
Question

With regard to Health Canada's review of the COVID-19 modRNA vaccine products: (a) did Health Canada consider the specific nature of the nanotechnology of the lipid particles used for the modRNA vaccine delivery; (b) if the answer to (a) is affirmative, what was their assessment; (c) why was the fact that modRNA vaccines contain nanotechnology omitted from the product monograph-label; (d) did Health Canada assess the toxicity of pegylated nanoparticles, specifically the risk for complement activation-related pseudoallergy (CARPA) with the lipid nanoparticles used in the mRNA vaccines; (e) if the answer to (d) is affirmative, why was this not included in the product labelling; (f) if the answer to (d) is negative, why wasn't this assessed; (g) did Health Canada assess the risk of toxicity due to the nanoformat of these vaccines; (h) if the answer to (g) is affirmative, what was the assessment result; (i) if the answer to (g) is negative, why not; (j) did Health Canada assess the lipid nanoparticles as a novel excipient; (k) if the answer to (j) is affirmative, what was the assessment; (l) if the answer to (j) is negative, why not; (m) with respect to nanotechnology products and their unique properties and behaviours, particularly in their application to the modRNA vaccines, did Health Canada examine (i) the safety, (ii) the effectiveness, (iii) the risk to the environment, (iv) its specific regulatory status; (n) if the answers to (m)(i) through (m)(iv) are affirmative, what were the assessment results; (o) if the answers to (m)(i) through (m)(iv) are negative, why not; (p) how do established safe levels of DNA apply (i) when using pegylated lipid nanoparticles as a delivery system, (ii) when a product that contains pegylated lipid nanoparticles requires repeated dosing; and (q) what assessment was performed to assess the risk of residual DNA when using pegylated lipid nanoparticles as a delivery system in a vaccine which requires repeated dosing?

Response

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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

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did Health Canada examine (i) the safety, (ii) the effectiveness, (iii) the risk to the environment, (iv) its specific regulatory status; (n) if the answers to (m)(i) through (m)(iv) are affirmative, what were the assessment results; (o) if the answers to (m)(i) through (m)(iv) are negative, why not; (p) how do established safe levels of DNA apply (i) when using pegylated lipid nanoparticles as a delivery system, (ii) when a product that contains pegylated lipid nanoparticles requires repeated dosing; and (q) what assessment was performed to assess the risk of residual DNA when using pegylated lipid nanoparticles as a delivery system in a vaccine which requires repeated dosing?

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](#)

Once vaccines are authorized, Health Canada releases information about the vaccine, including summaries of the data considered by Health Canada. This includes non-clinical, clinical and other studies, as well as how the decision was made. This information can be found on Health Canada's [website](#).

Studies supporting the safety of the COVID-19 vaccines were conducted and were submitted as part of the pre-clinical and clinical data packages that companies are required to submit to regulatory agencies, including Health Canada. Health Canada reviewed these data before granting authorizations for the COVID-19 vaccines.

The toxicity evaluation of the COVID-19 mRNA vaccines focused on the vaccines, their components and the delivery system. In non-clinical studies, the toxicity of vaccines was tested either as the whole product containing the delivery system as marketed in Canada, medicinal ingredients (COVID-19 antigens), or non-medicinal ingredients, including the components in the formulation.

Polyethylene glycol is an ingredient that is widely used in cosmetics, food products, and pharmaceuticals. Monoclonal antibodies, for example, are frequently conjugated with polyethylene glycol to increase stability. Products containing polyethylene glycol lipid nanoparticles, such as Onpattro, have been on the Canadian market for several years and are not unique to the COVID-19 vaccines.

The product monograph lists the vaccine's composition/components, including the lipid nanoparticles, in the Table of "Dosage Form, Strength, Composition and Packaging". It also presents important data from the required toxicity tests.

The manufacturing data provided to Health Canada demonstrated the ability to produce a vaccine with consistent quality. Impurities, including residual DNA, are controlled through maximum permissible limits during the manufacturing process and before the product is released on the market to ensure safety. These impurities are evaluated using validated assays, and limits are set to ensure product quality and safety. These requirements are informed by science and are aligned with international standards, including the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.

More information is publicly available in the Summary Basis of Decision available on the [COVID-19 vaccines and treatments portal](#).

Following authorization, Canada has a robust and well-established vaccine safety surveillance system 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.

