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

POLICY-0001

Compliance and Enforcement Policy, Version 2

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Canada

Health Products and Food Branch Inspectorate's

COMPLIANCE AND ENFORCEMENT POLICY No. POL-0001

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1. PURPOSE

This document provides the staff and stakeholders of the Health Products and Food Branch Inspectorate (Inspectorate), as well as the public, with guiding principles for the fair, consistent, and uniform application and enforcement of the *Food and Drugs Act* (FDA) and its associated Regulations under the Inspectorate's mandate. The document clearly describes the Inspectorate's role in delivering a national compliance and enforcement program for all products under the Health Products and Food Branch (HPFB) mandate, with the exception of products regulated as foods, which are the responsibility of the Canadian Food Inspection Agency (CFIA). The policy also describes the roles of regulated parties, and the Inspectorate's relationship with consumers and health care professionals in relation to products and activities regulated by the HPFB.

2. BACKGROUND

Responsibility for health and safety is shared among healthcare professionals, industry, consumers, government, and other stakeholders. Laws are in place in order to promote the safety of products to which Canadians have access.

The mandate of the HPFB is to take an integrated approach to the management of the risks and benefits of health products and food by minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food; and, promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health. The HPFB administers its legislative and regulatory frameworks using risk management and scientific evidence to maximize the safety and quality of products available to Canadians.

The Inspectorate is responsible for branch-wide compliance and enforcement activities, enabling consistency of approach across the spectrum of regulated products. The Inspectorate core functions are compliance monitoring,

and compliance verification and investigation, supported by establishment licensing of drugs[1] and medical devices, and laboratory analysis.

This version 2 of Policy-0001 is the result of the first comprehensive revision since the Policy was first developed in 2001. The policy has been developed in cooperation with the Health Canada - Legal Services (Department of Justice) and is within the framework of Treasury Board guidelines. The policy is also the result of consultations with concerned Health Canada partners. The Inspectorate reviews this document periodically. The Inspectorate's Compliance and Enforcement Policy is a foundation document within the Inspectorate's Quality System Framework and is supported by an integrated set of documents guiding Inspectorate and regulated parties' activities.

3. SCOPE

This policy applies to all drugs and devices as defined by the FDA. This includes medical devices; human drugs, including NHPs; blood and blood components for transfusion; semen for assisted conception; cells, tissues, organs for transplantation; and veterinary drugs.

4. DEFINITIONS

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 FDA 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 Verification: Actions taken to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the FDA and its associated Regulations. This includes actions such as information gathering either off-site or via on-site visits.

Enforcement: Actions that may be taken to induce, encourage or compel compliance with the FDA and its associated Regulations.

Inspection: On-site monitoring and assessment against the applicable requirements of the FDA and its associated Regulations. Inspections are routinely conducted on a predetermined cycle or as required to assess compliance.

Inspector: Any person designated as an inspector for the purpose of the enforcement of the FDA under subsection 22(1).

Investigation: Actions taken to gather evidence to support a case referral for potential judicial determination regarding specific violations of the FDA and its associated regulations. This includes taking statements and activities carried out under the *Criminal Code,* i.e., executing search warrants.

[1] Site licensing of natural health product sites falls under the responsibility of the HPFB Natural Health Products Directorate.

Marketing authorization: A legal document issued by Health Canada, authorizing the sale of a drug or a device based on the health and safety requirements of the FDA and its associated Regulations. The marketing authorization may be in the form of a Drug Identification Number (DIN), a device licence for classes II, III and IV medical devices, or a natural health product licence (NPN or DIN-HM).

5. POLICY STATEMENT

The following guiding principles govern the Inspectorate in the application of the Act and *Regulations* under its mandate.

- **Transparency**

  The *Compliance and Enforcement Policy* is a public document.

  Consistent with and in the spirit of the *Privacy*[2] and *Access to Information*[3] Acts, the Inspectorate makes information on compliance and enforcement activities available to the public.

- **Fairness**

  The Act and *Regulations* are applied in a fair and equitable manner.

  The Inspectorate follows a predictable, uniform, and national approach to enforcement in Canada for all of HPFB's regulated products (except food), irrespective of where or by whom these products are sold, advertised, fabricated, processed, packaged/labelled, imported, distributed, tested or stored.

