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# Compliance and enforcement policy for health products



POL-0001

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Canada 

## Compliance and enforcement policy for health products (POL-0001)

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### **Disclaimer**

This document does not constitute part of the *Food and Drugs Act* (the Act) or its regulations and in the event of any inconsistency or conflict between the Act or regulations and this document, the Act or the regulations take precedence. This document is an administrative document that is intended to facilitate compliance by the regulated party with the Act, the regulations and the applicable administrative policies.

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# 1. Introduction

The *Food and Drugs Act* (Act) and its regulations establish the framework to protect the safety of health products available to Canadians and to prevent deception in relation to these products. This framework includes a set of prohibitions and penalties, provides oversight and for the licensing of health products and activities conducted in relation to products imported or sold in Canada, and establishes national standards on how such activities should be conducted to protect public health and safety.

## 2. Purpose

As part of its regulatory responsibilities, Health Canada monitors compliance, undertakes enforcement activities and works towards preventing non-compliance. This policy describes Health Canada's national compliance and enforcement approach for health products regulated under the Act and its regulations (hereinafter referred as the Act).

## 3. Background

Established on April 4, 2016, the Regulatory Operations and Enforcement Branch (ROEB) is a dedicated compliance and enforcement Branch within Health Canada. ROEB brings together Health Canada compliance and enforcement functions within one organization.

The current regulatory environment is characterized by complex global supply chains generating products that are manufactured and distributed around the world; rapid scientific innovation and advanced technologies; changing consumer behaviors; and increased demands for transparency regarding regulatory decision-making. Canadians are increasingly exposed to:

- products originating from jurisdictions which may not have a regulatory regime comparable to Canada's
- the sale of unapproved health products that may pose safety issues from suppliers conducting transactions via the internet

It has become increasingly important to have a strong and dynamic compliance and enforcement function to protect Canadians' health through modern legislation and effective compliance and enforcement actions supported by strong border oversight and international cooperation.

ROEB's mission is to lead compliance and enforcement activities and complementary scientific programs to inform and protect Canadians from health risks associated with products,

substances and their environment. ROEB is also the centre for regulatory and policy expertise related to compliance and enforcement activities.

## 4. Scope

This policy applies to Health Canada compliance and enforcement activities conducted in relation to health products that fall under the Act.

The regulated products under this Act include:

- medical devices
- human drugs
- natural health products
- semen for assisted conception
- blood and blood components for transfusion
- cell, tissues and organs for transplantation
- veterinary drugs

The regulated activities under this Act include, but are not limited to:

- selling
- manufacturing/fabricating
- processing
- packaging/labelling
- testing
- importing
- distributing
- wholesaling

The regulatory landscape is constantly changing to adapt to new sectors and products. As new health products and activities become available and are regulated under the umbrella of the Act, this policy will apply to the oversight of these products and activities.

## 5. Guiding principles

The work of Health Canada serves to advance the purposes of the Act, which are to protect the safety of the public and prevent deception, including the conduct of an activity that would create a false or misleading impression in relation to health products. [Health Canada's Compliance and Enforcement Policy Framework](#) identifies a number of principles that guide Health Canada in carrying out its compliance and enforcement activities. Health Canada emphasizes the following guiding principles in the application of the Act under its mandate.

### a. Evidence-based

Health Canada's compliance and enforcement actions and decisions are based on the best available evidence, information and science. Evidence is assessed objectively and is based on the [Health Canada Decision Making Framework for Identifying, Assessing, and Managing Health Risks](#). Where relevant evidence is incomplete or inconclusive, a precautionary approach may be taken. As new information becomes available, the risk may change and require a different approach to compliance and enforcement.

### b. Risk-based approach

Health risks can happen in a variety of ways, such as through the sale of an unauthorized health product; by diverging from quality and safety requirements in manufacturing a product or by using an active pharmaceutical ingredient that is contaminated or of substandard quality. Contraventions to labelling and advertising regulatory requirements may also put the health of Canadians at risk as they rely on this information to select and use these products. The choice of a particular compliance and enforcement action is informed by a risk-based approach that encompasses identifying, assessing and managing health risks.

