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Vol. 138, No. 50 — December 11, 2004

## Regulations Amending the Food and Drug Regulations (1390 — Data Protection)

*Statutory authority*

*Food and Drugs Act*

*Sponsoring department*

Department of Health



### REGULATORY IMPACT ANALYSIS STATEMENT

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

#### **Description**

These proposed amendments to C.08.004.1 will codify more clearly Canada's data protection commitments under the North American Free Trade Agreement (NAFTA) and the Trade Related Aspects of Intellectual Property (TRIPS) Agreement of the World Trade Organization. These commitments require that signatories provide protection against the unfair commercial use of undisclosed test or other data submitted for obtaining approval of pharmaceutical or agricultural chemical products, where such products utilize new chemical entities, for a minimum of five years. This data cannot be relied on to approve an equivalent second-entry (generic) drug product for

marketing in the country in which the originator obtained that approval, without the originator's permission. The intent of this protection is to allow the originator of the data to protect the investments made in the development of the product by allowing a period of market exclusivity in the country in which it obtained approval.

Under the current Regulations, in order for data protection to arise, the Minister of Health must examine and rely on an innovator's undisclosed data in order to grant a notice of compliance (required to market the product) to the equivalent generic product. However, to receive a notice of compliance in Canada, a generic manufacturer is required to demonstrate bioequivalence to the innovator product by comparing the generic product to the innovator product. Therefore, in actual practice, the Minister typically does not examine the data contained in the innovator's submission in order to grant a notice of compliance for a generic product. As a result, recent jurisprudence has affirmed that data protection does not arise where bioequivalence forms the basis of the submission.

While the comparison necessary to demonstrate bioequivalence rarely involves an examination of the innovator's data, it does involve reliance on the innovator product. These amendments, therefore, are being introduced to clarify that such reliance will give rise to data protection.

In addition, these amendments will alter the term of data protection from five to eight years to better reflect market exclusivity resulting from data protection for innovative new drugs worldwide. An additional one-half year will be provided for submissions that include pediatric studies that were designed and conducted with the purpose of increasing knowledge about the drug in pediatric age groups in which the drug may be used. Extending market exclusivity in this manner will encourage pediatric research and improve drug information regarding pediatric usage for health professionals, thus providing health benefits to children.

The term of data protection is intended to run from the date of issuance of the first notice of compliance for a drug containing a medicinal ingredient not previously approved in Canada. Only one term of protection is intended for each new medicinal ingredient.

Protection does not apply where the drug identification number

for the innovator drug has been cancelled pursuant to paragraph C.01.014.6(a). This is to prevent the situation where the originally marketed version of an innovator drug is withdrawn from the Canadian market by the innovator, but no equivalent generic drug is allowed on the Canadian market until the protection period has expired (and, therefore, Canadians do not have access to the drug).

Generic manufacturers will continue to be permitted to file a submission with the Minister within the term of data protection. Where the submission is approvable under the *Food and Drug Regulations* but for the data protection, the submission will be placed on hold until the term of protection has expired. At the date of expiry, a notice of compliance for the purpose of marketing in Canada can be issued, subject to any other requirements in the *Patented Medicines (Notice of Compliance) Regulations*.

#### Type of submission eligible for protection

The NAFTA and TRIPS provisions apply only to new chemical entities. [\(see footnote 1\)](#) To market a new chemical entity in Canada, a manufacturer must receive a notice of compliance. Given that the relevant regulation-making authority under the Act is limited to implementing NAFTA and TRIPS, the type of submissions eligible for protection is, therefore, limited to submissions for drugs containing new medicinal ingredients granted a notice of compliance under Division 8 of Part C to the Regulations.

#### Schedule D drugs

The same provisions will apply to drugs listed on Schedule D to the *Food and Drugs Act*, namely drugs of biological origin. It is recognized that instances where it is possible to establish that a second-entry biological drug is bioequivalent to an innovator drug may be rare; nevertheless, the same eight-year protection period will apply to submissions with reduced requirements where the comparison is the basis upon which a notice of compliance is sought.

#### Terms of protection available internationally

Currently, the United States offers a five-year term of protection to manufacturers who file a submission for a new active ingredient, with an additional three years of protection available

for new uses or other significant changes approved on the basis of new and essential clinical investigations. The United States established an incentive program in 1997 that extends by six months any existing exclusivity for drugs for which pediatric studies were conducted and deemed acceptable by the Food and Drug Administration.

The European Union offers a ten-year period of market protection, which can be extended to eleven years on the basis of the authorization of one or more new therapeutic indications. The European Commission has proposed new regulations that will enhance data protection by an extra six months for drugs with pediatric studies.

