Health Canada Santé Canada

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 on Counterfeit Health Products

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Disclaimer:
This document does not constitute part of the Food and Drugs Act (Act) or its associated Regulations and in the event of any inconsistency or conflict between that 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. This document is not intended to provide legal advice regarding the interpretation of the Act or Regulations. If a regulated party has questions about their legal obligations or responsibilities under the Act or Regulations, they should seek the advice of legal counsel.

Canada

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1.0 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 of Health Canada's Decision-Making Framework for Identifying, Assessing, and Managing Health Risks to address the issue of counterfeit health products. These principles will mitigate the health and safety risks posed by counterfeit health products to further promote the safety, quality, and efficacy of all health products in the Canadian supply chain.

The primary objective of the response strategy is to manage the risk to Canadians and to have the counterfeit product removed from market using the most appropriate level of intervention and notifying parties at risk.

2.0 Background

Although the presence of counterfeit health products in the regulated supply chain are infrequent in Canada, the Inspectorate Anti-Counterfeit Policy is intended to focus on potential vulnerabilities to the infiltration of counterfeit health products into the regulated supply chain. The health products supply chain includes the manufacturing, packaging/labelling, wholesaling, importation, distribution, sale and use of health products. Take note that, within the health products supply chain, Health Canada regulates the manufacturing, packaging/labelling, wholesaling, importation, distribution, and sale of health products.

Not adhering to market authorization requirements, counterfeit health products lack any assurance of safety, quality, and efficacy. As a result, public health is severely endangered, reputations of genuine brands are threatened, and consumer confidence in the supply chain is diminished.

Counterfeit health products and associated activities constitute violations of the *Food and Drugs Act* (FDA) and its *Regulations*. Consequently, the Inspectorate has the authority, pursuant to the FDA, to take appropriate enforcement measures against the manufacture, importation, and sale of non-compliant health products, including counterfeits, thereby further promoting the integrity of the supply chain. However, the ultimate responsibility in protecting Canadian consumers against counterfeit health products is shared with other government bodies, provincial regulators, healthcare professionals, and industry stakeholders. Such organizations include the Royal Canadian Mounted Police (RCMP), the provincial and territorial colleges of pharmacy, and similar foreign regulatory authorities.

Compliance verifications are 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 via either off-site or on-site visits.

Investigations are actions taken to gather evidence to support case referral for potential judicial determination regarding specific violations of the FDA & its associated *Regulations*. This includes activities carried out under the *Criminal Code* such as taking witness statements and executing search warrants.

3.0 Scope

This policy applies to all suspect and confirmed counterfeit health products under the mandate of the Health Products and Foods Branch, with the exception of food. Counterfeiting may apply to finished products, ingredients/materials used in the preparation/manufacture of the product, packaging (primary and secondary), and advertising of the product, including the materials used.

4.0 Definitions

Health Canada has defined a counterfeit health product as:

A counterfeit health product is one that is represented as, and likely to be mistaken for, an authentic product.

Counterfeiting can apply to both branded and generic products, and could relate to a product's identity or source, could include products with the correct ingredients/components, with the wrong ingredient/components, without active ingredients, with insufficient active ingredients or with misleading packaging or labelling.

For functional purposes, the Inspectorate will consider counterfeit health products to be those which are unapproved and:

- fraudulent,
- fraudulently labelled with respect to identity, composition, origins, and/or source
- falsifications which may look genuine, or
- forgeries (i.e. printed)

The range of "counterfeit health products" includes:

1. Products attempting to replicate genuine brand (i.e. products sold under authorized product name without proper authorization)
2. Products falsifying information such as the DIN, medical device licence number, or other information implying the products are authorized for sale in Canada.

Although counterfeit products may include one of the following characteristics, products based exclusively on one of the following criteria will not necessarily be confirmed as counterfeit. As such, in most cases products will not be deemed counterfeit solely based on any one of the following characteristics:

- Diverted products (see explanation below)
- Products using patented ingredients/design but which do not mislead or claim to be the rights holder, hold a Drug Identification Number (DIN), etc.
- Products not disclosing all ingredients, or with labelling issues

In addition, as circumstances vary between incidents, counterfeit products will be confirmed on a case-by-case basis.

Typically, counterfeit products are illegal products which are packaged or marked to indicate that they have been legally manufactured by, or on behalf of, the market authorization holder. In contrast, diverted products are genuine products manufactured by an authorized manufacturer that end up on a different market than intended, one for which they are not specifically authorized (e.g. theft of expired or recalled product, illegal redirection of prescription drugs from legitimate sources). Although these products may or may not be obtained under suspicious circumstances, the integrity of the products is compromised due to the unknown manner of storage and distribution. While diverted products are to be included in the policy, they are not to be considered "counterfeit" unless proven otherwise. Within the policy, diverted products need to be considered as a potential indicator of counterfeit distribution.

5.0 Policy Statement

It is the policy of the Inspectorate to immediately secure *suspected* counterfeit health products to verify their compliance, inform the appropriate law enforcement authorities, and to perform compliance verification and enforcement actions as required.

