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[Notice](#)

Vol. 139, No. 11 — June 1, 2005

Registration  
SOR/2005-141 May 10, 2005

- [News and announcements](#)
- [Mandate](#)
- [Consultation](#)
- [Recent \*Canada Gazette\* publications](#)
- [Part I: Notices and proposed regulations](#)
- [Part II: Official regulations](#)
- [Part III: Acts of Parliament](#)
- [Learn more about the \*Canada Gazette\*](#)
- [Publishing information](#)
- [Publishing requirements](#)
- [Deadline schedule](#)
- [Insertion rates](#)
- [Request for insertion form](#)
- [Subscription information](#)
- [Useful links](#)
- [Archives \(1998-2004\)](#)

FOOD AND DRUGS ACT

**Regulations Amending the Food and Drug Regulations (1402 — Drugs for Developing Countries)**

P.C. 2005-859 May 10, 2005

Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to section 30 ([see footnote a](#)) of the *Food and Drugs Act*, hereby makes the annexed *Regulations Amending the Food and Drug Regulations (1402 — Drugs for Developing Countries)*.

**REGULATIONS AMENDING THE FOOD AND DRUG REGULATIONS (1402 — DRUGS FOR DEVELOPING COUNTRIES)**

AMENDMENT

1. Part C of the *Food and Drug Regulations* ([see footnote 1](#)) is amended by adding the following after Division 6:

DIVISION 7

SALE OF DRUGS FOR THE PURPOSES OF IMPLEMENTING THE GENERAL COUNCIL DECISION

Interpretation

**C.07.001.** The definitions in this section apply in this Division.

"Commissioner of Patents" means the Commissioner of Patents appointed under subsection 4(1) of the *Patent Act*. (*commissaire aux brevets*)

"General Council Decision" has the meaning assigned by subsection 30(6) of the Act. (*décision du Conseil général*)

Application

**C.07.002.** This Division applies to the sale of drugs for the purposes of implementing the General Council Decision.

Application for Authorization

**C.07.003.** An application by a manufacturer for authorization to sell a drug under this Division shall be

submitted to the Minister and shall contain the following information and documents:

- (a) a statement that the manufacturer intends to file an application with the Commissioner of Patents under section 21.04 of the *Patent Act*;
- (b) in respect of a new drug, the submission number and date of filing of the new drug submission or abbreviated new drug submission filed under section C.08.002 or C.08.002.1, respectively, and of any supplement filed under section C.08.003 in respect of the drug;
- (c) in respect of a drug that is not a new drug,
  - (i) the application number and date of filing of the application that has been filed under section C.01.014.1 in respect of the drug, or
  - (ii) the drug identification number, if one has been assigned in respect of the drug pursuant to section C.01.014.2;
- (d) for a drug in a solid dosage form, the manner in which the drug is marked in accordance with paragraph C.07.008(a) and evidence that such manner does not alter the safety and efficacy of the drug;
- (e) for a drug in a dosage form that is not solid, the manner in which the immediate container is marked in accordance with paragraph C.07.008(a); and
- (f) a sample of the label for the drug that includes the information required by paragraph C.07.008(c).

#### Authorization

**C.07.004.** The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.04(3)(b) of the *Patent Act* that the manufacturer's drug meets the requirements of the Act and these Regulations if

- (a) the manufacturer has submitted to the Minister an application in accordance with section C.07.003 and a copy of the application filed by the manufacturer with the Commissioner of Patents under section 21.04 of the *Patent Act*;
- (b) in respect of a new drug, an examination of the new drug submission or abbreviated new drug submission or supplement to either submission by the Minister demonstrates that the submission or supplement complies with section C.08.002, C.08.002.1 or C.08.003, as the case may be, and section C.08.005.1;
- (c) in respect of a drug that is not a new drug, a drug identification number has been assigned pursuant to section C.01.014.2; and
- (d) the Minister is satisfied that the manufacturer and the drug comply with the Act and these Regulations.

