Question

With regard to Health Canada, the Public Health Agency of Canada and reports of myocarditis and pericarditis following COVID-19 vaccination: (a) what is the standard operating procedure when an Adverse Event Following Immunization report containing a potential safety signal is received or identified; (b) what federal teams, working groups, contract companies and persons were responsible for requesting, receiving, reviewing and monitoring any Adverse Event Following Immunization reports with respect to myocarditis and pericarditis following the COVID-19 vaccines from (i) international sources, (ii) the provinces and territories; (c) after the information in (b) was received, what steps or actions were taken next, by whom, and on what date; (d) was the Public Health Agency of Canada or Health Canada notified of Adverse Event Following Immunization reports for myocarditis and pericarditis following COVID-19 vaccination, and, if so, for each notification, what was the (i) name of the notifier, (ii) title of the notifier, (iii) form of notification, (iv) name of the person who was notified, (v) date of the notification; (e) did the Public Health Agency of Canada or Health Canada receive the initial reports of myocarditis and pericarditis following COVID-19 vaccination from the Israeli Ministry of Health in February 2021, and, if so, (i) who received the notification, (ii) what was the date of the notification, (iii) what actions were taken after the notification, (iv) who authorized these actions, including their name, their title and the date of authorization; (f) for each communication between the Public Health Agency of Canada, Health Canada and all Public Health Agency of Canada or Health Canada COVID-19 task forces or working groups related to the Israeli Ministry of Health myocarditis and pericarditis safety signal notification, what was the (i) date, (ii) subject, (iii) type and content, of the communication; and (g) what communication related to the myocarditis and pericarditis safety signal occurred between the Public Health Agency of Canada, Health Canada or the Public Health Agency of Canada or Health Canada COVID-19 task forces and the COVID-19 vaccine manufacturer, including the (i) date, (ii) subject, (iii) type and content, of the communication?

Response

This response was tabled in the House of Commons on March 11, 2026, as Sessional Paper 8555-451-766.

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House of Commons

Question number	Asked by	Date asked
Q-766	Ted Falk (Provencher)	January 22, 2026

Presented by

Kevin Lamoureux

Parliamentary Secretary to the Leader of the Government in the House of Commons

Health Canada

Reply by: the Minister of Health

Name of Signatory: Maggie Chi

Reply

Health Canada

(a) what is the standard operating procedure when an Adverse Event Following Immunization report containing a potential safety signal is received or identified?

Adverse events following immunization reports are collected in two databases. The Canada Vigilance Program, managed by Health Canada, receives adverse events following immunization reports from manufacturers who are required to submit domestic and international reports in accordance with the *Food and Drugs Act* , Canadian hospitals, healthcare professionals, and consumers. Adverse events following immunization reports submitted by provincial and territorial public health authorities are captured in the Canadian Adverse Events Following Immunization Surveillance System, which is managed by the Public Health Agency of Canada.

Reports from these databases are monitored continuously by Health Canada and the Public Health Agency of Canada. The most recent COVID-19 vaccine safety reports can be found here. It is important to note that these reports do not necessarily imply a causal relationship between the adverse event and the vaccine. However, they are an important source of information supporting ongoing safety monitoring.

(b) what federal teams, working groups, contract companies and persons were responsible for requesting, receiving, reviewing and monitoring any Adverse Event Following Immunization reports with respect to myocarditis and pericarditis following the COVID-19

vaccines from (i) international sources, (ii) the provinces and territories; (c) after the information in (b) was received, what steps or actions were taken next, by whom, and on what date; (d) was the Public Health Agency of Canada or Health Canada notified of Adverse Event Following Immunization reports for myocarditis and pericarditis following COVID-19 vaccination, and, if so, for each notification, what was the (i) name of the notifier, (ii) title of the notifier, (iii) form of notification, (iv) name of the person who was notified, (v) date of the notification?

Health Canada monitors safety information from multiple sources, including the scientific literature, manufacturers and international regulators. Furthermore, Health Canada assesses COVID-19 vaccine adverse events following immunization reports submitted to the Department's Canada Vigilance Program. Health Canada medical experts evaluate reported events to determine whether they are causally linked to the vaccine. A causality assessment involves careful consideration of many factors including, but not limited to, the biology of the reported event and how it could be related to the vaccine, patient medical history and concurrent conditions as well as the timing between the administration of the vaccine and the onset of the event. If new safety issues are confirmed, Health Canada will take appropriate action.

