Health Products and Food Branch
Inspectorate
Graham Spry Building, 2nd Floor
250 Lanark Avenue
Address Locator # 2002B
OTTAWA, Ontario
K1A 0K9

December 1, 2007

07-117987-250

To: ALL INTERESTED PARTIES

I am pleased to inform you that Health Canada has finalized the guidance document entitled "Inspection Strategy for Canada's Access to Medicines Regime (POL-0055)", which is now available on Health Canada's Compliance and Enforcement website at:

http://www.hc-sc.gc.ca/dhp-mps/compli-conform/index_e.html

The purpose of this document is to detail the Health Product and Food Branch Inspectorate's strategy for the effective and uniform implementation of Canada's Access to Medicines Regime (CAMR) inspection program to assess compliance with the regulatory requirements as detailed in the *Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, formerly Bill C-9, and in the *Regulations Amending the Food and Drug Regulations (1402 – Drugs for Developing Countries).* This inspection strategy applies to manufacturers of drug products intended for exportation under Canada's Access to Medicines Regime.

A draft version of the document was posted on the Health Canada website for a 60 day comment period in June 2006. Comments received from stakeholders and interested parties were reviewed and those that were accepted have been incorporated in this new version.

Inquiries about this guidance document can be submitted in writing by mail to the Manager, Drug GMP Inspection Unit, HPFB Inspectorate, Graham Spry Building, A.L. #2002B, 250 Lanark Avenue, Ottawa, Ontario, K1A 0K9, by fax at 613 957-6709, or by e-mail at GMP_questions_BPF@hc-sc.gc.ca .

***Original signed by***

Diana Dowthwaite
Director General

**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

# Inspection Strategy for Canada's Access to Medicines Regime

# POLICY-0055

Supersedes:
New Document

Date issued:
August 2007

Date of implementation:
September 2007

Ce document est aussi disponible en français.

Canada

# Table of Contents

1.0 PURPOSE . . . . . Page 3

2.0 BACKGROUND . . . . . Page 3

3.0 SCOPE . . . . . Page 3

4.0 DEFINITIONS . . . . . Page 3

5.0 COMPLIANCE AND MONITORING ACTIVITIES . . . . . Page 4

5.1 Pre-export inspection . . . . . Page 4
5.1.1 Inspection activities . . . . . Page 4
5.1.2 Duration of inspections . . . . . Page 5
5.1.3 Inspection Rating and Reporting: . . . . . Page 5
5.2 Compliance Verification . . . . . Page 6

6.0 RESPONSE TO NON-COMPLIANCE . . . . . Page 6

7.0 RESPONSIBILITIES . . . . . Page 6

8.0 PROCEDURES . . . . . Page 6

9.0 EFFECTIVE DATE . . . . . Page 6

10. REFERENCES . . . . . Page 7

## 1.0 PURPOSE

The purpose of this document is to detail the Health Product and Food Branch Inspectorate's strategy for the effective and uniform implementation of Canada's Access to Medicines Regime (CAMR) inspection program to assess compliance with the regulatory requirements as detailed in the *Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, formerly Bill C-9, and in the *Regulations Amending the Food and Drug Regulations (1402 – Drugs for Developing Countries).*

## 2.0 BACKGROUND

There are two key components to the compliance and enforcement efforts with respect to Canada's Access to Medicines Regime: the pre-export inspection and the amendment to section 37 of the *Food and Drugs Act* that requires a drug manufacturer under this program to adhere to all applicable requirements of the *Food and Drugs Act* and its regulations.

Health Canada has committed to pre-export inspections of manufacturers exporting to developing or least-developed countries under Canada's Access to Medicines Regime. Pre-export inspections, as part of anti-diversion measures, will confirm the existence of distinguishing characteristics on the products, their immediate containers, if applicable, and their labels.

Inspections will be conducted by Health Canada under the authority of sections 23 and 24 of the *Food and Drugs Act*. These activities will be conducted by the Health Products and Food Branch Inspectorate (Inspectorate). Collaboration with all stakeholders taking part in Canada's Access to Medicines Regime will be essential to ensure compliance with the new regulations.

