Ontario

AstraZeneca COVID-19 Vaccine & Thromboembolic events

Global situation

- Ontario is aware of reports of adverse events in Europe following immunization with the AstraZeneca COVID-19 vaccine whereby the European Medicines Agency's (EMA) safety committee has initiated a rapid investigation into cases of thromboembolic events (blood clots).
- The EMA has indicated that several countries in Europe have either temporarily paused the use of specific batches of the AstraZeneca COVID-19 vaccine or the use of the AstraZeneca vaccine altogether as a precautionary measure, pending the outcome of the EMA investigation.
- At this time there is no indication that the vaccine caused these events.
- Thrombosis is not a rare health event and occurs more frequently among older people. The United Kingdom's (UK) Medicines and Healthcare products Regulatory Agency has reported that, following the administration of 11 million doses of the AstraZeneca COVID-19 vaccine in the UK, reports of blood clots have not occurred at a frequency greater than what would be expected to occur based on usual trends.

Canadian context

- Health Canada and the Public Health Agency of Canada have indicated that none of the identified batches under investigation in Europe have been shipped to Canada.
- Health Canada authorized the AstraZeneca COVID-19 vaccine based on a thorough, independent review of the evidence and determined that it meets Canada's stringent safety, efficacy and quality requirements.

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- COVISHIELD (the same vaccine formulation as AstraZeneca manufactured by Serum Institute of India) was delivered to Ontario earlier this week and is now being offered to individuals 60-64 year old through pharmacy and primary care partners.
- Vaccine safety monitoring is an important part of the immunization system in Ontario and Canada.
- Adverse Events Following Immunization (AEFI) are reportable in Ontario under the *Health Protection and Promotion Act* (HPPA). The report must be sent to your local Public Health Unit.
- Public Health Ontario, in collaboration with the Ministry and local Public Health Units, carries out provincial vaccine safety surveillance. Since January 2021, PHO has been producing a weekly summary of Ontario AEFIs specific to COVID-19 vaccines on its website.
- The most recent AEFI summary includes data up to March 6, 2021 and describes a total of 665 AEFI reports, following 890,604 doses of Pfizer and Moderna COVID-19 vaccines administered in Ontario. These AEFIs represent 0.07% of all doses administered to date in the province.
- AEFIs reported in Ontario are also sent to the Public Health Agency of Canada for inclusion in the Canadian Adverse Event Following Immunization Surveillance System (CAEFISS) as part of national vaccine safety monitoring.

Summary

- Vaccines are safe, effective and the best way to protect you and those around you from serious infections like COVID-19.
- The Government of Canada continues to work with international regulators, including the EMA, to gather and assess the information available to determine whether there is a need to take action in Canada.
- COVID-19 vaccine safety will continue to be monitored closely, in collaboration with Public Health Ontario, the Public Health Agency of Canada and Health Canada.

Ontario

Related Links

Ontario Adverse Event Following Immunization Form

Public Health Ontario weekly AEFI epidemiologic summary

Thrombosis Canada Statement On AstraZeneca Covid-19 Vaccine And Thrombosis

Adverse Events In Europe Following Immunization With The AstraZeneca COVID-19 Vaccine (Health Canada)

https://www.ema.europa.eu/en/news/covid-19-vaccine-astrazeneca-prac-preliminary-view-suggests-no-specific-issue-batch-used-austria

https://www.gov.uk/government/news/mhra-response-to-danish-authorities-action-to-temporarily-suspend-the-astrazeneca-covid-19-vaccine?utm_medium=email&utm_campaign=govuk-notifications&utm_source=b95d175a-8501-4233-a6b5-d8d0048f5b58&utm_content=immediately