When a regulated product or activity does not comply with the law, Health Canada makes an assessment to determine the most appropriate type of intervention. This assessment takes into account the characteristics of the product or the activity that may pose a risk to the health of Canadians such as:

- the safety and efficacy profile or risk classification of the health product
- the route of administration of the health product
- the significance of the deviation from a prescribed standards in the conduct of a regulated activity

- the complexity of the regulated activities or operations conducted in relation to the health product
- the site or establishment status of the party conducting the regulated activity
- the exposure of Canadians to the product

In determining the most appropriate type of intervention, Health Canada also considers factors related to the conduct of the regulated party and the need to maintain public confidence in the overall integrity of the regulatory regime including the public's perception of risk. For example, Health Canada will take into consideration:

- the behaviours of the regulated party conducting the activity, such as whether the regulated party acted with indifference, recklessness or premeditation
- the degree of co-operation and responsiveness offered by the regulated party
- the compliance history of the regulated party and previous compliance issues, including the regulated party's past and recent actions to comply with the law
- the likelihood of repeat compliance issues
- the likelihood of the enforcement action being effective in bringing the party into compliance or in mitigating the risk

Depending on the issue, additional factors may be taken into considerations such as the need to allow Canadians to have continued access to medically necessary products or other unique circumstances.

### **c. Fairness, consistency and impartiality**

Health Canada works to apply the Act in a fair, consistent and impartial manner. Qualified and authorized personnel are trained to carry out compliance and enforcement activities in a professional, unbiased and unprejudiced manner.

Health Canada follows a national approach to compliance and enforcement, regardless of where or by whom the products are produced, distributed, advertised, sold, imported or exported. To work towards ensuring consistency in the compliance and enforcement approach requires Health Canada inspectors to be trained on the relevant policies, guidelines and standard operating procedures.

While Health Canada strives for consistency in decision-making, the context and the circumstances applicable to a particular situation may trigger different compliance and enforcement responses to address issues of non-compliance and to hold a non-compliant party accountable.

Health Canada staff are guided by the [Values and Ethics Code for the Public Sector](#).

## d. Transparency

Health Canada strives to make information about compliance and enforcement activities public. By making policies and guidance documents public, information on the decision-making process is clear and understandable to everyone. The Department provides access to information regarding compliance and enforcement actions while respecting privacy rights, where appropriate. For example, Health Canada makes available the results of health product establishment inspections so that consumers in Canada and abroad can make informed choices when buying health products.

Regulated parties can expect to see an increase in the type and scope of compliance and enforcement decisions made public. This approach is consistent with the Government of Canada's Open Government commitment to make government decisions, data and information more accessible to everyone.

## 6. Role of Health Canada

ROEB is the organization in Health Canada responsible for the delivery of a national compliance and enforcement program for all health products regulated under the Act.

ROEB carries out inspections and other compliance and enforcement activities that follow applicable laws, policies and guidance documents. ROEB staff includes trained inspectors and laboratory analysts.

Inspectors' powers are described under section 23 of the Act. Section 23 states that "an inspector may, at any reasonable time, enter any place where the inspector believes on reasonable grounds any article to which the Act or the regulations apply is manufactured, prepared, preserved, packaged or stored." Respecting the parameters prescribed by section 23, this includes the authority to enter any place to verify that a regulated party still conducts an activity for which an establishment licence has been issued under the Act. The inspector may also enter dwelling houses for inspection purposes under the authority of an administrative entry warrant. During an inspection, an inspector may examine any article, take samples for laboratory analysis, make copies, open packages, and seize and detain articles. The Act also contains provisions for the destruction of articles regulated under the FDA regime in certain circumstances. ROEB provides support to regulated parties, consumers and other stakeholders to become aware of their responsibilities with respect to the legislation governing health products in Canada, including the consequences associated with non-compliance.



## 7. Roles and responsibilities of other parties

It is against the law to advertise, import or sell—at retail or through the Internet—drugs or devices that are not approved for sale in Canada. Anyone conducting a regulated activity under the Act has clearly defined responsibilities for the safety, efficacy and quality of health products imported or sold in Canada. Other parties may also be subject to the Act although they may not require an authorization from Health Canada to perform certain activities. For example, while wholesalers of non-prescription drugs and active pharmaceutical ingredients do not require authorisation from Health Canada (such as an establishment or a site licence) to conduct their activity, they are subject to section 8 of the Act that prohibits the sale of a drug that is adulterated or manufactured, prepared, preserved, packaged or stored under unsanitary conditions.

The primary responsibility of a regulated party is to understand its obligations under the Act and to comply with these requirements. Regulated parties who fail to comply will be subject to compliance and enforcement actions.

### a. Regulated parties

Regulated parties have **mandatory** responsibilities under the Act. Any party conducting a regulated activity can be inspected. Foreign establishments that conduct regulated activities in Canada or in relation to a product sold, imported or advertised in Canada are also subject to Canadian law.

During an inspection, a regulated party is required to provide all reasonable assistance and information necessary for the inspector to perform their duties. An inspector may request that a regulated party provides evidence that its facility, equipment and practices and procedures meet the applicable requirements. Obstructing or hindering an inspector who is carrying out their duties or functions is an offence under the Act.