**C.07.005.** Despite sections C.01.014, C.08.002 and C.08.003, a manufacturer may sell a drug under this Division if

- (a) the Minister has notified the Commissioner of Patents for the purposes of paragraph 21.04(3)(b) of the *Patent Act* that the drug meets the requirements of the Act and these Regulations; and
- (b) the manufacturer has received authorization under section 21.04 of the *Patent Act*.

**C.07.006.** Sections C.01.005 and C.01.014.1 to C.01.014.4 do not apply to new drugs sold under this Division.

#### Notice to Commissioner of Patents

**C.07.007.** The Minister shall notify the manufacturer and the Commissioner of Patents for the purposes of paragraph 21.13(b) of the *Patent Act* in the event that the Minister is of the opinion that

the manufacturer's drug authorized to be sold under this Division has ceased to meet the requirements of the Act and these Regulations.

#### Marking and Labelling

**C.07.008.** No person shall sell a drug under this Division unless

(a) the drug itself permanently bears the mark "XCL", in the case of a drug in a solid dosage form, or the immediate container permanently bears the mark "XCL", in the case of a drug in a dosage form that is not solid;

(b) the colour of the drug itself is significantly different from the colour of the version of the drug sold in Canada, in the case of a drug in a solid dosage form; and

(c) the label of the drug permanently bears the mark "XCL", followed by the export tracking number assigned by the Minister under section C.07.009 and the words "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA." or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA."

**C.07.009.** The Minister shall assign an export tracking number to each drug in respect of which the Minister has notified the Commissioner of Patents under section C.07.004.

#### Records

**C.07.010.** The manufacturer shall, with respect to a drug authorized to be sold under this Division,

(a) establish and maintain records, in a manner that enables an audit to be made, respecting the information described in section C.08.007; and

(b) provide to the Minister the reports referred to in section C.08.008.

#### Notice to Minister

**C.07.011.** The manufacturer shall notify the Minister in writing not less than 15 days before commencing the manufacture of the first lot of a drug authorized to be sold under this Division and not less than 15 days before the exportation of each subsequent lot of the drug.

#### COMING INTO FORCE

**2. These Regulations come into force on the day on which *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)*, being chapter 23 of the Statutes of Canada, 2004, comes into force.**

#### REGULATORY IMPACT ANALYSIS STATEMENT

*(This statement is not part of the Regulations.)*

##### **Description**

In the November 2001 Doha Declaration, the World Trade Organization (WTO) members recognized the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from the human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS), tuberculosis, malaria and other epidemics.

On August 30, 2003, negotiations among WTO members resulted in the General Council Decision (GCD) waiving certain provisions of the Agreement on Trade-Related Intellectual Property Rights (TRIPS), which were thought to be a barrier to effective responses to such public health problems. The waived TRIPS obligations relate to the terms and conditions under which member states can authorize the use of a patented invention without the consent of the patent holder. Prior to the waiver of the TRIPS obligations, such use could only be authorized predominantly for the supply of the domestic market. This had the effect of preventing developed WTO member countries, such as Canada, from authorizing the production of low-cost versions of patented medicines solely for export

to least developed and developing countries unable to manufacture their own.

Canada moved quickly to implement the GCD with Bill C-9, *An Act to amend the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa)* [hereafter referred to as "the Act"]. The Act, which received Royal Assent on May 14, 2004, sets out the legislative framework which will allow manufacturers to obtain an authorization (i.e. compulsory licence) allowing them to make, construct and use a patented invention solely for the purpose of exporting a pharmaceutical product to eligible importing countries, provided that manufacturers meet certain conditions. Canada's Access to Medicines Program will be operational with the coming into force of the Act and these Regulations.

In addition to amending the *Patent Act*, the Act amended sections 30 and 37 of the *Food and Drugs Act* (FDA).

Section 30 of the FDA was amended to provide the Governor in Council with the authority to make the regulations it considers necessary to implement the GCD.

Section 37 was amended so that the FDA and regulations (*Food and Drug Regulations* and the *Medical Devices Regulations*) would apply to all pharmaceutical products manufactured and exported in accordance with the GCD.

