Question

With regard to Health Canada, the Public Health Agency of Canada, Innovation, Science and Economic Development Canada, reports of myocarditis and pericarditis following COVID-19 vaccination and the March 3, 2021, International Regulatory Meeting for Pharmacovigilance Cluster on myocarditis following COVID-19 vaccination, at which Canada was represented: (a) what data were provided at this meeting in relation to myocarditis and pericarditis reports; (b) who attended this meeting on behalf of Canada; (c) what was the conclusion of the cluster meeting and did Health Canada agree with this conclusion; (d) whether the answer to (c) is affirmative or negative, what was Health Canada's rationale; (e) following this meeting, (i) what was Health Canada's action plan, (ii) was there a plan to investigate this signal further by Health Canada or any other regulatory body, and, if so, when, by whom and what was the plan; (f) were there meetings between Health Canada and other international regulatory agencies and the Marketing Authorization Holder, and, if so, what terms and conditions were placed upon the vaccine companies by Health Canada in relation to the reports of myocarditis and pericarditis; (g) what actions were taken by Health Canada or the Public Health Agency of Canada to identify cases of myocarditis or pericarditis following COVID-19 immunization in Canada with respect to (i) diagnostic parameters, (ii) research, (iii) reporting from health care providers, (iv) provincial guidance; and (h) for communications regarding the risk of myocarditis and pericarditis following COVID-19 vaccination for the public, (i) what input from non-government organizations and institutions was considered for public and media communications and messaging, (ii) what were the dates of the communication, (iii) what strategies and media scripts were developed, (iv) where are these communications posted or archived, (v) how and when was guidance to health care professionals updated to ensure informed consent with respect to myocarditis and pericarditis following COVID-19 vaccination?

Response

This response was tabled in the House of Commons on March 11, 2026, as Sessional Paper 8555-451-767.

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Question number	Asked by	Date asked
Q-767	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 data were provided at this meeting in relation to myocarditis and pericarditis reports; (b) who attended this meeting on behalf of Canada; (c) what was the conclusion of the cluster meeting and did Health Canada agree with this conclusion; (d) whether the answer to (c) is affirmative or negative, what was Health Canada's rationale; (e) following this meeting, (i) what was Health Canada's action plan, (ii) was there a plan to investigate this signal further by Health Canada or any other regulatory body, and, if so, when, by whom and what was the plan?

Health Canada delegates who have subject matter expertise attended the Pharmacovigilance Cluster on March 3, 2021. The Cluster meetings are designed for collaboration and exchange of information, including adverse event information, among international regulators on emerging safety issues or signals. Regulatory authorities from the European Medicines Agency, the United States Food and Drug Administration, the United Kingdom Medicines and Healthcare products Regulatory Agency and Health Canada provided the number of reports of myocarditis in their respective jurisdiction, as well as additional information on the reports. In addition, HC 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 potential risk.

(f) were there meetings between Health Canada and other international regulatory agencies and the Marketing Authorization Holder, and, if so, what terms and conditions were placed upon the vaccine companies by Health Canada in relation to the reports of myocarditis and pericarditis; (g) what actions were taken by Health Canada or the Public Health Agency of Canada to identify cases of myocarditis or pericarditis following COVID-19 immunization in Canada with respect to (i) diagnostic parameters, (ii) research, (iii) reporting from health care providers, (iv) provincial guidance?

The monitoring of adverse events following immunization in Canada is a collaborative effort between Health Canada and the Public Health Agency of Canada, with Health Canada and the Public Health Agency of Canada reviewing information stemming from different sources.

Information submitted by manufacturers is reviewed by Health Canada to monitor the safety and efficacy of COVID-19 vaccines. Health Canada introduced strategies to enhance regulatory surveillance measures for COVID-19 vaccines. Terms and conditions (Guidance for market authorization requirements for COVID-19 vaccines (canada.ca)) were added to the authorizations requiring manufacturers to quickly gather critical safety and effectiveness information in order to mitigate risks during the product lifecycle, as well as to implement additional risk monitoring activities and post-market studies (post-authorization studies on safety and effectiveness). Health Canada also required the frequent submission of Periodic Benefit-Risk Evaluation Reports; these documents presented the manufacturer's assessment of all relevant information including scientific literature and a conclusion on the benefit/risk profile of the product at a point in time. The regular submission of safety information, as required by the Terms and Conditions, contributed to Health Canada's ability to promptly detect and evaluate the emerging safety information related to the risks of myocarditis and pericarditis. These enhanced measures enabled Health Canada to perform ongoing assessments of the benefit-risk balance of COVID-19 vaccines. Detailed information on Terms and Conditions for COVID-19 vaccines, can be accessed by visiting online, and selecting the desired vaccine; the Authorization Terms & Conditions can be found under the "all resources" tab.