Regulated parties are expected to:

- understand the relevant law and their obligations
- ensure their products, activities and processes comply with the applicable laws
- assist inspectors during an inspection as required by law

## b. Healthcare practitioners

Professional bodies regulate healthcare practitioners under provincial law. However, they may also have obligations under the Act if they conduct a regulated activity.

The [Food and Drugs Regulations](#) define the term practitioner as “a person who is entitled under the laws of a province to treat patients with a prescription drugs and who is practicing in that province.” According to that definition, practitioners include physicians, dentists, pharmacists, veterinarians and other professionals working directly in the healthcare field.

Physicians and other healthcare professionals are responsible for the health products that they administer, sell or prescribe to patients. Healthcare professionals should ensure that the health products they buy, use, or sell are authorized for sale in Canada and purchased through a Health Canada licensed, registered - or authorized sources.

Healthcare professionals should inform Health Canada of any problems they suspect or encounter related to health products including adverse events, malfunctions, and any issues of non-compliance or general health product concerns. In some cases, healthcare institutions must disclose by law certain health product related incidents to Health Canada. For more information on [how to report an adverse reaction to Health Canada](#) you can consult Health Canada website.

## c. Retailers

Although an establishment license is not required for retail sale, retailers can only sell health products that Health Canada has authorized for sale (for products where authorizations are required). This prohibition applies whether the sale occurs through the internet or in a physical location in Canada.

# 8. Compliance and enforcement actions and tools

Health Canada manages the risk posed to public health and safety by health products through various types of compliance and enforcement activities. Health Canada chooses the actions and tools that are most appropriate for the situation, based on a number of factors. Some activities are designed to help regulated parties understand their responsibilities under the Act. Others are designed to induce or compel compliance with the law.

[Health Canada’s Compliance and Enforcement Policy Framework](#) provides an illustration of the different levels of compliance and enforcement actions and shows how the different types of actions and tools can be used.

Informed by the assessment of available evidence and risks pertaining to the situation of non-compliance, the inspector will decide to use these actions and tools individually or together. The Inspector will also decide if the seriousness of the non-compliance and the risk posed to the health and safety of Canadians warrants an immediate strong and unequivocal response such as a licence suspension, an injunction or prosecution. In other circumstances, a compliance and enforcement response proportionate to the identified risk will provide the regulated party with an opportunity to come into compliance. When the risk changes or considerations related to risk management evolve, Health Canada will adapt the type of enforcement response and the type of actions to the situation. If the situation of non-compliance persists, additional actions will be taken and will graduate towards stronger compliance and enforcement actions.

The compliance and enforcement activities include:

- active prevention of problems through compliance promotion
- targeted oversight of risks through proactive compliance monitoring
- rapid response and enforcement to address detected public health risks

## a. Compliance promotion

Health Canada strives to support regulated parties in actively preventing problems from occurring in the first place. Compliance promotion focuses on raising awareness and educating regulated parties about their obligations under the Act. Health Canada publishes policies and guidance documents so that regulated parties understand Health Canada's interpretation of the legislation, the processes to be followed and the scientific standards or principles that will be applied. Health Canada raises awareness amongst regulated parties regarding the range of compliance and enforcement actions available in cases of non-compliance. Compliance promotion also includes providing information to consumers to enable them to make well-informed choices with respect to health products.



### Consumers

Consumers have a role to play when they buy and use health products. For example, consumers should only use health products for the purposes intended and follow the directions on the label and their healthcare practitioner's instructions.

Consumers also have a responsibility to educate themselves when buying

health products and to be careful when buying health products from the Internet. Consumers can recognize products authorised for sale in Canada by their Drug Identification Number (DIN) or their Natural Product Number (NPN). DIN and NPN are assigned to each product marketed under or in accordance with the relevant regulations. Consumers can check information about a product's [marketing authorization](#) on Health Canada's website.

Consumers can also find [recall and safety alerts on](#) Health Canada's website.

Canadians are encouraged to [report to Health Canada](#) any problems they encounter with health products. This will help Health Canada to identify safety concerns.