As of January 26, 2026 the Canada Vigilance Program of Health Canada has received 2,040 domestic and 29,619 foreign adverse events following immunization reports for myocarditis and pericarditis following COVID-19 vaccination.

The table below provides a summary of the domestic reports received with the following information for each adverse events following immunization report:

Adverse Reaction Report Number	(i) name of the notifier *	(ii) title of the notifier	(iii) form of notification	(iv) name of the person who was notified	(v) date of the notification

*personal information (including their name) is protected as per the *Privacy Act*.

The table below provides a summary of the foreign reports received with the following information for each adverse events following immunization report:

Adverse Reaction Report Number	(i) name of the notifier*	(ii) title of the notifier	(iii) form of notification	(iv) name of the person who was notified	(v) date of the notification

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(e) did the Public Health Agency of Canada or Health Canada receive the initial reports of myocarditis and pericarditis following COVID-19 vaccination from the Israeli Ministry of Health in February 2021, and, if so, (i) who received the notification, (ii) what was the date of the notification, (iii) what actions were taken after the notification, (iv) who authorized these actions, including their name, their title and the date of authorization; (f) for each communication between the Public Health Agency of Canada, Health Canada and all Public Health Agency of Canada or Health Canada COVID-19 task forces or working groups related to the Israeli Ministry of Health myocarditis and pericarditis safety signal notification, what was the (i) date, (ii) subject, (iii) type and content, of the communication; (g) what communication related to the myocarditis and pericarditis safety signal occurred between the Public Health Agency of Canada, Health Canada or the Public Health Agency of Canada or Health Canada COVID-19 task forces and the COVID-19 vaccine manufacturer, including the (i) date, (ii) subject, (iii) type and content, of the communication?

In February 2021, Health Canada received notification from the Israeli Ministry of Health that they were investigating a safety signal of myocarditis/pericarditis. To ensure the ongoing safety of health products on the Canadian market, Health Canada took part in international discussions on the real-world safety and effectiveness of COVID-19 vaccines. Health Canada delegates from the Marketed Health Products Directorate (Health Products and Food Branch) attended the Pharmacovigilance Cluster, on March 3, 2021. The topic of myocarditis and pericarditis was added to the agenda and participants provided the number of reports of myocarditis in their respective jurisdiction, as well as additional information on the reports. Health Canada provided information on the roll-out of the COVID-19 vaccines in Canada and summarized the three reports of myocarditis and pericarditis received in Canada as of February 27, 2021. Health Canada, along with

other regulatory agencies, committed to continue to closely monitor these events, as additional information was required to better characterize the risk.

On June 3, 2021, Health Canada and the Public Health Agency of Canada sent a Communique to Health practitioners informing about reports of myocarditis and pericarditis after COVID-19 vaccination.

On June 30, 2021, Health Canada updated the product monographs (labels) for both Pfizer-BioNtech and Moderna COVID-19 to inform Canadians and healthcare professionals of these possible side effects and to provide information about the signs and symptoms and when to seek prompt medical attention.

Other communications, specific to myocarditis and pericarditis, were issued by Health Canada or Health Canada and the Public Health Agency of Canada in 2021 to provide healthcare professionals and patients with information to guide their decisions.

- June 14, 2021 – The content of the web site COVID-19: Vaccine safety and side effects was updated to include information on myocarditis and pericarditis.
- June 24, 2021 - InfoWatch bulletin - Article on COVID-19 vaccines and myocarditis and pericarditis, wider distribution email: June 25, 2021.
- June 30, 2021 – A public advisory on this risk was issued.
- July 16, 2021 − the Office of the Chief Science Advisor completed a report on COVID-19 Vaccine-Associated Myocarditis and Pericarditis.
- September 30, 2021 − Statement from the Council of Chief Medical Officers of Health: Update on COVID-19 Vaccines and the Risk of Myocarditis and Pericarditis

Public Health Agency of Canada

(a) what is the standard operating procedure when an Adverse Event Following Immunization report containing a potential safety signal is received or identified?