Amendments to the *Patent Act* set out the conditions under which an authorization is given to allow a manufacturer to use another manufacturer's patented inventions in order to make and export the drug or device under Canada's Program to implement the GCD.

The Act also requires that the Minister of Health notify the Commissioner of Patents that the product meets the requirements of the FDA and its regulations *before* the Commissioner of Patents can issue an authorization to a manufacturer. These Regulations outline the conditions to be met before the Minister of Health can issue this notification. They are to be read in addition to all the other requirements that must be met by manufacturers.

As the WTO General Council Decision's definition of "pharmaceutical products" includes products that Canada regulates as drugs or medical devices, regulatory changes have been made to both the *Food and Drug Regulations* as well as the *Medical Devices Regulations*.

The GCD sets out conditions that must be met before an exporting member country may issue a compulsory licence (i.e. authorization). For example, products must be clearly identified as being produced under the GCD through specific labelling or marking. Additionally, the GCD refers to suppliers distinguishing products "through special packaging and/or special colouring/ shaping of the products themselves". As an exporting WTO member, Canada must ensure that it meets its obligations under the GCD. As a result, regulations are necessary to ensure that the requirements are clearly set out and consistently applied.

#### **Amendments to the Food and Drug Regulations**

These regulatory amendments create a new Division 7 to the *Food and Drug Regulations*, entitled "*Sale of Drugs for the Purposes of Implementing the General Council Decision*".

Division 7 outlines:

- conditions for the Minister of Health to notify the Commissioner of Patents;
- notice to the Commissioner of Patents; and
- pre-export notification requirements.

#### **1. Conditions for the Minister to notify the Commissioner of Patents**

In addition to the filing of a submission, as is currently required under the *Food and Drug Regulations*, manufacturers must submit to Health Canada, a "distinguishing features" package in accordance with Division 7 and a Statement of Intent to apply for an authorization from the Commissioner of Patents.

#### *Distinguishing Features Package*

These Regulations require the pharmaceutical product to be easily identifiable as a product being exported under Canada's Program to implement the GCD. This is accomplished through

requirements of markings, colouring and labelling.

For solid dosage forms, such as tablets and capsules, the letters "XCL" must be marked on the dosage form, and the colour must be significantly different from the version sold in Canada. For non-solid forms, such as suspensions and powders for reconstitution, the letters "XCL" must appear on the immediate container.

All product labels must have "XCL" permanently displayed, followed by the Health Canada issued export tracking number. An export tracking number is generated for each notification by the Minister of Health to the Commissioner of Patents. In addition, all labels must display the phrase "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA" or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA". The manufacturer must provide sample labels to Health Canada.

## 2. Notice to the Commissioner of Patents

Following the successful review of both the submission and the additional distinguishing features package, and upon receipt of a copy of the application to the Commissioner of Patents for an authorization, the Minister of Health will notify the Commissioner of Patents that the pharmaceutical product meets the requirements of the FDA and its regulations. Health Canada will issue an export tracking number for each notification to the Commissioner of Patents. The export tracking number is an alphanumeric number where the two-letter country code corresponds to the intended importing country. The Commissioner of Patents has committed to adopting this Health Canada generated export tracking number as their authorization number.

## 3. Pre-Export Notification Requirements

Manufacturers must, in writing, notify the Minister of Health no less than 15 days prior to the start of manufacturing of the first lot, and no less than 15 days prior to the exportation of each subsequent lot. This requirement has been slightly modified from the version pre-published in the *Canada Gazette*, Part I, in response to comments received during the 75-day comment period, the rationale of which is discussed later. This provision provides the Health Products and Food Branch Inspectorate with adequate notice to facilitate the scheduling of inspections.

### **Amendments to the *Medical Devices Regulations***

The Act created Schedule 1 to the *Patent Act* which lists the "pharmaceutical products" (drugs and medical devices) eligible to be exported under this Program. Although there are currently no medical devices listed on Schedule 1, it is contemplated that medical devices (e.g. HIV diagnostic test kits) could eventually be added to Schedule 1.

