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Health Product Compliance Directorate
Ottawa, Ontario K1A 0K9
Mail Stop: 1913B

November 13, 2025

MECS 25-107621-786

Information to Market Authorization Holders (MAHs) of Human Pharmaceutical Products Regarding Nitrosamine Impurities

Health Canada's change in expectation for reporting on the detection of nitrosamine impurities

Dear Stakeholders,

This communication is to advise you of a change in reporting expectations to Health Canada when nitrosamine impurities are detected in drug products marketed in Canada.

As noted in the letter issued on July 11th, 2025 regarding the Department's expectations for the Step 3 timeline of our Call for Review:

- Health Canada recognizes the challenges faced by Market Authorization Holders (MAHs) to decrease levels of impurity(ies) in their drug product(s).
- To support MAHs in maintaining drug supply in Canada, Health Canada has allowed MAHs up to 3 years to implement corrective and preventive actions (CAPA).

During CAPA implementation and effective immediately, Health Canada will no longer be issuing No Objection Letters for the release of drug products with elevated nitrosamine levels. It is the responsibility of Drug Establishment Licence holders to determine whether market action is necessary for the product(s) in question after thoroughly evaluating the potential impact of the elevated nitrosamine levels on the safety and quality of the product(s). This assessment must be clearly documented, retained on record, and be based solely on safety and quality principles.

Additionally, effective immediately, MAHs no longer need to inform Health Canada every time an elevated level of a nitrosamine impurity is detected. MAHs are only expected to notify Health Canada if a decision to initiate a recall is made and reporting should be



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conducted as specified in the [Drug, natural health product and biocide recall guide \(GUI-0039\)](#).

You are reminded that it is Health Canada's expectation that MAHs implement risk mitigation measures to reduce the levels of nitrosamine impurities to below the acceptable intake limits as soon as possible despite the 3-year CAPA implementation timeline.

Health Canada's [Guidance on Nitrosamine Impurities in Medications](#) will be updated to reflect the latest reporting expectation soon.

If you have any nitrosamine-related enquiries, please refer to [Appendix: Contact Information](#).

Sincerely,

Kim Godard
Director General
Health Product Compliance Directorate
Regulatory Operations and Enforcement Branch

Cc

Kelly Robinson, Director General, Pharmaceutical Drugs Directorate, Health Products and Food Branch (HPFB)

Sophie Sommerer, Director General, Biologic and Radiopharmaceutical Drugs Directorate, HPFB

Stephen Norman, Director General, Natural and Non-Prescription Health Products Directorate, HPFB

Appendix: Contact Information

Communications should be directed as follows:

- Nitrosamine-related enquiries for drug products containing **chemically synthesized and semi-synthetic active pharmaceutical ingredients**, please email bpsenquiries@hc-sc.gc.ca.
- Nitrosamine-related enquiries **for biological and radiopharmaceutical drug products**, please email brdd.nitrosamines.dnbr@hc-sc.gc.ca.
- Enquiries **related to applicable acceptable intake (AI) limit(s), including new AI limit proposals, for all medications in scope of Health Canada's nitrosamines guidance**, please email nitrosamines@hc-sc.gc.ca.
- To submit **recall information** or for general enquiries on the recall of drugs, communications should be directed as follows:

Location of recalling firm	Recall reporting address
New Brunswick, Newfoundland and Labrador, Nova Scotia, Prince Edward Island, Québec	Health Products Compliance Unit East 1001 Rue St-Laurent Ouest Longueuil PQ J4K 1C7 Phone: 1-800-561-3350 Email: qpc-coq@hc-sc.gc.ca
Ontario	Health Products Compliance Unit Central 2301 Midland Ave Toronto ON M1P 4R7 Phone: 416-973-1600 Toll free: 1-800-267-9675 Email: insponoc-coon@hc-sc.gc.ca
Manitoba, Saskatchewan, Alberta, British Columbia, Yukon, Northwest Territories, Nunavut	Health Products Compliance Unit West 400-4595 Canada Way Burnaby BC V5G 1J9 Phone: 604-666-3704 Toll free: 1-800-267-9675 Email: hpcw-cps@hc-sc.gc.ca