

March 25, 2021

**To:** Provincial and Territorial Ministries of Health

**Subject:** Purchase and use of face masks that contain nanoform graphene.

We are writing to advise you of a potential emerging risk concerning face masks that are coated with nanoform graphene materials, and cautioning the use of these devices in your healthcare networks, schools and daycares.

Face masks that make antiviral claims or use antiviral materials, including those coated with nanoform graphene, are classified as Class I medical devices under the *Medical Devices Regulations* (MDR), pursuant to the *Food and Drugs Act* (Act).

Health Canada has conducted a preliminary risk assessment which identified a potential for early pulmonary toxicity associated with the inhalation of nanoform graphene. To date, Health Canada has not received data to support the safety and efficacy of face masks containing nanoform graphene.

As such, and in the absence of manufacturer's evidence to support the safe and effective use of nanoform graphene coated masks, Health Canada considers the risk of these medical devices to be unacceptable.

To address this risk, Health Canada has:

- 1) Contacted the known distributors, importers and manufacturers of these medical devices to inform them that these devices are in violation of the Act.
- 2) Requested that companies that have sold these devices immediately stop sale and initiate a recall requesting that the affected devices be returned.
- 3) Drafted a risk communication to inform the Canadian public of the potential risks of using face masks containing nanoform graphene materials.
- 4) Initiated a safety review concerning the use of nanoform graphene materials in face masks and requested that manufacturers submit additional information to support this assessment.

We understand that these devices may be distributed and in use within your province/territory. At this time, Health Canada recommends you stop purchasing and using face masks containing nanoform graphene. For these reasons, we are seeking your assistance to ensure that healthcare networks, schools and daycares within your respective jurisdictions are aware of Health Canada's concerns regarding the potential risks to the health of Canadians.

Should you have any questions, do not hesitate to contact me.

Thank you for your attention to this matter.

Yours sincerely,

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