  The Inspectorate takes a non-discriminatory and unbiased approach to its activities. The same practices and procedures are used when administering the legislation, irrespective of the race, national or ethnic origin of the seller, user or consumer.

- **Risk Management**
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  The Inspectorate's activities are guided by the *Health Canada Decision-Making Framework*[4]. Risk assessment and risk management are important components of this framework. Risk can manifest in a variety of ways, such as a sale in the absence of market authorization. The Inspectorate's activities are structured to achieve the greatest impact and efficiency in addressing the identified risks.

- **Commitment to Quality**

[2] R.S. 1985, c. P-21, as amended.

[3] R.S. 1985, c. A-1, as amended.

[4] *Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks*, Health Canada, August 2000, http://www.hc-sc.gc.ca/hpfb-dgpsa/hcrisk_cp_e.html.

The Inspectorate's commitment to quality, is demonstrated through the integration and promotion of quality management principles within the organization. The Inspectorate quality objective is uniformity in fulfilling our compliance and enforcement responsibilities.

- **Qualified Staff**

  Inspectorate employees receive training to ensure they are qualified and knowledgeable of the products and activities being regulated, and the environment in which they are operating.

6. RESPONSIBILITIES

It is the Inspectorate's responsibility to conduct compliance and enforcement activities in accordance with this policy. Inspectors' powers are described under section 23 of the FDA.

The maintenance and enhancement of health and safety is a responsibility that is shared among government and industry, consumers, healthcare professionals and their respective associations.

Regulated parties that market drugs and medical devices have the primary responsibility for the safety of any product they sell, manufacture, import or distribute to the Canadian public. These regulated parties must comply with all Canadian legislative and regulatory requirements.

Consumers have a responsibility for the maintenance of their health and the safe use of marketed health products. Consumers should use manufactured products according to the manufacturer's instructions. In addition, consumers are asked to inform the HPFB of any problems that they encounter (hazards, adverse reactions, malfunctions, and non-compliance) through the use of drugs and medical devices. They should also ensure that the health products they buy have been authorized for sale in Canada.

Healthcare professionals are encouraged to inform the HPFB of any problems they encounter (hazards, adverse reactions, malfunctions, and non-compliance) that may be related to these drugs and medical devices. The primary responsibility for safety of patients lies with the hospital and the treating physician. Physicians have professional standards and obligations and it is the responsibility of professional regulatory bodies (such as Colleges of Physicians and Surgeons) to ensure that these professional standards are met. Physicians handling drugs and devices must comply with requirements of the FDA and its associated Regulations.

7.0 COMPLIANCE ACTIVITIES

7.1 Education, Consultation, and Information

Compliance is facilitated when legislative and regulatory requirements are clearly identified and understood, and accessible to all stakeholders. The HPFB encourages industry and other stakeholders to participate in the development of all health and safety standards and regularly consults with industry on legislative, regulatory, and policy issues, and proposed amendments thereto.

The Inspectorate promotes compliance through educational activities and the sharing of information on regulatory matters. The Inspectorate also provides information to consumers to enable them to be active participants in maintaining their health and the safe use of marketed products.

7.2 Compliance Monitoring

The Inspectorate conducts monitoring activities to assess the compliance of regulated parties with the Act and its associated Regulations, in accordance with established policies and procedures. These proactive activities include a wide variety of fact gathering and assessment activities such as inspections, market surveys and a product sampling program.

7.3 Compliance Verifications and Investigations

Where the Inspectorate identifies or is notified of a potential non-compliance, the Inspectorate takes steps to determine whether non-compliance has occurred. Potential non-compliance may be identified by consumer complaints, industry complaints, referrals from other provincial and federal regulatory agencies, international partners or the Inspectorate's compliance monitoring activities.

8.0 RESPONSES TO NON-COMPLIANCE

Where non-compliance is brought to the attention of a regulated party, it is the regulated party's responsibility to take timely and appropriate action to comply with legislative and regulatory requirements. The Inspectorate will clarify what is necessary to achieve compliance, but will not dictate how compliance is to be achieved. Compliance is normally achieved through a cooperative approach among the regulated party, the Inspectorate and other relevant organisations within Health Canada. However, a number of enforcement options are available if necesssary, particularly when the regulated party is unable or unwilling to correct non-compliance. The Inspectorate’s role is to ensure that the regulated party complies with the regulatory decisions.

