy to be proven. This is summarized in the following table.

Regular Drugs	Covid-19 Vaccines
Safety of the drug must be proven ✔	**Safety of the vaccine does NOT need to be proven** ✘
The drug must be proven to work (efficacy) ✔	**The vaccine does NOT need to be proven to work (efficacy)** ✘
Benefits of the drug must be proven to exceed the risks ✔	**Benefits of the vaccine do NOT need to be proven to exceed the risks** ✘
The Minister can withdraw the approval for safety or efficacy concerns ✔	**For a year the Minister cannot withdraw the approval for safety or efficacy concerns** ✘

Analysis and reasons to enter the evidence

This is a request under Inquiry Rule 25 to admit the following into the Inquiry Record:

1. *Food and Drug Regulations*, C.R.C, c. 870 section C.08.002 as it read in 2020 and up to March 18, 2021 (Pre-Covid Drug Approval Test).

2. Interim Order exempting Covid-19 vaccines from the regular drug approval process and creating a substitute process for their approval. This Interim Order was made on September 16, 2020 pursuant to section 30.1 of the *Food and Drugs Act*, R.S.C., 1985, c. F-27 (*Interim Order*).

3. Order in Council dated October 3, 2020, extending the exemption of Covid-19 vaccines from the regular drug approval process, and continuing the substitute process for their approval. *Canada Gazette*, Part I, Volume 154, Number 40: Orders in Council.

4. Regulation SOR/2021-45 which on March 18, 2021, incorporated the provisions of the *Interim Order*, with some minor changes, into the *Food and Drug Regulations*, C.R.C., c. 870.

5. Regulation SOR/2024-238 sections 24-40, which on November 29, 2024, amended the *Food and Drug Regulations*. The main change was to replace the term *designated COVID-19 drug* with the term *public health emergency drug*.

6. List of Conditions for *public health emergency drugs*. The only condition on the list is Covid-19. This enables Covid-19 vaccines to remain exempt from proving safety and efficacy when seeking approval for use.

7. *Guidance for market authorization requirements for COVID-19 vaccines*. October 29, 2021 Health Canada policy document.

Purpose

Panel Members should understand the legal test under which the Covid-19 Vaccines were approved, and continue to be approved.

Documents 1-5 are all regulations or orders officially published in the *Canada Gazette*. Number 6 is an official list made under section C.08.001.2 of the *Food and Drug Regulations*. Number 7 is a public Health Canada policy document published on the Health Canada website.

The request is to enter documents 1-6 to show the law that applied, and applies, to the approval of Covid-19 vaccines.

The request for Document 7 is to show Health Canada's interpretation of the law on October 29, 2021. Document 7 is not being sought to be entered for the truth of its contents.

The following is an explanation of the documents to illustrate their relevance.

Health Canada does not test vaccines for safety or efficacy

It is important for Members of Parliament to understand that *Health Canada does not do any testing of drugs, including vaccines,* when determining whether to approve a drug for human use.

All testing is done by the pharmaceutical company with a financial interest in having the drug approved by Health Canada.

In the discussion below of the drug approval process, it should be understood that Health Canada does no independent testing. Health Canada relies solely on testing done by the pharmaceutical company seeking the approval of a vaccine.

For all Covid-19 vaccines Health Canada did no independent testing.

Summary of Pre-Covid Drug Approval Test

Before the Covid-19 vaccines, three things needed to be objectively proven before a drug could be approved for the general population, namely, that:

1. the drug is safe;
2. the drug is effective, and
3. the benefits of the drug outweigh the risks.

The requirement to prove safety and efficacy were set out in *Food and Drug Regulation* c.08.002 which reads in part:

> C.08.002(2) A new drug submission shall contain sufficient information and material to enable the Minister to assess ***the safety and effectiveness*** of the new drug, including the following...
>
> (g) ***detailed reports*** of the tests made ***to establish the safety*** of the new drug for the purpose and under the conditions of use recommended;
>
> (h) ***substantial evidence*** of the clinical ***effectiveness*** of the new drug for the purpose and under the conditions of use recommended[.]

The requirement that the benefits of the drug outweigh the risks is not set out in the regulations, it is implied. It would be a violation of criminal law to knowingly authorize a drug for the general population that causes more harm than good.