#### 1. Conditions for the Minister to notify the Commissioner of Patents

Amendments to the *Medical Devices Regulations* were made in order to place conditions upon medical device manufacturers (similar to the *Food and Drug Regulations* described above) that must be met before the Minister of Health can notify the Commissioner of Patents that the product meets the requirements of the FDA and regulations. The requirements for unique markings, labelling and notification to the Commissioner of Patents necessitate the addition of new provisions to the *Medical Devices Regulations*.

#### *Distinguishing Features Package*

Similar to the regulations respecting drugs, medical devices are required to be permanently marked with the "XCL" identifier on all permanent components. Labels are also required to be permanently marked with an "XCL" identifier followed by the control number assigned to Class III and IV devices by the manufacturer, and the phrase "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA" or "POUR EXPORTATION AUX TERMES DE LA DÉCISION DU CONSEIL GÉNÉRAL. VENTE INTERDITE AU CANADA."

#### 2. Notice to the Commissioner of Patents

The Minister of Health will notify the Commissioner of Patents that the medical device meets the requirements of the FDA and regulations if:

- the manufacturer holds a medical device licence for the device in question;

- the manufacturer and the device meets the requirements of the FDA and Regulations;
- a copy of the application for an authorization has been provided by the manufacturer to the Minister of Health;
- a sample of the label has been provided by the manufacturer to the Minister of Health; and
- information relating to the manner in which the mark is to be applied to the permanent components of the device has been provided by the manufacturer to the Minister of Health.

The notification to the Commissioner of Patents will be similar to the form issued for drugs.

### 3. Pre-Export Notification Requirements

The manufacturer is required to notify the Minister of Health no less than 15 days prior to commencing the manufacture of the device.

#### **Non-regulatory amendments**

In addition to the regulations discussed above, a number of Health Canada policies, guidelines and standard operational procedures (SOP) must be updated or created to reflect a slight variation in the operational processes involved in processing submissions under this Program. These will contribute to the effective and efficient implementation of the Access to Medicines Program.

#### ***Alternatives***

Health Canada has aimed to limit the number of amendments to existing regulations to those necessary to support the implementation of the GCD. Amendments made to the *Patent Act* and the FDA by "the Act" contains the requirements for notification to the Commissioner of Patents and for product distinguishing features. The detailed requirements for these are set out in regulation so that they will be transparent and have the force of law.

Pharmaceutical products exported under this Program must meet the Canadian standards set out in the current Regulations. Consequently, few changes are required to be made to the existing regulatory requirements beyond those relating to distinguishing features, and the Minister of Health's notification to the Commissioner of Patents that the product meets the requirements of the FDA and regulations.

Various alternatives were considered to fulfil Canada's obligation as an exporting WTO member to ensure that products produced under an authorization are clearly identified as being produced under the GCD. For example, consideration was given to allowing manufacturers to self-determine what the distinguishing markings would be. This was found to be unacceptable, because it would be difficult to maintain a consistent application of this requirement. The GCD places responsibility on the exporting country and suppliers to distinguish products through various means - including labelling, marking, special packaging, special colouring and shaping. From a scientific perspective, it is known that some of these means of distinguishing products may have an effect on the product's safety, or quality. As Health Canada is the regulatory authority responsible for the review of manufacturers' evidence that a product is safe, efficacious and of high quality, such requirements are best outlined in regulation in order to develop and maintain a consistent and transparent framework.

Another consideration was that the current markings used on generic products may be sufficient in terms of distinguishability. This option was rejected because the GCD requires products to be identified as "being produced under the system set out in the GCD". Markings that a manufacturer currently uses on Canadian products (often to identify the name of the generic manufacturer) do not identify the product as belonging to this Program. It was further considered that a common and unique marking could be an effective and efficient mechanism to readily identify products belonging to this Program.

