

Drug and Natural Health Product Recall Reporting Form

[For Industry Use Only]

This form is intended to provide a mechanism for the notification of a drug or natural health product (NHP) recall by responsible parties to Health Canada. Refer to the [Drug and Natural Health Products Recall Guide](#) (GUI-0039) for more information. Please provide as much information as available. **Fields denoted with an asterisk (*) are required to meet the regulatory obligations set out in the Food and Drug Regulations (FDR) or the Natural Health Product Regulations (NHPR).** For any questions, please contact the respective Health Products Compliance Unit (formerly know as the Inspectorate Program), listed at the end of this form.

[1] Type of Report	
Initial Notification or Follow Up Information	

[2] Recall Information	
Product Brand / Trade Name(s)*	
Product Type	
Market Authorization Number* (DIN/DIN-HM or NPN)	
Risk Classification	<p>Type I: a situation in which there is a reasonable probability that the use of, or exposure to, a product will cause serious adverse health consequences or death.</p> <p>Type II: a situation in which the use of, or exposure to, a product may cause temporary adverse health consequences or where the probability of serious adverse health consequences is remote.</p> <p>Type III: a situation in which the use of, or exposure to, a product is not likely to cause any adverse health consequences.</p>
Recall Depth	
Reason for recall* <i>Note: Add additional information as attachments.</i>	
Recall Initiation Date (anticipated or initiated)	

[3] Recalling company's details

Note: Contact names provided should be available for contact by Health Canada at any time. Complete all company information.

Recalling Company			
Contact Name			
Email			
Title			
Telephone		Fax	
Alternate Contact Name			
Email			
Title			
Telephone		Fax	
Regulated Activity			
Address			
City		Province / State	
Country		Postal / Zip Code	

[4] Product/Distribution Details *Note: Add additional information as attachments.*

Proper/Common Name of Drug/Medicinal Ingredient(s)*			
Lot / Batch Number(s)*			
Manufacturing Date(s)		Expiry Date(s)	
Dosage Form		Strength	
Package Size		Other identifier (UPC, GTIN)	
Quantity of drug manufactured or imported*			

Quantity of the drug distributed*	
Estimate amount remaining on the premises of the manufacturer, importer or distributor* <i>(Additional distribution details may be attached in section 6.)</i>	
Geographic Distribution <i>(Include information on geographic areas of distribution including foreign countries.)</i>	
Any other action taken by the manufacturer/importer or distributor with respect to the recall* <i>Note: Add additional information as attachments.</i>	

[5] Manufacturer or Importer Information, if different from Recalling Company*			
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Name			
Address			
City		Province / State	
Country		Postal / Zip Code	
License Number			
Contact Name			
Email or Telephone			

[6] Additional information (Attachments)

(Refer to the Drug and Natural Health Products Recall Guide (GUI-0039))

Please check the appropriate box if you are including attachments.

<input type="checkbox"/> Health Risk Assessment
<input type="checkbox"/> Recall Strategy
<input type="checkbox"/> Distribution Information
<input type="checkbox"/> Recall Communications
<input type="checkbox"/> Template for determination of medical necessity of a drug product
<input type="checkbox"/> Product label, product image

Any other relevant information about the recall *Note: Add additional information as attachments.*

Privacy Notice Statement

Privacy Notice: The personal information you provide to Health Canada is governed by the *Privacy Act*. We only collect personal information required to administer the notification of a drug or natural health product recall by responsible parties to Health Canada. The personal information provided in this document is collected under the authority of *the Food and Drugs Act*, the Food and Drug Regulations and/or the Natural Health Products Regulations.

Purpose of Collection: Health Canada requires the personal information to support Health Canada's compliance and enforcement activities related to drugs and natural health products.

Other uses or disclosures: Your personal information may be shared with other regulators through international agreements.

For more information: The personal information collected in this form is described in Info Source, available online at [Info Source](#) and is described in Personal Information Banks HC PPU 406, HC PPU 407, HC PPU 408.

Your rights under the Privacy Act: In addition to protecting your personal information, the *Privacy Act* gives you the right to request access to and correct your personal information. For more information about these rights, or about our privacy practices, please contact hc.privacy-vie.privee.sc@canada.ca. You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

Health Canada contacts for reporting drug and natural health product recalls

Contact Health Canada to submit recall information or for general enquiries on the recall of drugs or natural health products.

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 QC J4K 1C7 Phone: 450-646-1353 Toll free: 1-800-561-3350 Fax: 450-928-4184 Email: HC.qoc-coq.SC@canada.ca
Ontario	Health Products Compliance Unit Central 2301 Midland Ave Toronto ON M1P 4R7 Phone: 416-973-1600 Toll free: 1-800-267-9675 Fax: 416-973-1954 Email: HC.insponoc-coon.SC@canada.ca
Manitoba, Saskatchewan, Alberta, British Columbia, Yukon, Northwest Territories, Nunavut	Health Products Compliance Unit West Suite 400 – 4595 Canada Way Burnaby BC V5G 1J9 Phone: 604-666-3350 Toll free: 1-800-267-9675 Fax: 604-666-3149 Email: insp_woc-coo@hc-sc.gc.ca