Except for Covid-19 vaccines, most other drugs (a vaccine is a drug), have had to be proven safe and effective prior to being approved by Health Canada.

Substitute approval test for Covid-19 Vaccines

The Covid-19 vaccines were exempted from the regular drug approval test set out above. Rather, a substitute approval test was used. Under this substituted test:

1. ***safety did not need to be proven***;

2. ***efficacy did not need to be proven***, and

3. ***that the benefits of the vaccine outweighed the risks of the vaccine did not need to be proven***.

The test for approving the Covid-19 vaccines was a mandatory test. In other words, if the test was met, Health Canada was legally obligated to authorize the vaccine for human use. The test Covid-19 vaccines were approved under is:

> 5 The Minister must issue an authorization in respect of a COVID-19 drug if the following requirements are met...
>
> (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.
>
> (*Interim Order* section 5)

You will note that the words "safety" and "efficacy" are not even in the approval test.

Some points to consider about the test under which Covid-19 vaccines were approved:

1. safety ***did not*** have to be proven;

2. efficacy ***did not*** have to be proven;

3. the test only requires the pharmaceutical company seeking approval, to make an argument that the Minister does not need to agree with. The wording is not:

   > the Minister has sufficient evidence to conclude (which would require the Minister to be convinced), or
   >
   > the Minister has concluded (which would require the Minister to be convinced).

   Rather the wording is:

   > the Minister has sufficient evidence to support ***the*** conclusion (not the Minister's conclusion).

   This wording does not require the Minister (Health Canada) to conclude anything. Rather there only needs to be evidence to support a conclusion that the Minister is not making.

Approval must be granted if there is evidence to support the subjective argument being made by the pharmaceutical company seeking approval to earn a profit.

In other words, the Minister is legally obligated to approve a vaccine even if the Minister does not believe it is in the best interests of Canadians. For greater clarity, the test requires the Minister to issue an authorization if the test is met. The Minister could be concerned that the vaccine is neither safe nor effective and still be legally obligated to approve it under the substitute test. All that is required is that there is evidence to support a subjective argument being made by the drug company;

4. the test does not require the Minister to conclude that the benefits of the drug outweigh the risks. Consider:

    a. you cannot know if the benefits outweigh the risks, without the benefits (efficacy) being proven, and without the risks (safety) being proven;

    b. the words "having regard to the uncertainties relating to the benefits and risks" ***is a legal direction to Health Canada to ignore uncertainty concerning the benefits and risk (i.e. to guess)***;

5. the phrase "and the necessity of addressing the urgent public health need related to COVID-19" ***is a legal direction to presume approval is necessary***.

In other words, the test does not require anything to be proven (like safety, efficacy or that the benefits outweigh the risks). An argument has to be made that the benefits exceed the risk. There is a legal direction to ignore uncertainty concerning whether the benefits actually exceed the risks. There is a legal direction to assume there should be approval due to the urgent public health need related to Covid-19.

One could reasonably conclude that this is not a drug approval test at all, but rather it is a political direction to approve the vaccines.

Approval could be granted without evidence of safety and efficacy being provided by the pharmaceutical company to Health Canada

To be approved by Health Canada ***the pharmaceutical company did not even have to submit safety or efficacy data to Health Canada***.

Because pharmaceutical companies were not required to prove Covid-19 vaccines were safe or effective, they were only required to provide the "known" data on safety and efficacy[1]. The vaccines could be approved without even the known safety and efficacy data being given to Health Canada. If the drug company did not provide Health Canada with the known data on safety and efficacy, they were only required to advise Health Canada "as to how and when they will provide the Minister with the missing information or material"[2].

In addition to the plain wording of the law, Health Canada made this clear in other documents such as their *Guidance for market authorization requirements for COVID-19 vaccines*.[3] This Guidance document includes the following:

> **About market authorizations for a COVID-19 vaccine**
>
> ---
>
> Health Canada will grant authorizations only if we determine that the benefits of the vaccine outweigh its potential risks. We will base our decision on the evidence provided on the vaccine's safety, quality and efficacy. For vaccines relying on the modified requirements in C.08.002 (2.1) of the Food and Drug Regulations, the risk-benefit analysis weighs the uncertainties about a potential vaccine against the public health need for a vaccine at the time of the decision.
>
> Modified requirements for COVID-19 drugs ***make it possible for initial authorization, based on early data***, while the manufacturer continues working on developing a vaccine. We will use terms and conditions to manage uncertainties or risk mitigation measures related to the vaccine in the context of the public health.
>
> (emphasis added).