With regard to the pre-export notification requirements, the Regulations proposed in the *Canada Gazette*, Part I required that the manufacturer notify the Minister of Health not less than 15 days prior to commencing the manufacture of each lot of a drug. This has since been modified to read: "The manufacturer shall notify the Minister in writing not less than 15 days before commencing the manufacture of the first lot of a drug authorized to be sold under this Division and not less than 15 days before the exportation of each subsequent lot of the drug.". This change responds to a manufacturer's need for flexibility in planning manufacturing schedules while still maintaining the notification needed for Health Canada inspectors to plan and schedule their inspections.

### ***Benefits and Costs***

The Act and these Regulations set out the legislative framework implementing the GCD. This Access to Medicines Program demonstrates Canada's important role on the international stage in advancing global health and human rights. It also serves to encourage other G8 nations to implement similar programs. The intention of the GCD is to assist developing and least developed countries in need, in addressing their public health problems. Canada's Access to Medicines Program seeks to achieve a humanitarian objective, and is intended to complement Canada's other contributions towards the global fight on HIV/AIDS, malaria, tuberculosis and other public health problems.

Canada's Access to Medicines Program and these Regulations will not affect Canadians' access to drugs or medical devices, nor will they affect the established performance targets for product assessments, as the Government of Canada has approved funding for Health Canada to implement this Program. This funding, in part, will be used to establish a dedicated human resource capacity to review product submissions related to products to be exported under the GCD and to make a determination that the products meet Canadian standards. The requirement for manufacturers to submit a Statement of Intent to apply for an authorization is a signal that the product submission be reviewed pursuant to the new regulations, policies and procedures.

### ***Consultation***

#### Legislative Process

During the development of the Act, major stakeholders were consulted. Following the introduction of the Bill, major stakeholders were provided with the opportunity to make representations and provide written submissions to the House of Commons Standing Committee on Industry, Science and Technology, the Senate Standing Committee on Foreign Affairs and government officials. Comments that impacted the Regulations were taken into consideration during their development.

#### December 2003

An early workshop was held with representatives of the generic manufacturers in mid-December 2003, primarily to gain a better understanding of the range of possible methods for unique markings and the optimal method of identifying various product dosage forms. Consultation with representatives of the brand manufacturers was also undertaken in December 2003.

To provide a consistent and recognizable identification, it was decided that a standard marking would be prescribed in the Regulations. The letters "XCL" would be permanently marked on all solid dosages, and on the immediate container of all non-solid dosages. Additionally, all labels would contain the "XCL" identifier, and "FOR EXPORT UNDER THE GENERAL COUNCIL DECISION. NOT FOR SALE IN CANADA.", in either English or French.

The method used to mark the product has been left to the discretion of the manufacturer, provided it is permanent and does not alter the safety or efficacy of the drug. This flexibility allows manufacturers to employ new technologies as they become available, while preserving the integrity of the product and ensuring the identifying mark is present. Manufacturers are required to inform the Minister of Health of the method used to mark the product.

#### July 2004 Consultations on the Proposed Regulations

During the month of July 2004, consultations on the proposed Regulations were conducted with Canada's Research-Based Pharmaceutical Companies (Rx&D), the Canadian Generic Pharmaceutical Association (CGPA), and non-governmental organizations.

Some stakeholders were of the opinion that the distinguishing features requirements needed to be more stringent, in order to avoid diversion of products. While this Program needs to ensure that the requirements under the GCD have been met, and anti-diversion measures are present, the distinguishing features requirements cannot be too burdensome for manufacturers. Requirements such as those under the *Patent Act* for a manufacturer to develop and maintain a website containing details about the product(s) being exported (e.g. quantity), and the distinguishing features as discussed above, are designed to serve as anti-diversion measures.

Other stakeholders indicated some concern respecting distinguishing features requirements. For example, the requirement to have a significantly different colour from the product on the Canadian market was indicated to be problematic for a manufacturer since it could result in the additional

requirement to demonstrate that the new colour does not affect the safety and efficacy of the product.

It was also noted that the requirement to notify the Minister of Health prior to the manufacturing of each lot may be too onerous for manufacturers.

#### The Canada Gazette, Part I, Consultation Period

The proposed Regulations were pre-published on October 2, 2004 in the *Canada Gazette*, Part I, for a 75-day comment period, ending December 16, 2004. A number of comments were received, and are summarized below.

