



**Health Canada**  
**Health Products and Food Branch**

**OUR MANDATE:**

To promote good nutrition and informed use of drugs, food, medical devices and natural health products, and to maximize the safety and efficacy of drugs, food, natural health products, medical devices, biologics and related biotechnology products in the Canadian marketplace and health system.

# **Health Products and Food Branch Inspectorate**

## **Guidance to Industry**

# **How to Submit a Trade Complaint**

## **Guide-0038**

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## Background

Consistent with Health Canada's mission to help the people of Canada maintain and improve their health, it is the responsibility of the Health Products and Food Branch Inspectorate (referred to as the Inspectorate) to investigate complaints of alleged violations of the *Food and Drugs Act* and related Regulations with regard to health products. A health product includes any product under the mandate of the Health Products and Food Branch (HPFB), with the exception of food products. The HPFB has regulatory responsibilities in the following health product areas: drugs for human use; blood and blood products; medical devices; transplanted tissues and organs; biologics and genetic therapies; natural health products; and veterinary drugs.

The Inspectorate is committed to investigating trade complaints. The priority to investigating such complaints is guided by the level of risk to the public health.

A trade complaint is one in which the complainant is often a company or organization or their representative, and typically relates to the activities of a competitor. The Inspectorate has developed a separate document to address consumers' complaints whereby the complainant is a consumer, and the complaint typically relates to the perceived effectiveness or safety of a product. Complaints involving a health product and an alleged violation of the *Food and Drugs Act*, and related Regulations, are investigated by the Inspectorate.

## What information is recommended in the submission of a trade complaint?

Information about the alleged violation such as:

- written details of an incident and the rationale for the complaint (what, when, where, who and how something happened) including the names and phone numbers of individuals involved
- the complainant's assessment of the severity of the problem
- contact made with the alleged violator
- trade name/common name of the product
- Drug Identification Number (DIN), Natural Product Number (NPN), or Homeopathic Medicine Number (DIN-HM), Catalogue Number, Lot number, etc, if available
- device model number, catalogue number, lot or serial number and if known, licence number
- copies of labels for allegedly violative product; including the name and address of the vendor
- samples of allegedly violative product
- price lists or order forms; at a minimum, these should show the name of the company and product in question
- invoices indicating sale; including vendor and date
- advertising or promotional material; if taken from print media, the name of the newspaper or magazine and the date on which it appeared
- any other information which would assist the Inspectorate in investigating the complaint

## What happens when I submit my trade complaint?

When received, your complaint will be reviewed to determine whether further information is required and

whether the Inspectorate is the appropriate organization to handle your complaint.

Following the initial review:

- the company or organization submitting the complaint will be sent confirmation that the complaint was received and that appropriate action will be taken by the Operational Centre receiving the complaint, or;
- if applicable, the company or organization submitting the complaint will be advised that the complaint has been forwarded to another Operational Centre for appropriate action. This occurs when the company responsible for the alleged violative product is located in a geographical location served by a different Operational Centre, or;
- if the Inspectorate is not the appropriate organization to investigate the complaint, the originator will be notified of the organization (including its name and address) to which it will be referred. The complaint will be forwarded only upon authorisation by the complainant.

Since the Inspectorate must manage multiple compliance verifications, all complaints are initially prioritized according to the risk to health presented by the alleged violation. Incidents representing a higher risk will be investigated first.

The complaint, once accepted for compliance verification, will be assigned to an Inspector who will:

- determine whether non-compliance has occurred, communicate with the responsible agent for the product in question to verify that corrective action will be taken, and when appropriate, monitor the actions taken by that agent until the completion of the compliance verification;
- inform you by telephone, mail, or electronically, whether the complaint was valid, and when the compliance verification has been completed.

Actions taken by an Inspector will be consistent with the Inspectorate's compliance and enforcement policies and procedures. Not all complaints will result in enforcement action. The objective is to achieve compliance using the most appropriate level of intervention. When discussing non-compliance with a company, the Inspector will clarify the legislative and regulatory requirements, but it is the responsibility of the company to identify and implement actions to ensure compliance.

At the conclusion of the compliance verification, the complainant will be advised whether the complaint was verified, and what, if any, corrective action was taken. The Inspectorate may make information on compliance and enforcement activities available, subject to the provisions of the *Access to Information Act* and the *Privacy Act*.

## **Is there a redress mechanism?**

If you believe your complaint did not receive appropriate consideration or action, you may call or write to the closest Operational Manager, Health Products and Food Branch Inspectorate.

## **Whom do I contact?**

Trade complaints should be submitted in writing to the Health Products and Food Branch Inspectorate at the Operational Centre responsible for your province. You can also contact the same centre if you have any questions.

### **Health Products and Food Branch Inspectorate - Operational Centres**

#### **ATLANTIC OPERATIONAL CENTRE**

Health Products and Food Branch Inspectorate

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1505 Barrington Street

Halifax, Nova Scotia

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Fax: (902) 426-6676

E-mail: [insp\\_aoc-coa@hc-sc.gc.ca](mailto:insp_aoc-coa@hc-sc.gc.ca)

#### **QUEBEC OPERATIONAL CENTRE**

Health Products and Food Branch Inspectorate

1001 St-Laurent Street West

Longueuil, Québec

J4K 1C7

Tel: (450) 646-1353

Fax: (450) 928-4455

E-mail: [QOC-COQ@hc-sc.gc.ca](mailto:QOC-COQ@hc-sc.gc.ca)

#### **ONTARIO OPERATIONAL CENTRE**

Health Products and Food Branch Inspectorate

2301 Midland Avenue

Scarborough, Ontario

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Tel: (416) 973-1600

Fax: (416) 973-1954

E-mail: [insp\\_onoc-coon@hc-sc.gc.ca](mailto:insp_onoc-coon@hc-sc.gc.ca)

#### **MANITOBA AND SASKATCHEWAN OPERATIONAL CENTRE**

Health Products and Food Branch Inspectorate

510 Lagimodière Blvd

Winnipeg, Manitoba

R2J 3Y1

Tel: (204) 984-1341

Fax: (204) 984-2155

E-mail: [Insp\\_MSOC-COMS@hc-sc.gc.ca](mailto:Insp_MSOC-COMS@hc-sc.gc.ca)

WESTERN OPERATIONAL CENTRE  
Health Products and Food Branch Inspectorate  
4<sup>th</sup> Floor  
4595 Canada Way  
Burnaby, British-Columbia  
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Tel: (604) 666-3704  
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E-mail: [insp\\_woc-coo@hc-sc.gc.ca](mailto:insp_woc-coo@hc-sc.gc.ca)

## **Where can I obtain additional information about health products?**

The Health Canada's Health Products and Food Branch Inspectorate web site at:  
[http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index_e.html) can be consulted for further information.  
The Inspectorate toll free number is 1-800-267-9675.

Definitions and legal requirements are detailed in the *Food and Drugs Act* and the *Controlled Drugs and Substances Act* and related Regulations. Links to these documents can also be found on our web site.

Health Canada's Therapeutic Products Directorate web site at:  
[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/index_e.html) can provide further information on drug products and medical devices.

Health Canada's Natural Health Products Directorate web site at:  
[http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodnatur/index_e.html) can provide further information on natural health products.