The Pfizer and Moderna vaccines were first approved with a median of only two months of data

The Pfizer and Moderna vaccines were first approved from data with a median data collection time of only two months. In other words, there was an average of only two months of data when these vaccines were approved.

Celia Lourenco is a Health Canada employee that approved Covid-19 vaccines. She swore an Affidavit for Federal Court File No. T-145-22 in which she shares that the Pfizer and Moderna vaccines were approved based on data with a median duration of only two months. For the Pfizer vaccine she stated:

> 98. The interim authorization of the Pfizer.BioNTech COVID.19 Vaccine was based on quality (chemistry and manufacturing), non.clinical (pharmacology and toxicology), and clinical (immunogenicity, safety, and efficacy) information. Following review of the available information, Health Canada concluded that the evidence provided meets the Health Canada standards published in the Guidance for Market Authorization Requirements for COVID-19 Vaccines (a copy of which is attached as Exhibit "K"). The evidence supports the conclusion that the benefits associated with the Pfizer.BioNTech COVID.19 Vaccine outweigh the risks, ***having regard to a shorter term (median of 2 months) follow up of safety and efficacy at authorization***, and the necessity of addressing the urgent public health need related to COVID.19. Based on these considerations, the benefit.risk profile of the Pfizer.BioNTech COVID.19 Vaccine is considered favourable for active immunization to prevent COVID.19 caused by SARS.CoV.2 in individuals 16 years of age and older. Health Canada has also authorized the use of the Pfizer-BioNTech COVID-19 vaccine in children 5 to 11 years of age, and adolescents 12 years of age and older.

For the Moderna vaccine Celia Lourenco stated:

> 118. The interim authorization of the Moderna COVID.19 Vaccine was based on quality (chemistry and manufacturing), non.clinical (pharmacology and toxicology), and clinical (immunogenicity, safety, and efficacy) information. Following review of the available information, Health Canada concluded that the evidence provided met the Health Canada standards published in the Guidance for Market Authorization Requirements for COVID-19 Vaccines (a copy of which attached as Exhibit "K"). The evidence supported the conclusion that the benefits associated with the Moderna COVID.19 Vaccine outweighed the risks, ***having regard to a shorter term (median of 2 months) follow up of safety and efficacy at authorization***, and the necessity of addressing the urgent public health need related to COVID.19. Based on these considerations, the benefit.risk profile of the Moderna COVID.19 Vaccine was considered favourable for active immunization to prevent against COVID-19 caused by SARS-CoV-2 virus in individuals 18 years
>
> (Affidavit of Celia Lourenco sworn April 21, 2022 for Federal Court File T-145-22) .

These affidavit paragraphs are likely accurate on the median duration of data when the vaccines were approved. They are not being cited for any other purpose.

The Covid-19 vaccines were approved quickly and without the usual requirements to prove safety and efficacy. In this context the public would expect that if safety signals arose after approval, that the vaccine approvals would be revoked. However, the *Interim Order* took away the Minister's power to revoke the vaccine approvals.

The Covid-19 vaccines were approved quickly. They were approved without the usual requirements: (that safety, efficacy, and that the benefits outweighed the risks, be proven).

To protect against harm to Canadians that only becomes apparent after a drug approval is issued, the Minister of Health normally has the power to revoke an approval. Subsection C.08.006 of the *Food and Drug Regulations* normally enables the Minister to cancel a market authorization if evidence after the authorization was granted, raises a safety or efficacy concern. This evidence can include:

(a) evidence filed in other new drug applications. So in the normal course of events, if one company was granted an approval for a novel mRNA vaccine, and a later company applied for approval for a similar mRNA vaccine, the information in both applications could be used to revoke an approval (C.08.006(1));

(b) clinical or other experience not reported in the submission or supplement or not available to the Minister at the time the notice of compliance was issued (C.08.006(2)(a));

(c) tests by new methods or tests by methods not reasonably applicable at the time the notice of compliance was issued (C.08.006(2)(a));

(d) material misrepresentations in the drug application (C.08.006(2)(c)).

