Policy on inspector orders for health products

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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. Purpose

The purpose of this policy is to inform stakeholders of the legislative provisions for inspector orders as provided for under the *Food and Drugs Act* (Act).

This policy explains:

- the general circumstances where an inspector might issue an order
- the general conditions of using inspector orders
- the rights and responsibilities of parties
- the consequences for parties that obstruct, hinder or provide false information, or fail to provide reasonable assistance to an inspector and any person(s) accompanying them

2. Background

This policy is an administrative document. It is intended to help stakeholders comply with the *Food and Drugs Act* and its regulations, as well as applicable administrative policies. If there is inconsistency or conflict between the Act or regulations and this policy, the Act or regulations take precedence.

The Act and regulations establish a regulatory framework to help protect the health and safety of people who use regulated health products. The regulatory framework also helps to prevent deception in relation to these products.

Under Health Canada's Regulatory Operations and Enforcement Branch (ROEB), two directorates are responsible for the compliance and enforcement of health products:

- Health Product Compliance Directorate (HPCD)
- Medical Devices and Clinical Compliance Directorate (MDCCD)

HPCD and MDCCD staff monitor or verify that health products comply with the Act and its regulations.

The Minister of Health designates inspectors to administer and enforce the Act. They have the authority to enter certain places as described in the Act, as well as the power to issue orders with a view to verify or prevent non-compliance. These orders do not require judicial authorization. The authority to issue an order is provided for regulatory purposes related to

reducing health risks associated with health products or activities pertaining to regulated health products.

An order for documents or information gives inspectors a lawful authority to obtain information that may be governed under other statues. These include privacy legislation such as the *Privacy Act* or the *Personal Information Protection and Electronic Documents Act*.

3. Responsibilities

Inspectors designated under subsection 22(1) of the Act:

- issue orders under the Act
- make the decision to issue, amend or cancel an order under the Act
- report to their supervisor or manager if the regulated party obstructs, hinders, provides false or misleading statements or refuses to provide all reasonable assistance
- ensure information collected from the regulated party is safely controlled and stored

Parties regulated under the Act must:

- understand their legal obligations
- comply with the legislative provisions
- be prepared to be inspected at any reasonable time
- identify the people who are required to provide information to the inspector and any individual(s) accompanying them, and ensure that these people are present during the inspection
- provide all reasonable assistance to the inspector
    - includes providing information that establishes their identity to the inspector's satisfaction

Under subsection 24(1), a regulated party may not obstruct, hinder or knowingly make false or misleading statements, either orally or in writing, to an inspector.

Parties who are not regulated under the Act may have information concerning a regulated health product or related activity. An inspector may order them to provide information. They will have a duty to comply with the order.

Under these provisions, a person must provide an inspector with any information that an inspector may reasonably require.

Failure to comply with these provisions is an offence.

4. Scope

This policy applies to inspector orders as provided for in the Act. Inspectors designated under ss.22(1) of the Act may issue orders to verify compliance or prevent non-compliance with the Act and its regulations for a range of health products. These include:

- medical devices
- human drugs (pharmaceuticals, biologicals, radiopharmaceuticals)
- natural health products
- blood and blood components for transfusion or for the use in the manufacture of a drug for human use
- cells, tissues and organs for transplantation
- veterinary drugs and veterinary health products

5. Policy Statement

Any person whose activities are subject to the Act and its regulations must comply with the legislation. An inspector order is a statutory tool issued by an inspector. It is used to compel the person ordered to take one of the following actions, as laid out in subsections of the Act:

- 22.1(1) provide information, documents or samples
- 23(5) stop or move a conveyance
- 25(b) store or move seized product
- 25(c) dispose of seized product
- 27.2(1) remove non-compliant health products imported to Canada or destroy if removal is not possible

An order to provide information or documents is not limited to information or documents prepared and maintained as a requirement under the Act. Any person can be compelled to produce documents, information, or samples specified and used by the inspector to verify compliance or prevent non-compliance with the Act or its regulations.

The authority for inspectors to issue orders is essential to the effective administration of the Act. It also helps to protect consumers by mitigating risk to their health and safety. Failure to provide all reasonable assistance to an inspector and any individual(s) accompanying them is a serious offence. Health Canada may take action, using measures outlined in the *Compliance and enforcement policy for health products (POL-0001)*.