The primary objective of the response strategy is to manage the risk to Canadians and use the most appropriate level of intervention to ensure that the responsible regulated party brings the product or activity into compliance. To this end, the Inspectorate evaluates instances of non-compliance to determine the most appropriate action(s) to be taken. Such actions may be undertaken independently, concurrently or sequentially with other actions, if the circumstances warrant it. This determination considers the various circumstances of each case and takes into account, along with other applicable information, the following or any combination of the following factors:

- the risk to health and safety, including the absence of a valid marketing authorization;
- compliance history of the regulated party;
- whether the regulated party acted with indifference or premeditation;
- the degree of cooperation offered by the regulated party to the HPFB;
- the likelihood that the same problem will reoccur;
- the likelihood of the enforcement action being effective;
- the need to maintain public confidence in the programs administered by the HPFB and the Inspectorate; and,
- HPFB and Inspectorate priorities and available resources.

8.1 Compliance Measures Initiated by the Regulated Party

A number of compliance measures may be considered when it is felt that the risks associated with the non-compliance may be appropriately managed without recourse to regulatory measures. One or a combination of the following measures may be considered.

Consent to Forfeit

A consent to forfeit is an agreement between Health Canada and the regulated party for the regulated party to surrender control of a product to the Crown.

Recall

A recall is a method for removing or correcting a distributed health product, including its labelling, that violates the FDA and/or its associated Regulations, or that may present a risk to the health of the consumer.[5] Recalls of health products may be undertaken anytime, in response to a formal request by the Inspectorate or on the initiative of regulated party to carry out the combined responsibility to ensure compliance with the legislation, and to protect the health of consumers. A firm's recall does not preclude other actions which could be taken by the Inspectorate or the firm.

With respect to a health product, other than a medical device, "recall" means a firm's removal from further sale or use, or correction, of a distributed product that presents a risk to the health of consumers or violates legislation administered by the Health Products and Food Branch. A recall of a medical device as defined in the *Medical Devices Regulations* means, in respect of a medical device that has been sold, "any action taken by the manufacturer, importer or distributor of the device to recall or correct the device, or to notify its owners and users of its defectiveness or potential defectiveness, after becoming aware that the device: a) may be hazardous to health; b) may fail to conform to any claim made by the manufacturer or importer relating to its effectiveness, benefits, performance characteristics or safety; or c) may not meet the requirements of the Act or the Regulations."

Voluntary Detention

A voluntary detention is an agreement between a regulated party and Health Canada to maintain control of a particular product. While the FDA provides authority for product seizure or detention, a voluntary detention under the custody of the regulated party may be appropriate if the Inspectorate is confident that the company will comply with the conditions of the agreement. Health Canada will monitor the effectiveness of a detention and may take other enforcement action, eg. seizure, as appropriate.

Voluntary Disposal

A voluntary disposal is an action by a regulated party to prevent further distribution of a non-compliant product, by actions such as disposal, destruction, reconditioning, or returning it to the manufacturer.

[5] See *Drug and Medical Device Recall Listings,* http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/new_e.html; *Health Products and Food Branch Recall Policy (POL-0016)*, http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/pol_0016_tc_e.html

In considering whether voluntary disposal is an appropriate compliance action, the Inspectorate will consider the following factors:

- the degree of cooperation offered by a regulated party on prior occasions; and
- that the product will be rendered non-saleable/usable.

Voluntary Stop Sale

A voluntary consent by the distributor to stop the sale and distribution of a product at any level in the distribution chain.

8.2 Regulatory Measures

A number of regulatory measures are available to Health Canada in order to achieve compliance by regulated parties. These are generally exercised under the powers of the FDA and its associated Regulations and other relevant legislation, including the *Criminal Code*. The following measures can be considered.

Customs Activities /Target

In order to determine whether a product should be refused or permitted entry into Canada, the Inspectorate may request that the Canada Border Services Agency (CBSA) target a specific commodity or importer which has been identified as having potential for non-compliance with the *Food and Drugs Act* and its associated Regulations. The Inspectorate may recommend to the CBSA that a product be refused entry into Canada on the basis of non-compliance with legislative or regulatory requirements.

Forfeiture Following Seizure or Prosecution

Forfeiture is an action taken after a seizure or a conviction (see "prosecution"), whereby control of the product is surrendered to the Crown.