Health Canada also monitors and considers safety information from the scientific literature and international regulators.

The monitoring and review of reports of adverse events following immunizations is actively performed by both Health Canada and Public Health Agency of Canada. All adverse events following immunization reports submitted by provincial and territorial public health authorities and federal departments are captured in the Canadian Adverse Events Following Immunization Surveillance System, which is managed by the Public Health Agency of Canada. In addition, the Canada Vigilance Program, managed by Health Canada, receives adverse events following immunization reports from manufacturers, Canadian hospitals, healthcare professionals and consumers.

Through the monitoring of information originating from different sources, including information from the manufacturers, from scientific literature, from international regulators, as well as from adverse events following immunization reports, Health Canada continues to monitor the safety of COVID-19 vaccines once they are on the Canadian market to help ensure that the benefits continue to outweigh the risks. Should a new safety issue be confirmed, Health Canada will take appropriate action, which may include communicating new risks to Canadians and healthcare professionals or changing the recommended use of the product. Health Canada is responsible for ensuring that the product monographs of vaccines authorized in Canada are updated over time to adequately reflect the risks. Detailed information about the terms and conditions imposed on the COVID-19 vaccines, public advisories, risk communications, and post-authorization activities can be found on the Health Canada website: COVID-19 vaccines and treatments portal (canada.ca). In addition, summaries of safety reviews completed related to COVID-19 vaccines are published in the Health Product InfoWatch (canada.ca).

(h) for communications regarding the risk of myocarditis and pericarditis following COVID-19 vaccination for the public, (i) what

input from non-government organizations and institutions was considered for public and media communications and messaging, (ii) what were the dates of the communication, (iii) what strategies and media scripts were developed, (iv) where are these communications posted or archived, (v) how and when was guidance to health care professionals updated to ensure informed consent with respect to myocarditis and pericarditis following COVID-19 vaccination?

The following 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 3, 2021 – Health Canada and the Public Health Agency of Canada sent a Communiqué to health practitioners informing about reports of myocarditis and pericarditis after COVID-19 vaccination.
- 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. Health Canada updated the product monographs (labels) for both Pfizer-BioNtech and Moderna COVID-9 vaccines 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.
- July 16, 2021 − The Office of the Chief Science Advisor completed a report on COVID-19 Vaccine-Associated Myocarditis and Pericarditis. The report summarized scientific facts, uncertainties, and suggested priority areas for consideration.
- 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

(g) what actions were taken by Health Canada or the Public Health Agency of Canada to identify cases of myocarditis or pericarditis following COVID-19 immunization in Canada with respect to (i) diagnostic parameters, (ii) research, (iii) reporting from health care providers, (iv) provincial guidance; and

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 2021 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.

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 facts, uncertainties, and suggests priority areas for consideration.

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. Funded by the federal government, the Public Health Agency of Canada worked with the COVID-19 Evidence Network to support Decision-making to conduct a living evidence review of the emerging evidence. In addition, the Public Health Agency of Canada also funded 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.

(h) for communications regarding the risk of myocarditis and pericarditis following COVID-19 vaccination for the public, (i) what input from non-government organizations and institutions was considered for public and media communications and messaging, (ii) what were the dates of the communication, (iii) what strategies and media scripts were developed, (iv) where are these communications posted or archived, (v) how and when was guidance to health care professionals updated to ensure informed consent with respect to myocarditis and pericarditis following COVID-19 vaccination?

The Public Health Agency of Canada and Health Canada ensured that Canadians and health care professionals had access to the latest information to make informed decisions and were aware of symptoms through regular Adverse Events Following Immunization reporting, web content on Canada.ca, and regular updates during the Chief Public Health Officer's pressers.

The Chief Public Health Officer and the Deputy Chief Public Health Officer raised myocarditis both proactively and reactively in press conferences and technical briefings.

COVID-19 vaccine related information was also communicated via the monthly InfoWatch newsletter; the June version included an article specifically on myocarditis/pericarditis and other communication channels including Public Advisories and Health Product Risk Communications.