All records collected through inspector orders are handled in accordance with Health Canada's *Policy on collection and retention of records related to health product compliance and enforcement (POL-0140)*.

6. Inspector Orders

Under the Act, the inspector has certain powers to verify compliance with the Act and regulations, as well as to prevent non-compliance.

6.1 Authority for inspectors to issue orders

An inspector may issue an order in accordance with one of five separate subsections of the Act: 22.1(1), 23(5), 25(b), 25(c) or 27.2(1). An order issued in accordance with subsection 22.1(1) must be for the purpose of verifying compliance or preventing non-compliance with the Act. Each subsection authorizing an inspector order has one or more specific requirements that must be met to issue an order.

Provision of documents, information or samples (subsection 22.1(1))

An inspector may, for a purpose related to verifying compliance or preventing non-compliance with the provisions of this Act or the regulations, order a person to provide any documents, information or samples specified by the inspector. This information may be provided on or before the date and time, and at the place and in the manner specified by the inspector.

Stopping or moving conveyance (subsection 23(5))

For the purpose of entering a conveyance, an inspector may order the owner or person having possession, care or control of the conveyance to stop it or move it.

Storing, moving or disposing of seized articles (subsection 25)

An inspector may order its owner or the person having possession, care or control of a seized article to store it or move it at the expense of the person being ordered. Alternatively, with notice to its owner or the person having possession, care or control of it at the time of its seizure, an inspector may dispose of it at the expense of the person to whom the notice is given, if:

- the article is perishable or
- the inspector is of the opinion that the article presents a risk of injury to health or safety, and that its disposal is necessary to respond to the risk

Removal or destruction of non-compliant imported health products (subsection 27.2(1))

A non-compliant imported health product is an imported drug, cosmetic or device that does not meet the requirements of the regulations or was imported in contravention of the Act or the regulations. If an inspector has reasonable grounds to believe a product is non-compliant, the inspector may:

- order it to be removed from Canada at the person's expense
- destroy it at the person's expense if removal is not possible

6.2 Issuance of an inspector order

An order is made in accordance with the *Compliance and enforcement policy for health products (POL-0001)*. An order may be used when a specific action is required from the person ordered, as well as a response within a specified timeframe. The inspector will usually sign and issue the order in writing. If an order is issued verbally, in most cases it will be followed by a written order no later than the next business day. Orders under subsection 27.2 will always be in writing.

The following information will be included in the order:

- the name of the person who is being ordered is responsible for complying with the order in accordance with the respective subsection of the Act, as follows:
    - 22.1(1) any person
    - 23(5) the owner or person having possession, care or control of the conveyance
    - 25(b) the owner or person having possession, care or control of article(s) at the time of the seizure
    - 25(c) the owner or person having possession, care or control of the article(s) at the time of the seizure
    - 27.2(1) the owner, importer or person having possession, care or control of the non-compliant imported health products
- the subsection(s) of the Act or regulations authorizing the order and a short description:
    - 22.1(1) provide information, documents or samples specified by the inspector
    - 23(5) stop or move a conveyance
    - 25(b) store or move seized product
    - 25(c) dispose of seized product or
    - 27.2(1) remove non-compliant health products imported to Canada or destroy if removal is not possible
- sufficient detail so the person knows what is being ordered. For example, an order under subsection 22.1(1) order will include:

    - a clear description of the information or documents or samples
    - when the information must be provided to the inspector (on a specific date or before a specific date), including the time zone, for example, eastern standard time
    - where the documents or information or samples is given or received
    - how the documents or information or samples must be delivered (for example, email, traceable mail service, in person)
- deadline for required action
- a brief explanation for why the order is being issued

6.3 After the order is issued

The person ordered must comply with the order. An order is valid until the inspector is satisfied it has been fulfilled or has been cancelled. Once satisfied, the inspector will inform the person that it has been fulfilled.

If the order is to provide a sample, the inspector will provide the person with a sample receipt.

Under subsection 27.2, if an order deadline for the removal of an import from Canada, or its destruction if removal is not possible, has passed, the articles are forfeited to Her Majesty in right of Canada. They may be disposed of as the Minister may direct. A request for deadline extension under subsection 27.2(1) can be made by communicating directly with the inspector in writing.