The Canadian Immunization Guide provides a comprehensive description of vaccine safety monitoring in Canada. Adverse event following immunization reports submitted by provincial and territorial public health authorities and federal departments (including the Royal Canadian Mounted Police, Indigenous Services Canada, and Correctional Services Canada) are captured in the Canadian Adverse Events Following Immunization Surveillance System, which is managed by the Public Health Agency of Canada.

As explained in the Canadian Immunization Guide, a vaccine safety signal is defined as any information that arises from one or multiple sources and suggests a new potentially causal association, or a new aspect of a known adverse event (increased severity and/or increased frequency), between immunization and an event or set of related events, and is judged to be of sufficient concern to justify verification and remedial action if appropriate. The Public Health Agency of Canada detects safety signals by continuously monitoring reports submitted to the Canadian Adverse Events Following Immunization Surveillance System, monitoring scientific publications and other publicly available reports from Canadian and international public health organizations, regularly meeting with Health Canada to share intelligence (including information from the Canada Vigilance Program), regularly meeting with the Vaccine Vigilance Working Group (which includes representation from provinces and territories), and communicating directly with national and international regulatory and public health organizations.

In addition to the Canadian Adverse Events Following Immunization Surveillance System database, the Canada Vigilance Program, managed by Health Canada, receives adverse event following immunization reports from Canadian hospitals, healthcare professionals and consumers, as well as from vaccine manufacturers and distributors who are required to report all domestic and serious international Adverse events following immunizations.

Adverse event following immunization reports are monitored continuously by the Public Health Agency of Canada and Health Canada. Any new or unusual adverse events, or changes in trends or severity of specific events would trigger an investigation, including an in-depth medical review and risk assessment. If a safety issue is identified, Health Canada takes appropriate action as needed to protect the health and safety of Canadians. This could include warning Canadians of potential side effects, updating the information in the official product monograph such as changing the recommended use of the product, or even removing the product from the market.

(b) what federal teams, working groups, contract companies and persons were responsible for requesting, receiving, reviewing and monitoring any Adverse Event Following Immunization reports with respect to myocarditis and pericarditis following the COVID-19 vaccines from (i) international sources, (ii) the provinces and territories?

Canada's safety surveillance system includes a collaboration between pharmacovigilance partners including provincial and territorial immunization programs, the Public Health Agency of Canada, Health Canada, and vaccine manufacturers. Manufacturers are required to report serious adverse events to Health Canada as the national regulatory authority, as well as submit regular summaries of global safety information. Health Canada reviews these reports and takes appropriate regulatory actions should new safety issues be identified. In addition, the Public Health Agency of Canada receives and reviews reports of adverse events following immunization from provinces and territories as submitted by health care providers through the Canadian Adverse Events Following Immunization Surveillance System.

The Public Health Agency of Canada detects safety signals by continuously monitoring reports submitted to the Canadian Adverse Events Following Immunization Surveillance System, monitoring scientific publications and other publicly available reports from Canadian and international public health organizations, regularly meeting with Health Canada to share intelligence (including information from the Canada Vigilance Program), regularly meeting with the Vaccine Vigilance Working Group, which includes representation from provincial, territorial and federal immunization programs, and communicating directly with national and international regulatory and public health organizations. The Public Health Agency of Canada also collaborated with and funded active vaccine safety monitoring by the Canadian National Vaccine Safety Network and the Canadian Immunization Monitoring Program ACTive.

The primary purpose of vaccine post-market surveillance is to detect safety concerns, such as a possible increase in the severity or frequency of expected adverse events following immunization, or one or more unexpected events (such as an event that is not consistent with Canadian product information or labelling). For more information, please refer to World Health Organization. COVID-19 Vaccines: Safety Surveillance Manual and online.

International collaboration is also a key component of a robust vaccine surveillance system, facilitating the rapid dissemination of intelligence. Canada's participation in global safety surveillance networks and data sharing efforts aligns with the World Health Organizations' C*OVID-19 Vaccines: Safety Surveillance Manual and Global manual on surveillance of Adverse Events Following Immunization* . The Public Health Agency of Canada currently engages international partners in a variety of ways, including:

- Regular bilateral collaboration and ad hoc discussions with vaccine safety surveillance government experts and immunization advisory groups in selected countries (e.g., United States of America, Nordic countries, New Zealand) to discuss emerging information on potential and declared safety signals.
- Information sharing with international organizations such as the World Health Organization (various groups, e.g., the Global Advisory Committee on Vaccine Safety), Pan-American Public Health Agency, Caribbean Public Health Agency on Canadian data and special analyses related to identified safety signals, in order to inform World Health Organization guidance.
- Intelligence about adverse events was received from countries that were able to begin their vaccination campaigns before Canada. This enabled Canada to identify potential adverse events to monitor as the vaccine rollout progressed.