## 3.0 SCOPE

This inspection strategy applies to manufacturers of drug products intended for exportation under Canada's Access to Medicines Regime.

The notification required under the *Food and Drug Regulations* is linked to the exportation of the manufactured product. All manufacturers participating in the program must notify Health Canada as indicated in section C.07.011 of the *Food and Drug Regulations* and will be subject to pre-export inspections.

## 4.0 DEFINITIONS

**Authorization under section 21.04 of the *Patent Act*:** This is an authorization to use a patented invention granted by the Commissioner of Patents at the Canadian Intellectual Property Office (CIPO) under section 21.04 of the *Patent Act*. This authorization is often referred to as a "compulsory licence". (Autorisation en vertu de l'article 21.04 de la *Loi sur les brevets)*

**Compliance verification:** Action taken to verify compliance in response to information regarding known or suspected noncompliance with the applicable requirements of the *Food and Drugs Act* and its associated regulations. This includes actions such as information gathering via either off-site or on-site visits. (Vérification de la conformité)

**Inspection**: On-site monitoring and assessment against the applicable requirements of the *Food and Drugs Act* and its associated regulations. Inspections are routinely conducted on a predetermined cycle or as required to assess compliance. (Inspection)

**Inspectorate**: The Health Products and Food Branch (HPFB) directorate whose primary role is to deliver a national compliance and enforcement program for all products under the mandate of the HPFB, with the exception of products regulated as foods. (Inspectorat)

**Investigation**: Action taken to gather evidence to support case referral for potential judicial determination 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. (Enquête)

**Inspector:** Any person designated as an inspector for the purpose of the enforcement of the *Food and Drugs Act* under subsection 22(1). (Inspecteur)

**Manufacturer:** "manufacturer" or "distributor" means a person, including an association or partnership, who under their own name, or under a trade-, design or word mark, trade name or other name, word or mark controlled by them, sells a food or drug (A.01.010). (Fabricant)

For additional definitions, consult the documents listed as references at the end of this strategy.

## 5.0 COMPLIANCE AND MONITORING ACTIVITIES

The Inspectorate will provide information and encourage voluntary compliance with Canadian regulatory requirements. Compliance will be assessed through inspections and compliance verifications conducted by the Inspectorate.

### 5.1 Pre-export inspection

The Inspectorate will assess the compliance of manufacturers with the regulatory requirements pertaining to Canada's Access to Medicines Regime, including sections C.07.008 (Marking and Labelling), C.07.009 (Export Tracking Number), C.07.010 (Records) of the *Food and Drug Regulations*.

Note: All regulatory requirements that a manufacturer must meet for drug products destined for the Canadian market also apply to CAMR products, in addition to Part C Division 7 of the *Food and Drug Regulations.* Therefore, inspections regarding establishment licensing and good manufacturing practices (GMP) will continue to take place for manufacturers of these products.

The pre-export inspections under Canada's Access to Medicines Regime will begin in 2006. The inspection program will be assessed after the first year of operation in order to determine whether modifications are required.

#### 5.1.1 Inspection activities

- The Inspectorate will perform a pre-export inspection of each lot of drug product exported under the Authorization under section 21.04 of the *Patent Act*.

- A pre-export inspection will verify the existence of distinguishing characteristics on the products, the immediate containers if applicable, and their labels to identify them as having been manufactured under compulsory licence (authorization under section 21.04 of the *Patent Act*). The distinguishing characteristics are required by section C.07.008 of the *Food and Drug Regulations*, as a measure to prevent diversion and re-importation.

- A pre-export inspection will verify the quantity of drug product that is authorized to be manufactured and sold for export under Canada's Access to Medicines Regime and will check the information that identifies the parties that will be handling the product while it is in transit from Canada to the country or World Trade Organization (WTO) Member to which it is to be exported.

