Question

With regard to Health Canada, the Public Health Agency of Canada and the National Advisory Committee on Immunization and their statement, “the benefits of the COVID-19 vaccines outweigh the risks”: (a) what are the benefits of the COVID-19 vaccines, broken down by (i) benefit, (ii) supporting studies or documents and their published date, (iii) start and end dates of the benefit analysis, (iv) name and title of those who analyzed the benefit; (b) what are the risks of the COVID-19 vaccines, broken down by (i) risk, (ii) supporting studies or documents and their published dates, (iii) date on which the risk was identified, (iv) start and end dates of the risk analysis, (v) name and title of those who analyzed the risk; (c) was a risk and benefit analysis performed for each COVID-19 vaccine product; (d) if the answer to (c) is affirmative, (i) what are the start and end dates of each analysis, (ii) what are the differences between the product analysis results; (e) was a separate risk and benefit analysis performed for (i) various age groups, (ii) genders, (iii) pregnant women, (iv) the immunocompromised, (v) First Nations and Indigenous populations; (f) if the answer to (e) is affirmative, for each group in (e), what are the (i) start and end dates for each analysis performed, (ii) name and title of those who performed them; (g) was a risk and benefit analysis performed for Canadians who were previously infected with COVID-19; and (h) if the answer to (g) is affirmative, for each analysis performed, what (i) was the start date, (ii) was the end date, (iii) were the conclusions of the analysis?

Response

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Question number	Asked by	Date asked
Q-763	Cathay Wagantall (Yorkton—Melville)	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 are the benefits of the COVID-19 vaccines, broken down by (i) benefit, (ii) supporting studies or documents and their published date, (iii) start and end dates of the benefit analysis, (iv) name and title of those who analyzed the benefit; (b) what are the risks of the COVID-19 vaccines, broken down by (i) risk, (ii) supporting studies or documents and their published dates, (iii) date on which the risk was identified, (iv) start and end dates of the risk analysis, (v) name and title of those who analyzed the risk; (c) was a risk and benefit analysis performed for each COVID-19 vaccine product; (d) if the answer to (c) is affirmative, (i) what are the start and end dates of each analysis, (ii) what are the differences between the product analysis results; (e) was a separate risk and benefit analysis performed for (i) various age groups, (ii) genders, (iii) pregnant women, (iv) the immunocompromised, (v) First Nations and Indigenous populations; (f) if the answer to (e) is affirmative, for each group in (e), what are the (i) start and end dates for each analysis performed, (ii) name and title of those who performed them; (g) was a risk and benefit analysis performed for Canadians who were previously infected with COVID-19; and (h) if the answer to (g) is affirmative, for each analysis performed, what (i) was the start date, (ii) was the end date, (iii) were the conclusions of the analysis?

All vaccines made available for human use in Canada have undergone a rigorous scientific review process and are grounded in established regulatory standards. Information on these standards can be found at: Regulating vaccines for human use in Canada - Canada.ca.

Canada's vaccine safety surveillance system is a collaborative effort involving Health Canada, the Public Health Agency of Canada, provinces and territories, and manufacturers. Adverse events following immunization are collected and monitored through both the Canada Vigilance Program, managed by Health Canada, and the Canadian Adverse Events Following Immunization Surveillance System, managed by the Public Health Agency of Canada. Reports from both systems are monitored continuously and support ongoing safety oversight. Reported events do not necessarily imply a causal relationship with vaccination but are critical for detecting potential safety signals.

In the case of COVID-19 vaccines, Health Canada conducted a comprehensive benefit-risk analysis based on a wide range of available evidence, including clinical trial results supporting authorized indications (including specific age groups), non-clinical data, and the public health need at the time of review. The decision to issue a Notice of Compliance for vaccines was based on a positive benefit–risk profile.

Following authorization, Health Canada publishes information summarizing the evidence reviewed and the rationale for its regulatory decisions. Product-specific details are publicly available through the COVID-19 vaccines and treatments portal, including Regulatory Decision Summaries, Summary Basis of Decision documents, and Product Monographs, which outline known benefits and risks, including adverse reactions.

Benefit–risk assessments are ongoing throughout a vaccine's lifecycle. Health Canada requires manufacturers to comply with terms and conditions related to quality, clinical evidence, labelling, and risk management, and to submit regular safety updates and reports of adverse events following immunization. Health Canada continually evaluates whether new information affects a vaccine's benefit–risk profile.

Health Canada also reviews emerging evidence from scientific literature and international regulators. Outcomes of post-authorization safety reviews are summarized in the Post-Authorization Activity Tables, which are updated regularly and made publicly available through the COVID-19 vaccines and treatments portal, along with advisories and risk communications.

Up-to-date information on authorized COVID-19 vaccines, including known risks and side effects, is provided in the Canadian Product Monographs, updated as new safety information becomes available. The Product Monographs are available on Health Canada's Drug and Health Products Portal.

Health Canada continues to monitor COVID-19 vaccines as part of its routine oversight of all health products. If a new safety concern is identified and confirmed, appropriate regulatory actions are taken, including communicating risks to Canadians and healthcare professionals or adjusting recommended use, as necessary.