For example, myocarditis following mRNA vaccination was first signaled globally by officials in Israel in May 2021, which prompted other countries to increase monitoring for this rare event (COVID-19 subcommittee of the World Health Organization Global Advisory Committee on Vaccine Safety reviews cases of mild myocarditis reported with COVID-19 mRNA vaccines).

(c) after the information in (b) was received, what steps or actions were taken next, by whom, and on what date?

To date, one safety signal, myocarditis/pericarditis, has been confirmed for the COVID-19 mRNA vaccines in Canada. This signal is based on adverse events that were reported in Canada during the COVID-19 vaccination campaign in winter and spring of 2021, which followed their detection internationally.

Health Canada and the Public Health Agency of Canada sent health professionals a communiqué in early June 2021, providing guidance regarding case investigations, heightened vigilance, and reporting of these cases as adverse events. Health Canada authorized updated product monographs of both mRNA COVID-19 vaccines to include information about these risks (30 June 2021). COVID-19 vaccine related information was communicated via Health Canada's monthly InfoWatch newsletter. The June 2021 version included an article specifically on myocarditis and/or pericarditis and other communication channels including Public Advisories, Health Product Risk Communications and Government of Canada websites.

The National Advisory Committee on Immunization is an external advisory body that provides independent, expert advice to the Public Health Agency of Canada on the optimal use of authorized vaccines in Canada. The Public Health Agency of Canada publishes and disseminates the Committee's advice and translates the advice into the Canadian Immunization Guide, a comprehensive resource on immunization to support health professionals, vaccine program decision makers, and other Canadian stakeholders. Current and previous National Advisory Committee on Immunization guidance on COVID-19 vaccines is available online on the Committee's webpage on the Government of Canada website. The National Advisory Committee on Immunization first added information on myocarditis and/or pericarditis in its guidance from June 17, 2021. Subsequent updates from the Committee include updated evidence summaries and changes to recommendations based on the best available evidence at the time of publication. The statements online include all dates for when analyses were conducted, when decisions by the National Advisory Committee on Immunization were discussed and finalized, and when the advice was published and therefore communicated publicly.

In collaboration with the Canadian Institutes for Health Research and the Public Health Agency of Canada, a *Rapid Review of Incidence, Associated Risk Factors and Clinical Course of Myocarditis and Pericarditis following COVID-19 Vaccination* was conducted by COVID-END and posted online in November 2021, with an updated evidence summary posted in February 2022 and in September 2022. The review summarized the available evidence on this issue.

Since initial reports of myocarditis and pericarditis following mRNA vaccination, the Public Health Agency of Canada has worked with various partners to understand the emerging information. The Chief Science Advisor of Canada convened experts in June 2021 to discuss the reported incidence, presentation and possible causes of myocarditis and pericarditis associated with mRNA COVID-19 vaccines. The report summarized scientific knowns and uncertainties, and suggests priority areas for consideration.

Additionally, in partnership with federal, provincial and territorial public health authorities, enhanced public health monitoring of myocarditis following mRNA vaccination was put in place which allowed specialized analyses such as these scientific articles: Abraham et al. (2022) Myocarditis and/or pericarditis risk after mRNA COVID-19 vaccination: A Canadian head to head comparison of BNT162b2 and mRNA-1273 vaccines ; Buchan et al. (2021) Epidemiology of myocarditis and pericarditis following mRNA vaccines in Ontario, Canada: by vaccine product, schedule and interval; Naveed et al. (2022) Observed versus expected rates of myocarditis after SARS-CoV-2 vaccination: a population-based cohort study.