In mid/late April 2021 International reports (World Health Organization, United States Centers for Disease Control and Prevention, European Medicines Agency, Israel) indicated elevated numbers of cases of myocarditis and pericarditis following mRNA COVID-19 vaccinations. At that time, no clear association had been established between myocarditis/pericarditis and mRNA vaccines, therefore no regulatory actions were taken in Canada or internationally. The Public Health Agency of Canada, Health Canada and the provincial and territorial health authorities were aware of these cases and continued to monitor closely.

May 21, 2021 – Special bullet added to Adverse Events Following Immunization online report to indicate to the public that the Public Health Agency of Canada and Health Canada were monitoring the situation.

June 3, 2021 –The Public Health Agency of Canada and Health Canada sent health professionals a Communique to health care providers on myocarditis and pericarditis providing guidance regarding case investigations, heightened vigilance, and reporting of these cases as adverse events. The Public Health Agency of Canada consulted with expert cardiologists to understand this syndrome. Circulated to provinces and territories (Vaccine Vigilance Working Group, Canadian Immunization Committee, Special Advisory Committee) on June 3; and, Health professional organizations on June 4, 5, 10, 11.

June 14, 2021 – COVID-19: Vaccine safety and side effects Canada.ca web content updated to include information on myocarditis and pericarditis. To provide information for Canadians, acknowledging international reports, what to look out for and when to seek medical attention

June 17, 2021 – Media technical briefing Chief Public Health Officer's speech, using approved messaging (the Chief Public Health Officer and the Deputy Chief Public Health Officer raised myocarditis both proactively and reactively in press conferences/technical briefings)

June 24, 2021 – InfoWatch bulletin - Article on COVID-19 vaccines and Myocarditis, wider distribution email: June 25, 2021.

June 26, 2021 – Social Media - Health Canada is aware of yesterday's announcement by the United States Food and Drug Administration and its review of cases of myocarditis and pericarditis in a small number of people following vaccination with #Covid19 vaccines.

August 11, 2021 – The Office of the Chief Science Advisor released a report on COVID-19 Vaccine-Associated Myocarditis and Pericarditis. The report drew on the knowledge of many experts from within the Public Health Agency of Canada and Health Canada. The report can be found on the Office of the Chief Science Advisor's website. Media lines were also developed to support the publication of the report.

September 29, 2021 – Public Health Agency of Canada's statement - Update on COVID-19 Vaccines and the Risk of 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.

October 1, 2021 – Statement from the Council of Chief Medical Officers of Health: Update on COVID-19 Vaccines and the Risk of Myocarditis and Pericarditis.

October 4, 2021 – Media lines developed on reports of myocarditis and/or pericarditis following immunization with mRNA COVID-19 vaccines.

December 3, 2021 – The Public Health Agency of Canada released updates from the National Advisory Committee on Immunization: expanded booster recommendations and updated mRNA COVID-19 vaccine guidance for people 12 to 29 years of age and media lines were developed.

May 26, 2022 – Updated media lines on reports of myocarditis and/or pericarditis following immunization with mRNA COVID-19 vaccines.

July 2022 – National Advisory Committee on Immunization's statement on Recommendations on the use of Moderna Spikevax vaccine in children 6 months to 5 years of age (includes information on myocarditis and pericarditis).

October 2022 - Updated media lines on myocarditis for Deputy Chief Public Health Officer speaking engagement on October 27 at the Canadian Cardiovascular Society's annual Canadian Cardiovascular Congress meeting.

Furthermore, 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 summarizes the available evidence on this issue.

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.

More information on myocarditis and/or pericarditis following vaccination with mRNA and other COVID-19 vaccines can be found in the Canadian Immunization Guide.

Innovation, Science and Economic Development Canada

Reply by: the Minister of Industry and Minister responsible for Canada Economic Development for Quebec Regions

Name of Signatory: Mélanie Joly

Reply

Innovation, Science and Economic Development Canada

With regard to reports of myocarditis and pericarditis following COVID-19 vaccination and the March 3, 2021, International Regulatory Meeting for the Pharmacovigilance Cluster on myocarditis following COVID-19 vaccination, at which Canada was represented, Innovation, Science and Economic Development Canada did not participate in, attend, or provide information related to myocarditis or pericarditis reports.