

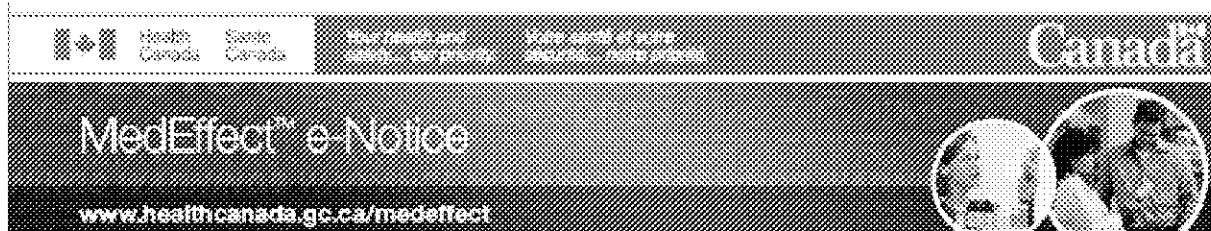
Klachkova, Anastasiya (CSC/SCC)

From: Boudreau Harold (NHQ-AC)
Sent: February 23, 2021 8:32 AM
To: Guirguis Bassem (NHQ-AC); Clement Chris (NHQ-AC); Morse Jennifer (NHQ-AC)
Subject: FW: COVID-19 Vaccine Moderna

FYI. Health Canada notice on Moderna. Essential they are reporting on cases of anaphylaxis with the product not seen in the clinical trials and the Product monograph was updated as a result. Also there are some changes to the vial label but I do not see these as significant to advertise out.

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Sent: February 22, 2021 5:28 PM
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<http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2021/75039a-eng.php>

Important Safety Information on COVID-19 Vaccine Moderna - Updated English-only Global Vial and Carton Labels and Post-Market Adverse Reaction Information - Moderna Biopharma Canada Corporation

The COVID-19 Vaccine Moderna was authorized on December 23, 2020, for use in accordance with the Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19. Since the time of authorization, new information pertaining to post-market adverse reactions has been identified following COVID-19 Vaccine Moderna administration outside of clinical trials. In addition, the PM and global English-only vial and carton labels have been updated with new product labelling information.

Any case of serious or unexpected adverse events in patients receiving vaccines should be reported to your local public health authorities or directly to the [Public Health Agency of Canada](#).
<http://www.phac-aspc.gc.ca/im/aeft-form-eng.php>

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