Injunction

An injunction is a court order that usually prohibits or orders a specific activity. Injunctive action will be considered when a violation constitutes a significant and immediate threat or when a regulated party is non-compliant with a court order.

Letters to Trade and Regulated Parties

A letter to trade or the relevant regulated parties is appropriate to inform targetted groups that a product or group of products is considered a potential health hazard or a non-imminent risk, especially in situations where it would be difficult to reach the consumer via the distribution chain.

Prosecution

A prosecution is a legal proceeding in which a court of criminal jurisdiction determines whether there has been a contravention of the applicable statute or regulation and if so, the appropriate penalty. The Inspectorate considers

recommending that charges be laid if the non-compliance of a product or activity can be linked to any of the following criteria:

- it creates a health risk;
- is continuing in nature;
- was premeditated, indifferent, reckless or a marked departure from a reasonable standard of care; or
- other enforcement activities have proven unsuccessful.
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Public Warning/ Public Advisory

When there is an imminent health hazard associated with a product or group of products present in the marketplace, the Inspectorate may recommend to the HPFB that Health Canada informs the population at risk by means of a public warning or public advisory. A public advisory will generally be accompanied by a letter to industry and healthcare professionals via their associations to inform them of the potential health hazards.

Refusal, Suspension or Amendment of Establishment Licence

The Inspectorate may refuse, suspend or amend an establishment licence under the authority provided in the *Food and Drug Regulations* and *Medical Devices Regulations* under certain circumstances. Such circumstances are where there are reasonable grounds to believe:

- that any provisions of the Act and its associated Regulations have been contravened;
- that the licensee has made a false or misleading statement in its application for an establishment licence, or, in the case of medical devices, that the failure to suspend an establishment licence would constitute a risk to the health or safety of patients, users or other persons; and
- if it is necessary to do so to prevent injury to the health or safety of the consumers, patients, users or other persons.

The Inspectorate may include or amend terms and conditions of a drug establishment licence or a medical device establishment licence if it is believed on reasonable grounds that it is necessary to do so to ensure compliance.

Regulatory Stop Sale

For health products with a marketing authorization, HPFB may require, in accordance with applicable regulatory provisions, that a regulated party provide evidence to address health and safety concerns and refrain from selling the product until those concerns have been addressed.

Search

A search is a measure executed under the authority of a search warrant obtained under section 489 of the *Criminal Code* in order to discover evidence of a breach of a law to be used in criminal proceedings. A search requires the belief, on reasonable grounds, that an offense has been committed.

Seizure and Detention

An administrative seizure and detention is an enforcement tool for immediately controlling non-compliance. The Inspectorate may take control of non-compliant articles (eg. drugs or medical devices) under the administrative seizure and detention authority provided in subsection 23(1)(d) of the FDA. When determining whether to implement an administrative seizure and detention, the Inspectorate will consider the risk to health and safety and the compliance history of the regulated party.

Evidentiary seizures are used to gather evidence for a prosecution. The Inspectorate may seize non-compliant articles as evidence under the authority of a search warrant obtained pursuant to section 489 of the *Criminal Code*.

Suspension or Cancellation of Marketing Authorisation/Product Licence

When a regulated party is not in compliance with legislative or regulatory requirements, a significant health risk exists and there is no indication that the regulated party will comply, HPFB may suspend or cancel the marketing authorization (eg. Notice of Compliance, Drug Identification Number, Medical Device Licence, Authorisation to Sell or Import a Drug for the Purposes of a Clinical Trial, or Natural Health Product Licence).

Warning Letter

The Inspectorate may issue a warning letter to a regulated party when it is believed that non-compliance has occurred or is continuing and the risk to human health or safety does not warrant an immediate and stronger enforcement action. The Inspectorate will consider the compliance history of the regulated party and any efforts to achieve compliance. Where a warning is ignored or disregarded, the Inspectorate may escalate its enforcement activities.

9. APPEALS

The Inspectorate recognizes that some of its decisions may be disputed by regulated parties. In the interest of transparency and fairness, the Inspectorate has implemented internal appeal processes to facilitate the resolution of contentious issues that arise in making some of its decisions (e.g. drug establishment licensing). The Inspectorate will, however, ensure that such internal appeals do not compromise its compliance and enforcement activities.

10. EFFECTIVE DATE

This second version of the Inspectorate's *Compliance and Enforcement Policy* is effective as of May 31, 2005.