Health Canada has considered stakeholder comments, and has made minor modifications to C.07.011, the provision on pre-export notification requirement. The requirement for a manufacturer to notify the Minister of Health still remains. However, the modification deals with the timing of pre-export notifications to the Minister of Health. This change has been made to address concerns that the proposed provision published in the *Canada Gazette*, Part I was too administratively burdensome. This is dealt with in more detail below. This is the only modification to the Regulations.

#### 1. Linkages between the Export Tracking Number and the Authorization

A few stakeholders suggested that a link must be made between the Health Canada issued export tracking number and the authorization issued by the Commissioner of Patents in order that the product can clearly be linked to a particular authorization. A Health Canada export tracking number is generated for each notification by the Minister of Health to the Commissioner of Patents. The export tracking number is an alphanumeric number where the two-letter country code corresponds to the intended importing country. The Commissioner of Patents has committed to adopting this Health Canada generated export tracking number as their authorization number.

#### 2. Lack of an Ongoing Requirement to Sell the Product in the Originally Approved Colour, Shape and Size

Some stakeholders noted that the notification from the Minister of Health to the Commissioner of Patents occurs at one point in time, and that there is no ongoing requirement for the holder of the authorization to maintain the same characteristics of a product. Currently, manufacturers must notify, or obtain Health Canada approval on any changes (e.g. colour) made to their products after receiving Health Canada's authorization to sell these products on the Canadian market. This will not change for products being exported under this Program. Current policies and guidance documents will be updated to include their application to products being exported under this Program. Consequently, any changes made to products following the Minister of Health's notification to the Commissioner of Patents that the product meets the requirements of the FDA and its regulations must be reported to Health Canada. If, as a result of these changes, the product ceases to meet the requirements of the FDA and its regulations, the Minister of Health must notify the Commissioner of Patents of the non-compliance.

#### 3. Distinguishing Features

##### "XCL"

Some stakeholders commented that the requirement to have all solid dosage products marked with "XCL" is not sufficient to prevent diversion and counterfeiting. A suggestion made was to require that each solid dosage form carry a marking that corresponds to the respective authorization. Under the GCD, one of the conditions to the compulsory licence is for products to be clearly identified as being produced under the system through specific labelling or marking. Health Canada has determined that the mark "XCL" would sufficiently achieve this condition by clearly identifying the product as being produced under Canada's Program to implement the GCD. There are additional distinguishing feature requirements for products such as being significantly different in colour from the version sold in Canada, and labelling requirements.

##### *Significantly Different Colour*

Some stakeholders wanted the colour to be significantly different from the version of the drug sold both in Canada and the United States of America. The requirement that the colour of the drug be significantly different from the version sold in the United States is not considered a viable option as the Minister of Health only has direct knowledge of the product that is on the Canadian market.

### Labelling

Stakeholders indicated that the labelling requirement should be specific to each importing country. For example, it was suggested that the label bear the words "FOR SALE ONLY IN COUNTRY X".

The Regulations require the label of the drug to bear the mark "XCL" followed by the export tracking number assigned by the Minister of Health. An export tracking number is generated for each notification by the Minister of Health to the Commissioner of Patents. As mentioned previously, the export tracking number is an alphanumeric number where the two-letter country code corresponds to the intended importing country. This allows the intended destination of a pharmaceutical product to be readily identified.

Other stakeholders have a general concern with the cumulative effect of the distinguishing feature requirements in the proposed Regulations. It was suggested by some stakeholders that the cumulative effect of the distinguishing feature requirements are too costly for manufacturers, and in fact, are not expressly required under the GCD. Some maintain that the proposed Regulations go beyond the requirements of the GCD in that it requires labelling, marking and colouring.

The GCD imposes certain conditions to the compulsory licence (authorization in Canada) issued by the exporting WTO member. The Act implements the GCD domestically, and permits the Commissioner of Patents to authorize the manufacture and export of a patented product if certain conditions are met. One of these conditions is that the Minister of Health must have notified the Commissioner that the product meets the requirements of the FDA and its regulations, including regulations relating to the marking, embossing, labelling and packaging that identify that version of the product as being manufactured in Canada as having been permitted by the GCD.