6.4 Amending or cancelling the order

If, after issuing an order, the inspector determines the order is no longer necessary, the inspector may cancel the order. The inspector will notify the recipient in writing that the order is no longer in effect.

If after issuing an order, the inspector determines an amendment is necessary, the inspector will cancel the original order and issue a new order.

6.5 Failure to comply with the order

Failure to comply with an order is a serious offence. It may result in the use of other enforcement tools, outlined in Health Canada's *Compliance and enforcement policy for health products (POL-0001)*.

6.6 Obstructing, providing false information or failing to provide assistance

Obstruction, hindering, knowingly lying, or failing to provide all reasonable assistance to an inspector who is carrying out their duties or functions are offences under the Act and will not be tolerated. Further compliance and enforcement actions that may be taken are outlined in the *Compliance and enforcement policy for health products (POL-0001)*.

The inspection provisions in the Act are designed to protect consumers who are vulnerable to risks posed by health products and their advertising. It is a violation of subsection 24(1) to prevent an inspector from inspecting or to make false or misleading statements, orally or in writing.

Depending on the classification of the health product involved and the election of the prosecutor to proceed summarily or on indictment, a violation may result in prosecution. If convicted, a person could be fined or be imprisoned.

Subsection 23(13) puts a duty on the owner or person in charge and any person found in a place entered by an inspector to provide:

- reasonable assistance
- required information

Appendix A – Glossary

Acronyms

HPCD: Health Products Compliance Directorate

MDCCD: Medical Devices and Clinical Compliance Directorate

ROEB: Regulatory Operations and Enforcement Branch

Terms

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

Compliance verification: Actions taken to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the Act and its regulations. This includes actions such as gathering information either off-site or through on-site inspections.

Consent: Consent given by an individual that is the result of free choice. The statement is obtained without compulsion or coercion.

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

Forfeiture (with consent): Relinquishing of property by the regulated party, where the Act or the regulations apply to the property. It is accomplished through the consent of the regulated party who is the owner of the article or the person who has possession, care or control of the article at the time of the seizure.

Health product: Includes any product regulated under the Act and falling within the mandate of the Medical Devices and Clinical Compliance Directorate (MDCCD) and Health Product Compliance Directorate (HPCD), such as:

- pharmaceutical, biological and radiopharmaceutical drugs for human use
- veterinary drugs
- medical devices
- natural health products

- blood and blood components for transfusion or for use in the manufacture of a drug for human use
- cells, tissues and organs for transplantation

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

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

Investigation: Actions taken to gather evidence to support case referral for potential prosecution regarding specific violations of the *Food and Drugs Act* and its associated regulations. This includes activities carried out under the *Criminal Code*, such as taking witness statements and executing search warrants.

Inspector order: A direction from an inspector that is authorized by statute. Failing to comply with an Order is an offence, which can be prosecuted.

Person: Defined in section 2 of the Act to mean an individual or an organization as defined in section 2 of the *Criminal Code*.

Reasonable grounds to believe: Beliefs based on compelling and credible information such as knowledge, experience, expert advice or other information from a reliable source. Vague suspicion, subjective opinion or speculations are not sufficient to meet the requirement of having reasonable grounds of belief.

Appendix B – References

Laws and regulations

Criminal Code of Canada
laws-lois.justice.gc.ca/eng/acts/C-46/

Food and Drugs Act
laws-lois.justice.gc.ca/eng/acts/f-27/

Interpretation Act
laws-lois.justice.gc.ca/eng/acts/i-21/index.html

Personal Information Protection and Electronic Documents Act
laws-lois.justice.gc.ca/ENG/ACTS/P-8.6/index.html

Privacy Act
laws-lois.justice.gc.ca/ENG/ACTS/P-21/index.html

Policies

POL-0001: Compliance and enforcement policy for health products
https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-manufacturing-practices/policies-standards/compliance-enforcement-policy-0001.html

POL-0140: Policy on collection and retention of records related to health product compliance and enforcement
https://canada-preview.adobecqms.net/en/health-canada/services/drugs-health-products/compliance-enforcement/policy-collection-retention-records-health-product-compliance-enforcement.html