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

Drug Identification Number (DIN) Enforcement Directive

Policy-0040

Supersedes:
January 1, 2004

Date issued:
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Date of implementation:
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Ce document est aussi disponible en français.

Canada

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1. PURPOSE

The purpose of this document is to provide the Health Products and Food Branch Inspectorate (HPFBI) with direction regarding the uniform enforcement of the *Food and Drugs Act* and *Food and Drug Regulations* as they pertain to Drug Identification Number (DIN) violations.

2. BACKGROUND

The POL-0001 *Compliance and Enforcement* Policy identifies the Inspectorate's role in delivering a national compliance and enforcement program for all health products under the HPFB mandate, with the exception of products regulated as foods.

The *Natural Health Products Regulations* came into force on January 1, 2004. Products that come within the purview of this regulatory regime require a product licence as indicated on a product's label by the prefix NPN followed by an eight digit number or, for a Homeopathic Medicine, a DIN-HM.

Compliance and enforcement of the requirements for NPN's and DIN-HM's are covered in the Natural Health Products Directorate documents:

- *Compliance Policy for Natural Health Products*
- *Natural Health Products Compliance Guide, and*
- *The Compliance Approach for Natural Health Products*.

This policy is an interpretive tool. To the extent there is an inconsistency between the policy and the law, the law governs over this administrative policy.

3. SCOPE

This policy applies to all human and veterinary drugs in dosage form for which a DIN is required by the *Food and Drugs Act* and *Food and Drug Regulations*. It also applies to Natural Health Products (NHPs) that are sold with a DIN pursuant to the transition provisions in the NHP Regulations. Persons who continue selling NHPs with a DIN until January 1, 2010 must do so in accordance with the requirements of the *Food and Drugs Act* and *Food and Drug Regulations*.

Whole blood, blood components, and radiopharmaceuticals are excluded from this policy since these drugs do not require a DIN.

This policy applies also to drugs that have received a DIN but which have not had a notification filed pursuant to section C.01.014.3 and C.01.014.5 of the Food and Drug Regulations.

This policy applies only to DIN violations. Other violations of the *Food and Drugs Act* and its associated Regulations may result in further compliance and enforcement actions in accordance with POL-0001 *Compliance and Enforcement Policy*.

4. DEFINITIONS

Drug: Under the *Food and Drugs Act*, a **drug** includes any substance or mixture of substances manufactured, sold or represented for use in:

a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals;
b) restoring, correcting or modifying organic functions in human beings or animals; or
c) disinfection in premises in which food is manufactured, prepared or kept.

Drug Identification Number (DIN): A DIN is an eight (8) digit numerical code preceded by the prefix DIN which is assigned to each drug product marketed under or in accordance with the *Food and Drugs Act* and *Food and Drug Regulations*.

5. POLICY STATEMENT

The Health Products and Food Branch Inspectorate enforces the requirements of the *Food and Drugs Act* and its associated Regulations to safeguard the health and safety of Canadians. To maximize the effective and efficient deployment of our finite enforcement resources, we concentrate our enforcement activities where we expect to have the greatest impact and efficiency which is at the point of manufacture or importation. Concentrating the deployment of enforcement resources at these points provides us with the greatest opportunity to prevent non-conforming drugs from entering the distribution chain and being made available to the public. Once products are distributed, we attempt to work at the highest appropriate level of distribution to prevent non-compliant drugs from reaching the retail level.

The *Food and Drugs Act* and *Food and Drug Regulations* require human and veterinary drugs to possess a valid DIN in order to be sold in Canada. Actions which may be taken to achieve compliance are further described in POL-0001 *Compliance and Enforcement Policy*. Specifically, the following principles apply:

- Drugs without valid DINs, including those in the possession of distributors and importers, will not be allowed to be sold in Canada.
- The focus of efforts regarding drugs without a valid DIN is to prevent their distribution at the manufacturer/importer/distributor level.
- Drugs may, under appropriate circumstances, be placed under voluntary detention, to be released upon issuance of a DIN and appropriate labelling.
- Enforcement action at retail, including seizure, may be taken at any time.

6. RESPONSIBILITIES

The implementation of this policy is the responsibility of the staff of the Health Products and Food Branch Inspectorate. It is the responsibility of the regulated party to ensure that drugs being sold in Canada comply with the *Food and Drugs Act* and *Food and Drug Regulations*.

