Gorodnichy v. CBSA (FPSLREB 566-02-48305)
Exhibit G-18

Exhibit sheet description:

New evidence submitted on October 22, 2026 – 2nd Book of documents, documents at pages 91, 92, and 98 (they all relate to the same subject matter)

Source documents and page ranges:

566-02-48305_Grievor_Book_of_Documents-NEW_02_HC_CHANGES_TO_C19V_SIDE_EFFECT_REPORTING-AND-ETHICAL_PROBLEMS.pdf:

PDF pages 90-91

566-02-48305_Grievor_Book_of_Documents-NEW_02_HC_CHANGES_TO_C19V_SIDE_EFFECT_REPORTING-AND-ETHICAL_PROBLEMS.pdf:

PDF pages 92-94

566-02-48305_Grievor_Book_of_Documents-NEW_02_HC_CHANGES_TO_C19V_SIDE_EFFECT_REPORTING-AND-ETHICAL_PROBLEMS.pdf:

PDF pages 98-99

Reader guidance:

Health Canada Removed the Link to The Vaccine Side-Effect Reporting on December 1, 2020 - Exactly When COVID-19 Vaccine Rollout Was Just About To Start.

Source:

Consumer page before the change—September 20, 2020

https://web.archive.org/web/20200920152607/https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/vaccine/consumer.html

Consumer page after the change—December 27, 2020; marked modified December 1, 2020

https://web.archive.org/web/20201227183130/https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/vaccine/consumer.html

Current Health Canada consumer vaccine-reporting page

https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/vaccine/consumer.html

Report a side effect to a vaccine: consumers

Everyone who witnesses or experiences a side effect (adverse reaction) following immunization is strongly encouraged to report it. You may ask your health care provider (doctor, health care provider, pharmacist) to help you.

Report a side effect

To mail your report to a Canada Vigilance Regional Office, use the postage paid label.

What is a vaccine

Vaccines are products that produce immunity to a specific disease. Most vaccines are given by injection (needle) but some are given orally (by mouth) or nasally (sprayed into the nose).

They protect people against serious and potentially deadly diseases, such as diphtheria, measles, polio and tetanus.

Related links

- Vaccines and immunization
- MedEffect Canada
- Drugs and health products

566-02-4805

- Canada Vigilance Program
- Adverse reaction database
- Advisories, warnings and recalls
- Drug and health product register
- A Patient Guide for Reporting Side Effects from Health Products

Date modified:
2019-12-30

Government of Canada / Gouvernement du Canada

Report a side effect to a vaccine: consumers

THE ENTIRE SECTION WITH THE LINK TO THE ONLINE FORM IS **REMOVED** ON 2020-12-01 -- IMMEDIATELY BEFORE COVID-19 VACCINATION BEGAN ON 2020-12-14

On this page

- What are vaccines
- Tracking adverse events following immunization

Everyone who witnesses or experiences a side effect to a vaccine is strongly encouraged to report it. Ask your health care provider (for example, doctor, nurse or pharmacist) to:

- complete an adverse events following immunization (AEFI) form
- submit it on your behalf to your local public health unit

Learn more about reporting adverse events following an immunization.

What are vaccines

Vaccines are products that produce immunity to a specific disease. Most vaccines are given by injection (needle) but some are given orally (by mouth) or nasally (sprayed into the nose).

They protect people against serious and potentially deadly diseases, such as diphtheria, measles, polio and tetanus.

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Tracking adverse events following immunization

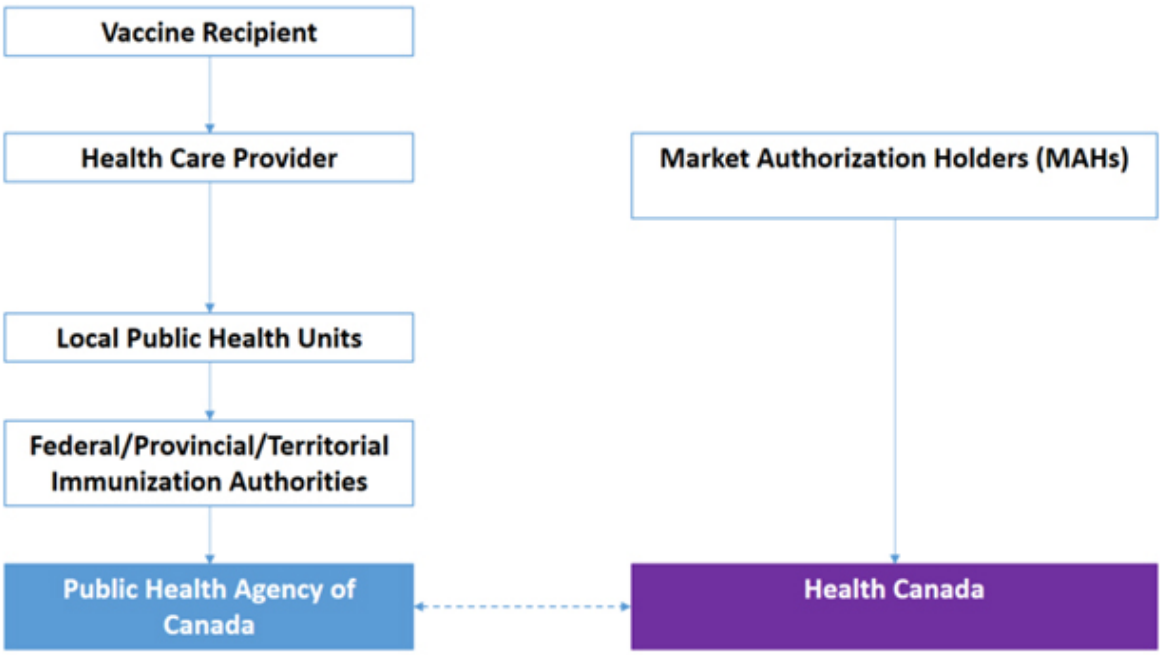
Health Canada and the Public Health Agency of Canada (PHAC) share the monitoring of the safety of vaccines in Canada.

