

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 Document

How to Submit a Consumer Complaint

Guide-0044

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How to Register a Complaint about a Product
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What is the mandate of the Health Products and Food Branch Inspectorate? Page 3

What is a Health Product? Page 3

What information does HPFBI need to process a complaint? Page 3

What happens after a complaint is submitted? Page 4

Client Satisfaction Page 5

Whom do I contact? Page 5

Health Products and Food Branch Inspectorate - Operational Centres Page 5

 ATLANTIC OPERATIONAL CENTRE Page 5

 QUEBEC OPERATIONAL CENTRE Page 5

 ONTARIO OPERATIONAL CENTRE Page 6

 MANITOBA AND SASKATCHEWAN OPERATIONAL CENTRE Page 6

 WESTERN OPERATIONAL CENTRE Page 6

Where can I obtain additional information about health products? Page 6

What is the mandate of the Health Products and Food Branch Inspectorate?

Health Canada's mission is to help the people of Canada maintain and improve their health. With this in mind, the Health Products and Food Branch Inspectorate (referred to as HPFBI) is committed to verifying complaints from consumers regarding the quality or safety of health products.

The priority given to verifying such complaints is guided by the level of risk to public health.

What is a Health Product?

Health products are any products represented with some health benefit and include pharmaceutical drugs, medical devices, biologics, blood, human cells, tissues, donor semen, organs for transplantation, and natural health products sold in Canada.

Strictly speaking, such products are defined as “drugs”, “natural health products (NHPs)”, or “devices” as per the *Food and Drugs Act* or the *Controlled Drugs and Substances Act* and related Regulations. Various levels of scrutiny are laid out in legislation and regulation of health products, depending on the risk of the health product to the patient, user, or public.

With respect to drugs and NHPs, consumers are encouraged to look for a Drug Identification Number (DIN), Natural Product Number (NPN), or Homeopathic Medicine Number (DIN-HM) which are eight digit numbers that should be easily identified on any drug product label. The DIN, NPN, or DIN-HM indicates that the drug product has been evaluated/reviewed by Health Canada. While exempted for low risk class 1 medical devices, manufacturers of higher risk class 2, 3, and 4 medical devices are required to have a Device Licence from Health Canada before their products can be sold. Refer to the Medical Device Active Licence Listing (MDALL), located at www.mdall.ca, for a listing of devices for which licences have been issued.

What information does HPFBI need to process a complaint?

The information you provide is of value to us. To assist us in our verification of a complaint, we look for information such as:

- written details (what, when, where, who and how something happened);
- any contact made with the company or store;
- trade name/common name of the health product, list of ingredients;
- DIN, NPN, DIN-HM, or Device Licence Number if applicable and known;
- catalogue number, lot number, expiry date, etc;
- copies of labels of the product in question;
- price lists or order forms or flyers which show the name of the company and product in question;

- invoices, receipts, etc. showing the date of sale, if of interest for the compliance verification;
- advertising or promotional material; if taken from newspapers or magazines, the name of the newspaper or magazine and the date on which it appeared;
- any other information which would assist the Inspectorate in verifying the complaint;
- complainant contact information.

The above information, along with the health product in question and its packaging, should be forwarded by mail to the HPFBI office responsible for your province (see “Whom do I contact”). Alternatively, you can call the Inspectorate toll free number at: 1-800-267-9675.

What happens after a complaint is submitted?

When the HPFBI receives a complaint, the information is reviewed to determine if the nature of the complaint falls within the jurisdiction of the HPFBI. Following the initial review:

- you will be sent confirmation that the complaint was received and that appropriate action will be taken by the Inspectorate, or;
- if the HPFBI is not the appropriate organization to verify the complaint, you will be notified of the organization (including its name and address) to which it should be referred and why. Before we refer your complaint, we will seek your written permission. The complaint will be forwarded only after your authorization has been given.

Since the HPFBI manages many complaints within its jurisdiction, these complaints are prioritized according to the risk to health that the product may impose on the general public. Incidents considered a higher risk will be dealt with first.

Once a complaint is accepted for verification, an Inspector will:

- determine if the health product violates any of the legislation or regulations for which the Inspectorate is responsible;
- communicate with the responsible agent in Canada for the health product in question to verify if a corrective action is required;
- when appropriate, monitor the actions taken by the responsible agent until the completion of the compliance verification, or;
- if the responsible agent is located in another operational centre, refer the incident to the HPFBI office in that other operational centre.

We will then inform you by telephone, mail, or electronically, whether the complaint will result in enforcement action, and will notify you when the action has been completed.

Actions taken will be consistent with the HPFBI’s compliance and enforcement policies and procedures. Not all complaints will result in enforcement action. Our objective is to achieve compliance using the most appropriate level of intervention. When verifying compliance with a company, the HPFBI will clarify the

applicable legislative and regulatory requirements to the company, but it is ultimately the responsibility of the company to identify and implement actions to ensure compliance. If a company does not take the necessary action, the HPFBI may take enforcement actions appropriate to the identified health risk.

Client Satisfaction

Your opinion is important to us. If you are not satisfied with the manner in which your complaint was handled, please let us know. You may call or write to the Health Products and Food Branch Inspectorate Operational Centre responsible for your province, listed below.

Whom do I contact?

Consumer complaints should be submitted in writing, whenever possible, 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
16th floor, suite 1625
1505 Barrington Street
Halifax, Nova Scotia
B3J 3Y6
Tel: (902) 426-2160
Fax: (902) 426-6676
E-mail: 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

ONTARIO OPERATIONAL CENTRE

Health Products and Food Branch Inspectorate
2301 Midland Avenue
Scarborough, Ontario
M1P 4R7
Tel: (416) 973-1600
Fax: (416) 973-1954
E-mail: 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

WESTERN OPERATIONAL CENTRE

Health Products and Food Branch Inspectorate
4th Floor
4595 Canada Way
Burnaby, British-Columbia
V5G 1J9
Tel: (604) 666-3704
Fax: (604) 666-3149
E-mail: 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 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 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 can provide further information on natural health products.