## b. Compliance monitoring

Health Canada carries out compliance monitoring activities to proactively verify compliance with the Act to respond to issues of non-compliance and to address the risk posed to the health of Canadians. Monitoring activities vary by product and include: pre and post establishment licensing inspections, product sampling and laboratory analysis of health products. Inspections may involve, but are not limited to, actions such as:

- visual examination of a facility, inventories, equipment, packaging, labelling and websites
- collection and review of documents and records
- collection of samples for laboratory analysis

The frequency, intensity and nature of compliance monitoring activities may vary according to the risks identified. Health Canada uses the information gathered through compliance monitoring to determine if further regulatory action is required. In particular, Health Canada

- administers establishment licences
- gathers and analyzes a range of information such as complaints and adverse drug reaction reports sent to Health Canada and compliance and enforcement information shared by foreign regulators
- carries out activities to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the Act
- collaborates with other regulatory agencies as appropriate

## c. Enforcement

Enforcement actions include any actions ROEB takes to compel or induce compliance in order to mitigate the risk identified by non-compliance with the Act.

### Enforcement Responses

Contravention of the provisions under the Act, whether intentional or unintentional, is unacceptable. When Health Canada identifies a contravention of the Act, it has a number of enforcement powers available to compel or induce compliance. There are a number of enforcement actions that Health Canada may take to prevent or address non-compliance, or to address an issue of public health and safety. These include:

- sending letters to non-compliant regulated parties requesting that the regulated party submit a plan for corrective measures
- issuing public advisories or other forms of risk communication
- requesting a voluntary stop sale or recall
- recommending the refusal or seizure of imports at the border
- requesting an importer take corrective measures on a product under certain conditions or consent to its removal from Canada or to its forfeiture
- ordering the removal or destruction of imports at the border
- ordering the holder of a therapeutic product authorisation to conduct an assessment of the product
- adding new terms and conditions to the establishment licence or product authorization
- issuing a recall order in relation to a therapeutic product
- seizure and detention, forfeiture and destruction
- refusal, suspension, cancellation or revocation of an authorisation, a licence or a registration

Health Canada may also apply for a court injunction to prevent conduct in relation to therapeutic products that would lead to the contravention of the Act.



#### Section 21.5

*If, on the application of the Minister, it appears to a court of competent jurisdiction that a person has done, is about to do or is likely to do anything*

*that constitutes or is directed toward the commission of an offence under this Act in respect of a therapeutic product, the court may issue an injunction ordering the person, who is to be named in the application, to*

*(a) refrain from doing anything that it appears to the court may constitute or be directed toward the commission of the offence; or*

*(b) do anything that it appears to the court may prevent the commission of the offence.*

Based on the severity of the risk posed by regulatory non-compliance, Health Canada determines the most appropriate level of intervention. In alignment with the [Health Canada Compliance and Enforcement Policy Framework](#) and informed by the specifics of each case, Health Canada will choose the most appropriate tool to achieve compliance and mitigate any risks to health.

Regulated parties who are subject to a regulatory action or a decision will be provided with a reasonable opportunity to be heard when prescribed by the Act.

## Other Enforcement Responses – Investigation and Prosecution

In certain circumstances, Health Canada's regulatory enforcement responses are not appropriate to achieve compliance. In these instances, Health Canada may conduct an investigation into potential offences under the Act or make a referral to law enforcement.

### Investigation

An investigation involves collecting evidence under the authorities available in the *Criminal Code of Canada* (e.g., search warrant and production order). Priority will be given to contraventions by parties who demonstrate a disregard for the legislative and regulatory requirements; who have a history of contravening the Act or who are engaging in activities that could cause serious harm (e.g. unlicensed activities, intentional avoidance of the law or sale of unapproved products).

### Prosecution

Health Canada may refer the results of its investigation to the Public Prosecution Service of Canada recommending prosecution in relation to offences under the Act and the *Criminal Code of Canada* where applicable.

Sections 31, 31.2, and 31.4 of the Act contain offence provisions which provide for a fine, a term of imprisonment, or both.



### Section 31

*Subject to sections 31.1, 31.2 and 31.4, every person who contravenes any of the provisions of this Act or of the regulations, or fails to do anything the person was ordered to do by an inspector under section 25 or 27.2, is guilty of an offence and liable*

*(a) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both and, for a subsequent offence, to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months or to both; and*

*(b) on conviction on indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both.*



### Section 31.2

*Subject to section 31.4, every person who contravenes any provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections 21.1 to 21.32 is guilty of an offence and liable*

*(a) on conviction by indictment, to a fine not exceeding \$5,000,000 or to imprisonment for a term not exceeding two years or to both; and*

*(b) on summary conviction, for a first offence, to a fine not exceeding \$250,000 or to imprisonment for a term not exceeding six months or to both and, for a subsequent offence, to a fine not exceeding \$500,000 or to imprisonment for a term not exceeding 18 months or to both.*



#### Section 31.4

*A person who contravenes section 21.6, or who knowingly or recklessly causes a serious risk of injury to human health in contravening another provision of this Act or the regulations, as it relates to a therapeutic product, or an order made under any of sections 21.1 to 21.32 is guilty of an offence and liable*