PHAC manages the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). This post-market vaccine safety surveillance system collects CAEFISS reports submitted by public health authorities in provinces and territories, which in turn receive them from local public health units. Nurses, doctors or pharmacists who provide immunizations or care for people who experience an adverse event from a vaccine generate most of these reports.

Once aware, manufacturers (market authorization holders) of all drugs, including vaccines, must report:

- serious adverse reactions in Canada
- unexpected serious adverse reactions in other countries
- unusual failures in efficacy for new drugs in Canada

Manufacturers report to Health Canada's Canada Vigilance Program.



566-02-48305

▶ Text Equivalent

Related links

- Vaccines and immunization
- MedEffect Canada
- Drugs and health products
- Adverse reaction database
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- Drug and health product register
- A Patient Guide for Reporting Side Effects from Health Products

Date modified:
2020-12-01

Government of Canada / Gouvernement du Canada

INQUIRY OF MINISTRY
DEMANDE DE RENSEIGNEMENT AU GOUVERNEMENT

PREPARE IN ENGLISH AND FRENCH MARKING "ORIGINAL TEXT" OR "TRANSLATION"
PRÉPARER EN ANGLAIS ET EN FRANÇAIS EN INDIQUANT "TEXTE ORIGINAL" OU "TRADUCTION"

QUESTION NO./Nº DE LA QUESTION	BY / DE	DATE
Q-2506	Mr. Allison (Niagara West)	April 8, 2024

Reply by the Minister of Health
Réponse du ministre de la Santé

Signed by Mr. Yasir Naqvi

PRINT NAME OF SIGNATORY
INSCRIRE LE NOM DU SIGNATAIRE

SIGNATURE
MINISTER OR PARLIAMENTARY SECRETARY
MINISTRE OU SECRÉTAIRE PARLEMENTAIRE

QUESTION

With regard to Health Canada's MedEffect website: (a) is the process outlined in the guide entitled "Adverse Reaction Reporting and Health Product Safety Information: Guide for Health Professionals", the protocol that healthcare providers have to follow since December 1, 2020, to report COVID-19 vaccine adverse reactions; (b) if the answer to (a) is negative, (i) when did the process change, (ii) which official in what department initiated the process change, (iii) what was the reason for the change; (c) since December 2020, what has been the new reporting protocol guidance to report COVID-19 vaccine adverse reactions; (d) how were health professionals informed of the change in (c); and (e) what were the substantive differences from the protocol for reporting a vaccine adverse reaction prior to December 2020 and the new protocol outlined in (c)?

REPLY / RÉPONSE

ORIGINAL TEXT / TEXTE ORIGINAL [X] TRANSLATION / TRADUCTION [ ]

Health Canada

(a) The "Adverse Reaction Reporting and Health Product Safety Information: Guide for Health Professionals", outlines the submission methods available to health care professionals and anyone living in Canada, wishing to voluntarily report adverse reactions (ARs), including adverse events following immunization (AEFIs) with vaccines, such as COVID-19 vaccines, and medical devices incident reports to the Canada Vigilance Program (CVP).

There have been no changes since December 2020 to the process for health care professionals and consumers to voluntarily report to the CVP on AEFIs, including AEFIs for COVID19 vaccines.

At the provincial and territorial level, legislation is in place that requires AEFIs to be reported by health care professionals to local provincial health units. These reports are shared with PHAC via the the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). Health Canada and PHAC collaborate to continuously monitor AEFIs with vaccines, including the COVID-19 vaccines, received through the CVP and the CAEFISS.

Following a December 2019 provincial / territorial (P/T) request, changes were made in December 2020 to the “Report a side effect” web page. The changes pertained only to the online reporting form and did not impact the ability for consumers and health professionals to voluntarily report AEFIs directly to Health Canada by telephone, mail, fax, or email.

The purpose of these changes was to minimise confusion due to the co-existing CVP and CAEFISS reporting paths and to acknowledge AEFI reporting through the long standing public health route. As a result, consumers and health care professionals were directed to report AEFIs with COVID-19 vaccines to local public health authorities.These changes were supported by and authorized by senior officials within Health Canada and the Public Health Agency of Canada (PHAC).

(b) N/A

(c) Following the December 2020 update to the vaccine section of the *“Report a side effect”* web page, comments were received from some health professionals and consumers seeking to more easily report AEFIs directly to Health Canada. Comments from health professionals and consumers indicated a need

for Health Canada to restore the ability to voluntarily report AEFIs online to the Canada Vigilance Program.

To address this, in February 2023, Health Canada reinstated the direct link to Health Canada's online reporting form on the *"Report a side effect"* web page. This change aimed to make direct AEFI reporting to Health Canada easily accessible to those who were unable to report AEFIs through other submission methods (e.g. fax, phone, mail). .

(d) PHAC was informed and had no objections to the webpage update that reinstated the direct link to Health Canada's online reporting form, as it co-leads AEFI surveillance along with Health Canada. Other stakeholders were not notified as it is not standard practice to announce web page changes.

(e) As noted in (a), (b), (c), the updates to the *"Report a side effect"* web page did not change the protocol of reporting AEFIs. Voluntary reporting of AEFIs online directly to the CVP by health care professionals and consumers has been available before and after these website updates.