The Act provides the Governor in Council with the authority to make any regulations it considers necessary for implementing the GCD. The GCD-imposed conditions relevant to the distinguishing features are that the products shall be "clearly identified as being produced under the system through specific labelling or marking". Additionally, suppliers are to take measures necessary to distinguish products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price.

As an exporting member, Canada has the obligation to identify products as being produced under the GCD. Health Canada has, therefore, decided to develop regulations specifying the distinguishing features required to identify products as being produced under the GCD. The decision to require "XCL" to be permanently marked on all product labels, that it be marked on solid-dosage products, and that solid-dosage products be significantly different in colour from the version sold in Canada serves to meet these obligations. Health Canada has determined that "XCL" ought to be marked directly on products in order to identify the solid-dosage pills as being produced under the GCD.

As a regulatory authority, Health Canada is responsible for the review of manufacturers' data on the product's safety, efficacy and quality. Therefore, measures to identify products as being produced under the GCD, such as colour and markings must be a part of Health Canada's scientific review. Such measures must be openly and consistently communicated to stakeholders, which are most effectively done through Regulations.

A number of alternatives to the cumulative requirements of labelling, marking and colouring have been discussed. It has been determined that the cumulative distinguishing feature requirements of marking and colouring (for solid-dosage products), and labelling are necessary in order to meet Canada's obligations as a WTO exporting member, and the legislative framework created under the Act. The distinguishing features act as a mechanism to prevent diversion or re-importation of these pharmaceutical products from their intended destinations.

Health Canada does not anticipate that the distinguishing feature requirements will have a significant financial impact on manufacturers, as these requirements do not necessitate new technologies or manufacturing processes. There will be no fees charged for the review and processing of these distinguishing feature requirements.

#### 4. Notice to the Minister

During the consultation process, a number of stakeholders indicated that the proposed amendments to the *Food and Drug Regulations* requiring written notification to the Minister not less than 15 days prior to commencing the *manufacture of each lot* of a product was too administratively burdensome. Other stakeholders suggested that there be a provision setting out a mandatory pre-export inspection of pharmaceutical products being exported under Canada's Program. The Health Products and Food Branch Inspectorate has committed to conducting pre-export inspections of the distinguishing

features of these products prior to initial exportation.

Health Canada has determined that the requirement to notify the Minister of Health in writing 15 days prior to the *manufacture of each lot* could be administratively burdensome for manufacturers as it does not allow enough flexibility for manufacturers to manage their manufacturing schedules. Consequently, the regulatory amendments have been slightly revised to require the manufacturer to notify the Minister of Health no less than 15 days before the manufacturing of the first lot of a drug, and no less than 15 days prior to the exportation (rather than the manufacturing) of each subsequent lot of a drug. The Inspectorate requires notification prior to initial *manufacturing* in order that it be able to check the manufacturing process, or the labelling process when necessary. The minor modification to the Regulations continues to provide the Inspectorate with the necessary notification to allow for the planning and scheduling of inspection activities.

#### ***Compliance and Enforcement***

These Regulations do not alter existing compliance mechanisms under the provisions of the FDA and regulations enforced by the Health Products and Food Branch Inspectorate. Section 23 of the FDA provides inspectors with the authority and the power to conduct compliance and enforcement procedures to pharmaceutical products including those under this Program. The Inspectorate has committed to inspecting the products prior to initial exportation. The requirement to provide the Minister of Health with notification of intended manufacturing and exporting will allow for adequate time to schedule inspections, if necessary.

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#### [Footnote a](#)

S.C. 2004, c. 23, s. 2

#### [Footnote 1](#)

C.R.C., c. 870

#### **NOTICE:**

The format of the electronic version of this issue of the Canada Gazette was modified in order to be compatible with hypertext language (HTML). Its content is very similar except for the footnotes, the symbols and the tables.



[Top of page](#)

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