*(a) on conviction on indictment, to a fine the amount of which is at the discretion of the court or to imprisonment for a term not exceeding five years or to both; and*

*(b) on summary conviction, for a first offence, to a fine not exceeding \$500,000 or to imprisonment for a term not exceeding 18 months or to both and, for a subsequent offence, to a fine not exceeding \$1,000,000 or to imprisonment for a term not exceeding two years or to both.*

Sections 31 and 31.2 offences are strict liability offences. This means that the accused can raise a defence of due diligence demonstrating that reasonable steps were taken to satisfy the requirements of the Act.

Section 31.2 of the Act provides for significant penalties and term of imprisonment when the committed offence relates to therapeutic products.

Section 31.4 provides for mens rea offences which may result in significant penalties and term of imprisonment. A mens rea offence means that the Public Prosecution Service of Canada has to prove that the accused:

- had the intention to commit the offence, or
- possessed the knowledge that the action or the lack of action would result in an offence being committed.



# Appendix A – Glossary

## Acronyms

DIN: Drug Identification Number

NPN: Natural Product Number

ROEB: Regulatory Operations and Enforcement Branch

## Terms



These definitions explain how terms are used in this document. If there is a conflict with a definition in the *Food and Drugs Act* or associated regulations, the definition in the Act or regulations prevails.

**Authorization (including establishment, site and product licences)** – A legal document issued by Health Canada authorizing a health product or a regulated activity based on the health and safety requirements of the Act.

**Compliance** – The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legislative or regulatory requirement.

**Compliance monitoring** – Actions planned to maintain regular surveillance in order to evaluate compliance with applicable requirements of the Act and its associated regulations. This includes a wide variety of fact gathering and assessment activities such as inspections, market surveys and a product sampling program.

**Compliance promotion** – Actions taken to educate about roles and responsibilities prescribed by the Act.

**Enforcement** – Actions that may be taken to compel or induce compliance in order to mitigate the risk identified by non-compliance with the Act and its associated regulations.

**Inspection** – Monitoring and assessment against the applicable requirements of the Act and its associated regulations. Inspections are routinely conducted based on risk to assess compliance.

**Inspector** – Any person designated as an inspector under section 22 of the Act.

**Therapeutic Products** – A drug or device or any combination of drugs and devices, but does not include a natural health product within the meaning of the *Natural Health Products Regulations*.

# Appendix B – References

## Laws and regulations

### [Criminal Code of Canada](#)

[laws-lois.justice.gc.ca/eng/acts/C-46/](https://laws-lois.justice.gc.ca/eng/acts/C-46/)

### [Food and Drugs Act](#)

[laws-lois.justice.gc.ca/eng/acts/f-27/](https://laws-lois.justice.gc.ca/eng/acts/f-27/)



Regulations made under the *Food and Drugs Act* include:

- Blood Regulations
- Cosmetic Regulations
- Food and Drug Regulations
- Medical Devices Regulations
- Natural Health Products Regulations
- Processing and Distribution of Semen for Assisted Conception Regulations
- Safety of Human Cells, Tissues and Organs for Transplantation Regulations

All regulations made under the Act can be accessed by clicking on the link attached to the *Food and Drug Act*.

## Other related documents

### [Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks](#)

[canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html](https://www.canada.ca/en/health-canada/corporate/about-health-canada/reports-publications/health-products-food-branch/health-canada-decision-making-framework-identifying-assessing-managing-health-risks.html)

### [Health Canada's Compliance and Enforcement Policy Framework](#)

[canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html](https://canada.ca/en/health-canada/corporate/mandate/regulatory-role/what-health-canada-does-as-regulator/compliance-enforcement-framework.html)

[Values and Ethics Code for the Public Sector](https://tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049)

[tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049](https://tbs-sct.gc.ca/pol/doc-eng.aspx?id=25049)

## Websites

[Drug products](https://canada.ca/en/health-canada/services/drugs-health-products/drug-products.html) on Health Canada's website

[canada.ca/en/health-canada/services/drugs-health-products/drug-products.html](https://canada.ca/en/health-canada/services/drugs-health-products/drug-products.html)

[How to report an adverse reaction to Health Canada](https://canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html)

[canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html](https://canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html)

[Recalls and safety alerts](https://healthykanadians.gc.ca/recall-alert-rappel-avis/index-eng.php)

[healthykanadians.gc.ca/recall-alert-rappel-avis/index-eng.php](https://healthykanadians.gc.ca/recall-alert-rappel-avis/index-eng.php)