- A pre-export inspection will be undertaken prior to export of each shipment. To facilitate these inspections, the manufacturer is required to notify the Minister in writing not less than 15 days before commencing the manufacture of the first lot of a drug product authorized to be sold under Part C Division 7 of the *Food and Drug Regulations* and not less than 15 days before the exportation of each subsequent lot of the drug product.

- In addition to the pre-export inspection, Health Canada's legislative/regulatory authority to conduct compliance and enforcement activities, including the delivery of unannounced/random inspections and sampling of finished products for analysis in Health Canada laboratories, continues to exist under Canada's Access to Medicines Regime. Regular good manufacturing practices (GMP) inspections will be performed on a scheduled basis. If a regularly scheduled GMP inspection coincides with the planned export of a shipment, then the inspections could happen simultaneously.

- Sampling of the finished product will be carried out at every pre-export inspection in accordance with SOP-0200 - *Sampling Procedures*. The subject of sampling will the be revisited to determine the frequency needed after the first year of pre-export inspections is complete.

- The Certificate of Pharmaceutical Product (CPP) is currently offered as an optional service to Canadian establishments desiring to export to countries which request the CPP as evidence of the status of the pharmaceutical product listed on the certificate and the GMP status of the applicant for the certificate. This option will continue to exist under Canada's Access to Medicines Regime.

### 5.1.2 Duration of inspections

The average duration of the inspection is estimated at one day. The average time for an inspection will be re-assessed after the first year of operation of the inspection program.

### 5.1.3 Inspection Rating and Reporting:

- Two ratings will be used:
  C - No objectionable conditions or practices were observed with regards to regulatory requirements
  NC - Objectionable conditions or practices were observed with regards to regulatory requirements
- An Inspection report will be issued to the inspected establishment in a timely manner. The Inspection Report will contain observations noted during the inspection. An Exit Notice will be issued to the establishment.
- Responses to observations noted in the Inspection Report (Inspection Exit Notice) will be required from the inspected establishment within a specified period of time. Responses should outline corrective actions to any deficiencies recorded.

### 5.2 Compliance Verification

When a potential non-compliance or risk has been identified by Health Canada, compliance verification will be conducted if deemed necessary. Problems or concerns related to the performance of Canada's Access to Medicines Regime may originate from:

- External sources or referrals from other jurisdictions.
- Internal Departmental and Branch sources, such as the Therapeutic Products Directorate (TPD), Biologics and Genetic Therapies Directorate (BGTD), and Marketed Health Products Directorate (MHPD).

## 6.0 RESPONSE TO NON-COMPLIANCE

Where non-conformity to the *Food and Drugs Act* and/or the *Food and Drug Regulations* is identified, the inspected establishment will have the opportunity to correct identified deficiencies.

In all cases, the results will be communicated to the appropriate Directorate(s): TPD or BGTD and/or MHPD if applicable.

Where a drug authorized to be sold under Canada's Access to Medicines Regime is determined to no longer meet the requirements of the *Food and Drugs Act* and the *Food and Drug Regulations*, the Inspectorate's Director General will notify the Commissioner of Patents (CIPO) in the form of a "Notice to the Commissioner of Patents".

## 7.0 RESPONSIBILITIES

It is the responsibility of the Inspectorate and all stakeholders to collaborate and act in partnership in the application of this inspection strategy.

## 8.0 PROCEDURES

Specific inspection, compliance verification and investigation activities will be documented and supported by detailed standard operating procedures.

## 9.0 EFFECTIVE DATE

The effective date of this Inspection Strategy is August 29, 2007.

## 10. REFERENCES

1. *Food and Drugs Act*
2. *Food and Drug Regulations*
3. *Act to amend The Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa) – Bill C-9*
4. *Regulations Amending the Food and Drug Regulations (1402 – Drugs for Developing Countries)*
5. Health Products and Food Branch Inspectorate's *Guidance for Access to Medicines Pre-manufacturing and Pre-exportation Notifications C.07.011)*, No. GUI-0072