The Government of Canada supported a variety of studies on the safety and effectiveness of COVID-19 vaccines, including myocarditis and pericarditis, via the COVID-19 Immunity Task Force. In addition, in 2022, the Public Health Agency of Canada announced funding to the Canadian Cardiovascular Society to conduct a pan-Canadian study of the clinical and

functional outcomes of adults and children who experienced myocarditis and/or pericarditis after receiving an mRNA COVID-19 vaccination. Research began in 2022 and is ongoing.

(d) was the Public Health Agency of Canada or Health Canada notified of Adverse Event Following Immunization reports for myocarditis and pericarditis following COVID-19 vaccination, and, if so, for each notification, what was the (i) name of the notifier, (ii) title of the notifier, (iii) form of notification, (iv) name of the person who was notified, (v) date of the notification?

The Public Health Agency of Canada and Health Canada received adverse event reports of myocarditis and pericarditis following mRNA COVID-19 vaccines in winter and spring of 2021, which followed detection of this safety signal internationally.

The Reporting Adverse Events Following Immunization in Canada guide identifies who can report an adverse event following immunization and the process to follow. The Public Health Agency of Canada receives reports to the Canadian Adverse Events Following Immunization Surveillance System from local or regional public health units through central provincial and territorial immunization programs. Details about individual reports (including identity of the notifiers) are confidential and protected under provincial and territorial privacy policies. Reports are forwarded to the Public Health Agency of Canada electronically by provinces and territories after all personal identifying information has been removed. On occasion, the Public Health Agency of Canada may receive direct reports from travel health clinics, pharmacists, physicians, or the public. These reports are redirected to the Canada Vigilance Program.

(e) did the Public Health Agency of Canada or Health Canada receive the initial reports of myocarditis and pericarditis following COVID-19 vaccination from the Israeli Ministry of Health in February 2021, and, if so, (i) who received the notification, (ii) what was the date of the notification, (iii) what actions were taken after the notification, (iv) who authorized these actions, including their name, their title and the date of authorization?

As part of ongoing COVID-19 vaccine safety efforts, the Public Health Agency of Canada and Health Canada closely monitored myocarditis/pericarditis in the passive and active Canadian safety surveillance systems, including the Canadian Adverse Events Following Immunization Surveillance System, the Canada Vigilance Program, the Canadian National Vaccine Safety Network and the Canadian Immunization Monitoring Program ACTive.

Health Canada and the Public Health Agency of Canada sent health professionals a communiqué in early June 2021, providing guidance regarding case investigations, heightened vigilance, and reporting of these cases as adverse events. Health Canada authorized updated product monographs of both mRNA COVID-19 vaccines to include information about these risks (30 June 2021). The Public Health Agency of Canada has also consulted with expert cardiologists to understand this condition. COVID-19 vaccine related information was communicated via Health Canada's monthly InfoWatch newsletter. The June version included an article specifically on myocarditis and/or pericarditis and other communication channels including Public Advisories, Health Product Risk Communications and the Government of Canada websites.

In collaboration with the Canadian Institutes for Health Research and the Public Health Agency of Canada, a *Rapid Review of Incidence, Associated Risk Factors and Clinical Course of Myocarditis and Pericarditis following COVID-19 Vaccination* was conducted by COVID-END and posted online in November 2021, with an updated evidence summary posted in February 2022 and in September 2022. The review summarizes the available evidence on this issue, and will be updated on a regular basis as the evidence evolves.

Since initial reports of myocarditis following mRNA vaccination, the Public Health Agency of Canada has worked with various partners to understand the emerging information. The Chief Science Advisor of Canada convened experts in June 2021 to discuss the reported incidence, presentation and possible causes of myocarditis and pericarditis associated with mRNA COVID-19 vaccines. The report summarized scientific knowns and uncertainties, and suggests priority areas for consideration.

(f) for each communication between the Public Health Agency of Canada, Health Canada and all Public Health Agency of Canada or Health Canada COVID-19 task forces or working groups related to the Israeli Ministry of Health myocarditis and pericarditis safety signal notification, what was the (i) date, (ii) subject, (iii) type and content, of the communication?

The Israeli signal was discussed over several months with numerous working groups, including the Vaccine Vigilance Working Group, the Canadian Immunization Committee (which are federal/provincial/territorial committees on immunization programs), and the National Advisory Committee on Immunization, among others.