The Interim Order took away the Minister's normal power to revoke drug authorizations for the Covid-19 vaccines. Section 2(1) of the Interim Order sets out that once a Covid-19 Vaccine is

approved under the Interim Order, most of the *Food and Drug Regulations* do not apply, including the section giving the Minister power to revoke a drug approval if safety or efficacy concerns arise (section C.08.006).

The *Interim Order* replaced the substantial safeguards found in C.08.006, with limited authority to cancel a market authorization.[4]

This non-applicability of the Minister's power to revoke market authorizations for Covid-19 vaccines was in force from September 16, 2020 to:

(1) September 15, 2021, for the Pfizer and Moderna Vaccines;

(2) November 18, 2021, for the AstraZeneca Vaccine, and

(3) November 22, 2021, for the Johnson & Johnson Vaccine.

(SOR/2021-45 s. 25).

I am not aware of any explanation from the Minister or from Health Canada concerning how Canadians were protected by removing the Minister's ability to cancel vaccine approvals if subsequent concerns about safety and efficacy arose.

Continuing to exempt Covid-19 vaccines from having to be proven safe, or effective, or that the benefits outweigh the risks

Covid-19 vaccines were exempted from the normal drug approval process on September 16, 2020, before any applications for approval were submitted to Health Canada.

From September 16, 2020, until now, Covid-19 vaccines have been exempt from the regular requirements: (that safety, efficacy, and that the benefits exceed the risks, be proven).

The legal chronology of having the Covid-19 vaccines exempted from the regular drug approval test is as follows:

- September 16, 2020, *Interim Order* pursuant to section 30.1 of the *Food and Drugs Act*, R.S.C., 1985, c. F-27. An Interim Order is only valid for 14 days unless approved by the Governor in Council;

- October 3, 2020, an Order in Council is made approving the *Interim Order* (*Canada Gazette*, Part I, Volume 154, Number 40: Orders in Council). Once approved by an Order in Council, an Interim Order is valid for up to a year;

- I believe the following vaccines were approved under the *Interim Order*:

  (1) Pfizer-BioNTech on December 9, 2020 for ages 16 and older, and May 5, 2021, for ages 12-15;

  (2) Moderna on December 23, 2020 for ages 18 and over, and August 27, 2021, for ages 12-17;

(3) AstraZeneca on February 26, 2021, for ages 18 and older, and

(4) Janssen (Johnson & Johnson) on March 5, 2021, for ages 18 and older.

- March 18, 2021, the provisions of the *Interim Order* were, with some minor changes, incorporated into the *Food and Drug Regulations* (by Regulation SOR/2021-45). These changes applied to the Covid-19 vaccines now referred to as *designated COVID-19 drugs*. *Designated COVID-19 drugs* was defined in the Regulations as:

> *designated COVID-19 drug* means a new drug for which the purpose and conditions of use recommended by the manufacturer relate to COVID-19.

- November 29, 2024, the *Food and Drug Regulations* were amended by Regulation SOR/2024-238. The main change was to replace the term *designated COVID-19 drug* with the term *public health emergency drug* which is defined as:

> *public health emergency drug* means a new drug for which the purpose and conditions of use recommended by the manufacturer relate to a condition that is described in the List of Conditions that Threaten Public Health.

The amended Regulations are specifically designed to permit Covid-19 vaccines to continue to be exempted from having to prove safety and efficacy despite Covid-19 no longer being a public health emergency. This is done as follows in the *Food and Drug Regulations*:

> C.08.001.2 (1) The Minister may add a condition to the List of Conditions that Threaten Public Health only if the Minister has reasonable grounds to believe that
>
> (a) the condition presents, or is the result of, a significant risk to public health in Canada; and
>
> (b) immediate action is required to deal with the risk.
>
> C.08.001.2(2) However, the Minister may add COVID-19 to the List of Conditions that Threaten Public Health, ***even if the criteria set out in subsection (1) are not met with respect to COVID-19*** at the time of the addition, as long as the Minister has reasonable grounds to believe that the addition is necessary to protect public health or safety.