The objectives of the Inspectorate as they relate to counterfeit health products are to:

a) educate the public, health professionals, and members of the supply chain on the risks of counterfeit health products and methods to enable Canadian consumers to make informed choices.

b) conduct compliance verification activities to identify suspect counterfeits and deploy compliance or enforcement measures appropriate to the incident.

c) identify the parties responsible for the entry and distribution of counterfeit products in Canada and action appropriately.

d) notify federal, provincial or municipal law enforcement and regulatory bodies and international regulators as appropriate, respecting constraints related to the sharing of commercial and personal information, as well as not jeopardising ongoing criminal investigations.

e) conduct examinations and laboratory analysis to verify product as counterfeit. This may include expertise from suppliers of authentic product.

f) remove counterfeit products from the supply chain and further distribution in an effective and timely manner, including monitor recalls in response to a counterfeit product in the marketplace, as per POL-0016 – HPFBI Recall Policy (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php). If the counterfeit health product is confirmed as Canadian in origin, the Inspectorate will exercise its powers of inspection to obtain distribution records to track the product back to its source.

g) collaborate with other international regulators, as required

h) publish public advisories and warnings on counterfeit products, as appropriate.

Compliance Verification and Enforcement Activities

Health products are examined for compliance at the border or at Canadian establishments during the course of compliance verifications or inspections. When health products are suspected or confirmed to be counterfeit the Inspectorate will notify the RCMP and take compliance verification and enforcement actions in accordance to POL-0001 – Compliance and Enforcement Policy. (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php)

Compliance is normally achieved through a cooperative approach among the regulated party, the Inspectorate and other relevant organisations within Health Canada. However, given the illegal and potential serious nature of counterfeit health products less emphasis will be placed on compliance actions and more emphasis will be placed on enforcement actions including the potential for prosecution.

6.0 Responsibilities

The Inspectorate has the authority, pursuant to the FDA, to take appropriate enforcement measures regarding the manufacture, importation, and sale of non-compliant health products, including counterfeits. However, the ultimate responsibility in protecting Canadian consumers against counterfeit health products is shared

with other government bodies, provincial regulators, healthcare professionals, and industry stakeholders. Such organizations include the Royal Canadian Mounted Police (RCMP), the provincial and territorial colleges of pharmacy and physicians.

The sale of counterfeit health products is also a violation of the *Criminal Code*. Therefore, incidents of suspected counterfeit products are also referred to the RCMP. The RCMP investigates reports of counterfeit health products being produced, imported, or sold in Canada, and pursues action, based on the potential risks, in an effort to dismantle the criminal element. In such cases, the Inspectorate has an auxiliary role in providing compliance and enforcement expertise and lab analysis to the RCMP, limited to our authorities. The Inspectorate must ensure the removal of the counterfeit product from the legitimate supply chain and act as the primary advisor to the general public.

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 Health Canada of any problems that they encounter (hazards, adverse reactions, malfunctions, and non-compliance) through the use of health products. They should also ensure that the health products they buy have been authorized for sale in Canada. Any questions concerning health products consumers should contact their physician, pharmacist, or Health Canada.

Healthcare professionals are encouraged to inform Health Canada of any problems they encounter (hazards, adverse reactions, malfunctions, and non-compliance) that may be related to the suspected counterfeit health products. In addition to complying with the requirements of the FDA and its associated *Regulations*, physicians and health care professionals handling drugs and devices are also required to adhere to Provincial legislation, and meet their respective professional standards.

Information on submitting a consumer complaint is available in the Health Canada guidance document entitled How to Submit a Consumer Complaint (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-44_consumer_complaint-plainte_consommateur-eng.php).

Information on reporting an adverse reaction to Health Canada's Canada Vigilance Program is outlined on the Medeffect Canada (http://www.hc-sc.gc.ca/dhp-mps/medeff/index-eng.php) website.

Draft guidance on voluntary and mandatory problem reporting for medical devices is also available in the Mandatory and Voluntary Problem Reporting for Medical Devices (http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/mavprfmd-rioevraim-eng.php).

7.0 Associated Documents

Legislation
Food and Drugs Act and its associated *Regulations*
(http://laws.justice.gc.ca/en/F-27/)

Policies and Guides
POL-0001 – Compliance and Enforcement Policy
(http://www.hc-sc.gc.ca/dhp-mps/compli-conform/gmp-bpf/pol/pol_1_tc-tm-eng.php)

POL-0016 – HPFBI Recall Policy
(http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/pol_0016_tc-tm-eng.php)

GUI-0044 – How to submit a Consumer Complaint
(http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/gui-44_consumer_complaint-plainte_consommateur-eng.php)

GUI-0055 – Mandatory and Voluntary Problem Reporting for Medical Devices
(http://www.hc-sc.gc.ca/dhp-mps/compli-conform/prob-report-rapport/mavprfmd-rioevraim-eng.php)