7. PROCEDURES

Note: The following measures are designed to deal with DIN violations. Should any specific health risk be identified during the course of implementing enforcement action, more forceful and immediate measures will be taken to ensure that no hazardous products continue to be sold. Additional measures, such as recall by the regulated party, may be necessary to remove violative drugs from the market.

Drugs will be examined for DIN compliance at the border or at establishments during the course of Good Manufacturing Practices inspections or compliance verifications.

7.1 At the border:

- A Health Canada Inspector determines if the product has a valid DIN.
- If there is no valid DIN associated with the drug and the importation is not conducted in accordance with A.01.044, refusal of entry will be recommended to the Canada Border Services Agency (CBSA) on the grounds that importation would violate A.01.040 of the *Food and Drug Regulations*.
- If a valid DIN exists, but is not on the label for the product, entry will be permitted by the Inspector if the importer has provided to an Inspector notice of the proposed importation and the drug will be relabelled or modified as may be necessary within three months after the importation to enable its sale to be lawful in Canada. The drug cannot be sold until these modifications have been completed, as per A.01.044(2).

7.2 At Manufacturers, Importers, Distributors:

- Drugs are checked for DINs by an Inspector. If there is no DIN on the label, the company will be asked for the DIN. DINs provided by the company will be verified against available information (e.g. Drug Product Database). If a proffered DIN does not appear in the Drug Product Database, it will be verified with the Submission and Information Policy Division, Therapeutic Products Directorate.
- If there is no DIN associated with the drug, a stop sale and recall will be requested on the grounds that sale in Canada would violate Section 9 of the *Food and Drugs Act* and C.01.003 and/or C.01.014 of the *Food and Drug Regulations*. Inspectors may ask the regulated party to voluntarily detain or dispose of the non-compliant drug.
- If the firm does not agree to a stop sale of the product in a manner satisfactory to the Health Products and Food Branch Inspectorate, the stock will be seized administratively under the authority of Section 23 of the *Food and Drugs Act* in accordance with the Inspectorate POL-0007 *Seizure Policy*.
- Prosecution and injunction are discretionary options that are available to Health Canada.

7.3 At Retail:

The following compliance and enforcement measures will be pursued, in the event of a complaint related to a DIN violation or during planned compliance monitoring of market authorizations:

- The sale by any person of a drug without a DIN or whose DIN has been cancelled is in violation of the *Food and Drug Regulations*. The retailer will be directed to comply with the *Food and Drug Regulations*, by removing the drug product from point of sale, and will be asked to provide the Inspector with the name and address of the supplier or Canadian legal agent of the violative drug.

- If successful in obtaining the information, the Inspector will follow up with the Canadian legal agent as per **7.2 At Manufacturers, Importers, Distributors** above. If the retailer is found to be the Canadian legal agent, the Inspector will proceed under **7.2 At Manufacturers, Importers, Distributors** described above.
- If a retailer does not provide the information within the specified time frame, the Inspector will follow up with the retailer to obtain the name and address of the supplier. If successful in obtaining the supplier information, the Inspector will follow up with the supplier as per **7.2 At Manufacturers, Importers, Distributors** above. If the retailer does not offer the necessary collaboration, the retailer will be treated as the Importer or Distributor.

8. EFFECTIVE DATE

This policy replaces version 1 of POL-0040 *Drug Identification Number (DIN) Enforcement Directive* and becomes effective on January 15, 2006.

9. ASSOCIATED DOCUMENTS

Food and Drugs Act http://laws.justice.gc.ca/en/F-27/index.html

Food and Drug Regulations http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/index.html

Natural Health Products Regulations http://laws.justice.gc.ca/en/F-27/SOR-2003-196/index.html

POL-0001 *Compliance and Enforcement Policy*

POL-0007 *Seizure Policy*

POL-0018 *Policy for the Importation or Sale of Active Pharmaceutical Ingredients for Veterinary Use*

Compliance Policy for Natural Health Products - Natural Health Products Directorate

Natural Health Products Compliance Guide - Natural Health Products Directorate

The Compliance Approach for Natural Health Products - Natural Health Products Directorate