The only condition on the List of Conditions is Covid-19.[5] This means that the only drugs exempted from the regular drug approval process continues to be Covid-19 vaccines.

Agreement to enter evidence into the Record

By signing below I agree that the listed materials should be entered as the following exhibits into the Inquiry Record under Inquiry Rule 25:

R25-1 *Food and Drug Regulations*, C.R.C, c. 870 section C.08.002 as it read in 2020 and up to March 18, 2021 (Pre-Covid Drug Approval Test).

R25-2 Interim Order exempting Covid-19 vaccines from the regular drug approval process and creating a substitute process for their approval. This Interim Order was made on September 16, 2020 pursuant to section 30.1 of the *Food and Drugs Act*, R.S.C., 1985, c. F-27 (*Interim Order*).

R25-3 Order in Council dated October 3, 2020, extending the exemption of Covid-19 vaccines from the regular drug approval process, and continuing the substitute process for their approval. *Canada Gazette*, Part I, Volume 154, Number 40: Orders in Council.

R25-4 Regulation SOR/2021-45 which on March 18, 2021, incorporated the provisions of the *Interim Order*, with some minor changes, into the *Food and Drug Regulations*, C.R.C., c. 870.

R25-5 Regulation SOR/2024-238 sections 24-40, which on November 29, 2024, amended the *Food and Drug Regulations*. The main change was to replace the term *designated COVID-19 drug* with the term *public health emergency drug*.

R25-6 List of Conditions for *public health emergency drugs*. The only condition on the list is Covid-19. This enables Covid-19 vaccines to remain exempt from proving safety and efficacy when seeking approval for use.

R25-7 *Guidance for market authorization requirements for COVID-19 vaccines*. October 29, 2021 Health Canada policy document.

Dated July 17, 2026.

Dean Allison,
Inquiry Chairperson

Shawn Buckley,
Inquiry Counsel

Endnotes

1. The provision that applicants only needed to provide the known safety and efficacy data is first found in paragraph 3(1)(o) of the September 16, 2020 *Interim Order* excluding Covid-19 vaccines for

the regular drug approval process. The *Interim Order* can be found at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html. The *Interim Order* was only valid until September 16, 2021. On March 18, 2021, the provisions of the *Interim Order* were, with some minor changes, incorporated into the *Food and Drug Regulations* (the amendments were made by Regulation SOR/2021-45). Under the amended Regulations Covid-19 vaccines were exempted from having to prove safety and efficacy to be approved (Regulation C.08.002(2.1)). Subsection C.08.002(2.3) was put into the regulations to permit approval without the regular safety and efficacy data being submitted to Health Canada as long as the pharmaceutical company gave the Minister a plan that specified how and when the manufacturer would provide the Minister with the missing information on safety and efficacy.

2. The provision allowing a vaccine approval application to proceed without submitting the known data on safety and efficacy is found subsection 3(2) of the September 16, 2020 *Interim Order* excluding Covid-19 vaccines for the regular drug approval process. Subsection 3(2) requires the pharmaceutical company to advise Health Canada as to how and when they will provide the Minister with the missing information on safety and efficacy. The *Interim Order* can be found at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/interim-order-import-sale-advertising-drugs.html. On March 18, 2021, the provisions of the *Interim Order* were, with some minor changes, incorporated into the *Food and Drug Regulations*. This was done with regulation SOR/2021-45. Subsection C.08.002(2.3) was put into the regulations to permit approval without the regular safety and efficacy data being submitted to Health Canada, as long as the pharmaceutical company gave the Minister a plan that specified how and when the manufacturer would provide the Minister with the missing information on safety and efficacy.

3. This document is located at: https://www.canada.ca/en/health-canada/services/drugs-health-products/covid19-industry/drugs-vaccines-treatments/guidance-market-authorization-drugs.html.

4. The only grounds for cancellation under the *Interim Order* were: (a) if the subjective test in s. 5(c) was no longer met; (b) if it was believed part of the *Interim Order*, the *Food and Drugs Act* or Regulations had been violated, or (c) for an approval based on an approval from a foreign government (allowed under s. 4 of the Interim Order), if the foreign government cancelled their approval.

5. The List of Conditions can be found at: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/food-drug-regulations-public-health-emergency/list-conditions-threaten-public-health.html.