Public Health Agency of Canada

(a) what are the benefits of the COVID-19 vaccines, broken down by (i) benefit, (ii) supporting studies or documents and their published date, (iii) start and end dates of the benefit analysis, (iv) name and title of those who analyzed the benefit; (b) what are the risks of the COVID-19 vaccines, broken down by (i) risk, (ii) supporting studies or documents and their published dates, (iii) date on which the risk was identified, (iv) start and end dates of the risk analysis, (v) name and title of those who analyzed the risk?

COVID-19 vaccines provide substantial protection against severe illness, hospitalization, and death, particularly for individuals at elevated risk such as older adults, people with underlying medical conditions, pregnant individuals, and residents of long-term care or other congregate settings. Updated vaccines help boost immunity that naturally wanes over time and maintain strong defense against circulating variants. Vaccination remains an essential public health measure that reduces the burden on healthcare systems and strengthens population-level resilience by decreasing the likelihood of severe outcomes across diverse groups.

Published National Advisory Committee on Immunization Statements including on COVID-19 vaccines include all evidence, data, and studies included within the analysis, the dates literature reviews were completed and when evidence was presented to, and decisions were made by, members of the Committee, and all individuals involved in the development of each Statement. Additional information is also available in the Canadian Immunization Guide Chapter on COVID-19 vaccines.

COVID-19 vaccines are generally well tolerated, with most local and systemic adverse events being mild to moderate and resolving within a few days. Pain at the injection site is very common, and redness, swelling, and lymphadenopathy can also occur. Systemic reactions such as fatigue, headache, muscle and joint pain, chills, and in young children, irritability, sleepiness, and reduced appetite, are commonly reported and consistent with typical post-vaccination responses.

A small number of rare adverse events have been reported, including myocarditis and pericarditis, though most cases respond well to conservative treatment and recover quickly. Very rare cases of Bell's palsy and extremely rare reports of multisystem inflammatory syndrome have occurred, though current evidence does not support a causal link to COVID-19 vaccines. Severe allergic reactions such as anaphylaxis are also very rare, usually occur within 30 minutes of vaccination, and individuals generally recover quickly with appropriate treatment; many can be safely revaccinated following medical assessment. Overall, while rare adverse events do occur, the accumulated global and national safety monitoring continues to demonstrate that COVID-19 vaccines maintain a strong safety profile across all age groups.

(c) was a risk and benefit analysis performed for each COVID-19 vaccine product?

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. National Advisory Committee on Immunization advice is based on a rigorous, independent review of available evidence. When developing its vaccine program recommendations, the Committee assesses the vaccine characteristics (e.g. efficacy, safety), the epidemiology of the disease, and factors such as program ethics, equity, feasibility, acceptability, and cost-effectiveness, using a standard, published approach. The Committee's advice to the Public Health Agency of Canada takes into consideration the information needs of both public health decision makers and health care providers. The National Advisory Committee on Immunization recommendations are based on disease burden and public health needs in Canada.

The National Advisory Committee on Immunization completes a comprehensive assessment of each immunization product prior to making recommendations.

(d) if the answer to (c) is affirmative, (i) what are the start and end dates of each analysis, (ii) what are the differences between the product analysis results?

Dates of each analysis are available within the published National Advisory Committee on Immunization Statements.

Further information on the analyses performed and the results from these analyses are available within the published National Advisory Committee on Immunization Statements and the Canadian Immunization Guide Chapter on COVID-19 vaccines.

(e) was a separate risk and benefit analysis performed for (i) various age groups, (ii) genders, (iii) pregnant women, (iv) the immunocompromised, (v) First Nations and Indigenous populations?

Yes, the National Advisory Committee assessed COVID-19 vaccination in all the groups identified above.

(f) if the answer to (e) is affirmative, for each group in (e), what are the (i) start and end dates for each analysis performed, (ii) name and title of those who performed them?

Published National Advisory Committee on Immunization Statements include the dates literature reviews were completed, when evidence was presented to and decisions were made by members of the Committee, and all individuals involved in the development of each Statement.

(g) was a risk and benefit analysis performed for Canadians who were previously infected with COVID-19?

Yes, the National Advisory Committee on Immunization completed an assessment of COVID-19 vaccination for those who were previously infected with COVID-19.

(h) if the answer to (g) is affirmative, for each analysis performed, what (i) was the start date, (ii) was the end date, (iii) were the conclusions of the analysis?

Published National Advisory Committee on Immunization Statements include all evidence, data, and studies included within the analysis, the dates literature reviews were completed, and when evidence was presented to and decisions were made by members of the Committee.

Current recommendations are that individuals with a prior SARS-CoV-2 infection are recommended to be vaccinated, as vaccination following infection provides more reliable and longer-lasting protection than infection alone. Recommendations for these individuals are the same as for those without prior infection, including annual vaccination for most people and a second annual dose for select high-risk groups. For those with a test-confirmed SARS-CoV-2 infection, the interval that can be considered from infection to vaccination in the primary series is the same as the recommended intervals between COVID-19 vaccine doses (8 weeks for those who are not moderately to severely immunocompromised, and 4 to 8 weeks for those who are moderately to severely immunocompromised). For those who are previously vaccinated and who test positive for SARS-CoV-2, a minimum of 3 months from test-confirmed infection to COVID-19 vaccination may be considered.

Further information on the analyses performed and the results from these analyses are available within the published National Advisory Committee on Immunization Statements and the Canadian Immunization Guide Chapter on COVID-19 vaccines.