Question

With regard to Health Canada's regulation of the modRNA COVID-19 vaccines: (a) what information does Health Canada possess on the identity of the facility or facilities responsible for manufacturing, linearizing and quality-controlling the plasmid DNA template used to produce mRNA for the authorized COVID-19 vaccines; (b) what inspections of the manufacturing facilities did Health Canada perform regarding manufacturing, testing and release of the linear DNA template that formed the starting material for the COVID-19 mRNA vaccines, and which manufacturers or vendors and sites were inspected, when and by whom; (c) if the inspections in (b) were not done, why not; (d) what quality assessment was performed with the sponsors (Pfizer Canada ULC or BioNTech SE) concerning the control of the linear DNA template, its plasmid source and the outsourcing of its production by (i) Canadian authorities, (ii) other regulators who shared the results with Canadian authorities; (e) did Health Canada determine if there were deficiencies, open questions or site qualifications related to the linear DNA template or plasmid manufacturing process, and, if so, what was the outcome, or, if not, why not; (f) were the linearization and residual DNA removal processes required to comply with standards in (i) ICH Q5A: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin (with respect to residual DNA limits and characterization), (ii) ICH Q5B: Quality of Biotechnological Products: Analysis of the Expression Construct in Cells Used for Production of r-DNA Derived Protein Products, (iii) USP <1047> and <1049>: Gene Therapy Products and DNA Templates-Residual DNA Testing and Limits; (g) if the answer to (f) is negative, why not; (h) is Health Canada aware of any shared or outsourced master plasmid cell bank stock arrangements between (i) Pfizer and other entities, (ii) Moderna and other entities, to produce mRNA templates across multiple facilities or jurisdictions; (i) has Health Canada received any deviation reports, corrective and preventive action plans, or lot investigations relating to incomplete linearization in (i) Pfizer's, (ii) Moderna's, COVID-19 vaccine drug substance or finished product; and (j) if the answer to (i) is affirmative, what were the dates and findings of those reports, and were any product quality complaints or safety concerns escalated to the Biologic and Radiopharmaceutical Drugs Directorate?

Response

This response was tabled in the House of Commons on May 8, 2026, as Sessional Paper 8555-451-990.

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Sessional Paper
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House of Commons

Order/Address of the House of Commons

Question number	Asked by	Date asked
Q-990	Ted Falk (Provencher)	March 23, 2026

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

Health Canada reviews all vaccines for safety, quality and efficacy through a rigorous scientific review process that is grounded in established regulatory standards. These requirements are set out in the Food and Drug Regulations. The requirements include providing information on product manufacturing and testing, which includes clearly identifying manufacturing sites and quality controls in place to support product safety and efficacy. During the review process, scientific experts determine whether the appropriate pharmacopeial and International Council for Harmonization guidance have been applied and whether the proposed control strategy is adequate. The Biologic and Radiopharmaceutical Drugs Directorate within the Health Products and Food Branch of Health Canada may perform on-site or virtual evaluations on a risk-informed basis.

A drug establishment license is required by any person in Canada engaged in one or more of the six licensable activities (fabricate, package/ label, test, import, distribute and wholesale), with respect to drugs (human and veterinary) in dosage form and Active Ingredients (including Active Pharmaceuticals Ingredients) and bulk intermediates of Schedule C (radiopharmaceutical) and Schedule D (biological drugs). These are listed in Table II of Section C.01A.008 of the Food and Drug Regulations and must comply with the requirements of Part C, Division 2 (Good Manufacturing Practices) of the Food and Drug Regulations.

Information regarding the inspection process can be found in Good manufacturing practices inspection policy for drug establishments (POL-0011). This policy describes the inspection strategy for Good Manufacturing Practices inspections of Canadian buildings that require a drug establishment license and foreign buildings that must be authorized on a drug establishment license.

In order to prepare for an inspection, refer to Good manufacturing practices guide for drug products (GUI-0001). There is a useful chart (‘Chart 1.0: Good Manufacturing Practices regulations applicable to which licensable activities’) that specifies what Health Canada would evaluate during an inspection. For additional information on establishment licensing, please refer to Guidance on Drug Establishment Licences (GUI-0002) - Canada.ca.

If a product has been authorized by Health Canada, it has been determined to be compliant with the relevant regulations.