Health Canada and the Public Health Agency of Canada sent health professionals a communiqué in early June 2021, providing guidance regarding case investigations, heightened vigilance, and reporting of these cases as adverse events. Health Canada authorized updated product monographs of both mRNA COVID-19 vaccines to include information about these risks (30 June 2021). The Public Health Agency of Canada also consulted with expert cardiologists to understand this condition. COVID-19 vaccine related information was communicated via Health Canada's monthly InfoWatch newsletter. The June version included an article specifically on myocarditis and/or pericarditis and other communication channels, including Public Advisories, Health Product Risk Communications and the Government of Canada websites.

Current and previous National Advisory Committee on Immunization guidance on COVID-19 vaccines is available online on the Committee's webpage on the Government of Canada website. The Statements online include all dates for when analyses were conducted, when decisions by the National Advisory Committee on Immunization were discussed and finalized, and when the advice was published and therefore communicated publicly. In addition, a summary of discussions and decisions made at each National Advisory Committee on Immunization meeting is available online on the Committee's website. The National Advisory Committee on Immunization first added information on myocarditis and/or pericarditis in its guidance on June 17, 2021 based on evidence presented and discussed at the June 9 and 15, 2021 meetings. Data and evidence from Israel relating to myocarditis and/or pericarditis continued to be presented and discussed at Committee meetings whenever an update was available. In December 2021, the National Advisory Committee on Immunization updated its guidance, which included evidence that the known risks of COVID-19 illness, includes complications like myocarditis/pericarditis, and that the known risks of COVID-19 illness outweigh the potential harms of having an adverse reaction following mRNA vaccination, including the rare risk of myocarditis or pericarditis which despite hospitalization, is relatively mild and resolves quickly in most individuals.

In collaboration with the Canadian Institutes for Health Research and the Public Health Agency of Canada, a *Rapid Review of Incidence, Associated Risk Factors and Clinical Course of Myocarditis and Pericarditis following COVID-19 Vaccination* was conducted by COVID-END and posted online in November 2021, with an updated evidence summary posted in February 2022 and in September 2022. The review summarizes the available evidence on this issue, and will be updated on a regular basis as the evidence evolves.

Since initial reports of myocarditis following mRNA vaccination, the Public Health Agency of Canada has worked with various partners to understand the emerging information. The Chief Science Advisor of Canada convened experts in June 2021 to discuss the reported incidence, presentation and possible causes of myocarditis and pericarditis associated with mRNA COVID-19 vaccines. The report summarized scientific knowns and uncertainties, and suggests priority areas for consideration.

(g) what communication related to the myocarditis and pericarditis safety signal occurred between the Public Health Agency of Canada, Health Canada or the Public Health Agency of Canada or Health Canada COVID-19 task forces and the COVID-19 vaccine manufacturer, including the (i) date, (ii) subject, (iii) type and content, of the communication?

Health Canada and the Public Health Agency of Canada have a robust vaccine safety surveillance system in place that engages healthcare professionals, vaccine manufacturers, the provincial and territorial health authorities. The Public Health Agency of Canada receives and reviews reports of adverse events following immunization from provinces and territories as submitted by health care providers through the Canadian Adverse Events Following Immunization Surveillance System. The information provided by the Canadian Adverse Events Following Immunization Surveillance System is complemented by the Canada Vigilance Program, Health Canada's post-market surveillance program that collects and assesses reports of suspected adverse events to health products marketed in Canada. Manufacturers are required to report serious adverse events to Health Canada as the national regulatory authority, as well as submit regular summaries of global safety information.

Market authorization holders (i.e., the sponsors or manufacturers that have the legal authority to market their drug in Canada) are required to report serious adverse events to the Canada Vigilance Program, as mandated by the *Food and Drugs Act and Regulations* . The Canada Vigilance Program also accepts reports from health professionals and consumers. This information is one of the tools that enables Health Canada to monitor the safety profile of vaccines to determine if their benefits continue to outweigh their risks. For a more detailed explanation of the roles of different stakeholders contributing vaccine pharmacovigilance in Canada, please consult the Canadian Immunization Guide.

In addition, the Public Health Agency of Canada leveraged existing regular vaccine procurement and supply dialogues with Moderna and Pfizer to inform them of the emerging data related to the myocarditis signal and to provide extracts from adverse events reports to support their responsibilities in pharmacovigilance.