#### *Amendments to the Patented Medicines (Notice of Compliance) Regulations*

These amendments are being enacted at the same time as amendments to the *Patented Medicines (Notice of Compliance) Regulations* [PM(NOC) Regulations]. Amendments to those Regulations are intended to reaffirm the requirements for listing patents on the patent register, thereby restoring the original policy intent of the PM(NOC) Regulations and reduce the number of court cases between innovator and generic manufacturers, which can delay the issuance of a notice of compliance to the latter. The changes also clarify that the PM(NOC) Regulations apply only to those second-entry submissions in which a comparison is made to the drug for which a patent is listed, where the comparison is for demonstrating bioequivalence. Neither the PM(NOC) Regulations nor data protection are intended to apply to submissions in which no such comparison is made, such as where the sponsor of the submission is required to conduct independent clinical studies to establish the safety and efficacy of its product. For further information on the proposed amendments to the PM(NOC) Regulations, refer to the RIAS prepared by Industry Canada and published on the same day as this RIAS.

#### ***Alternatives***

In determining how best to clarify Canada's NAFTA and TRIPS commitments, alternative options were considered.

Maintain the status quo

The first option considered was to maintain the status quo. Because these amendments are to clarify and reflect the original policy objective of the NAFTA and TRIPS agreements, as well as to harmonize with the terms of protection offered in other jurisdictions, maintaining the status quo is not an acceptable alternative to amending the Regulations.

Introduce a term of protection similar to the United States

Another option considered was to adopt a term of protection similar to that available in the United States, which provides a five-year term of protection to manufacturers who file a submission for a new active ingredient, with an additional three years of protection available for new uses or other significant changes approved on the basis of new and essential clinical investigations.

A single term of data protection of eight years is more stable and administrable than a stepped approach of five years plus three years, as offered in the United States. For this reason, this alternative was not pursued.

### ***Benefits and costs***

The proposed amendments to the *Food and Drug Regulations* will provide innovators with a stable, predictable period of market exclusivity that is internationally competitive, and encourage them to bring their drugs to the Canadian market.

The proposed amendments to the PM(NOC) Regulations will not impact significantly on the market exclusivity of innovators currently abiding by the spirit of those Regulations. They will, however, accelerate the market entry of lower-priced second-entry drugs that have been prevented from entering the market while court cases involving the innovator's patent listing are in progress.

Therefore, the net effect of amendments to the data protection provision of the *Food and Drug Regulations* concurrent with amendments to the PM(NOC) Regulations should be to provide a balanced, stable regime that encourages innovation while at the same time ensuring Canadians have access to affordable medicine. In addition, to maintain predictability, the amendment also includes a grandfathering provision, which provides that innovator submissions received by Health Canada prior to the date of coming into force remain subject to the data protection

provision as it was interpreted and applied prior to that date.

### ***Consultation***

No consultations were held with affected parties prior to publication in the *Canada Gazette*, Part I.

Publication in the *Canada Gazette*, Part I, will be followed by a 75-day consultation period, during which time stakeholders may provide their views on the proposed amendments to the *Food and Drug Regulations*.

### ***Compliance and enforcement***

This amendment does not alter existing compliance mechanisms under the provisions of the *Food and Drugs Act* and Regulations enforced by Health Canada inspectors.

### ***Contact***

Dr. Robert Peterson, Director General, Therapeutic Products Directorate, Holland Cross, Tower B, 6th Floor, 1600 Scott Street, Ottawa, Ontario K1A 1B6, Address Locator 3106B, (613) 957-0369 (telephone), (613) 952-7756 (facsimile), Proj1390@hc-sc.gc.ca (electronic mail).

## **PROPOSED REGULATORY TEXT**

Notice is hereby given that the Governor in Council, pursuant to subsection 30(3) ([see footnote a](#)) of the *Food and Drugs Act*, proposes to make the annexed *Regulations Amending the Food and Drug Regulations (1390 — Data Protection)*.

Interested persons may make representations with respect to the proposed Regulations within 75 days after the date of publication of this notice. All such representations must cite the *Canada Gazette*, Part I, and the date of publication of this notice, and be addressed to Dr. Robert Peterson, Director General, Therapeutic Products Directorate, Health Products and Food Branch, Department of Health, 1600 Scott Street, Holland Cross, Tower B, 6th Floor, Address Locator No. 3106B, Ottawa, Ontario K1A 0K9 (tel.: (613) 957-0368; fax: (613) 952-7756; e-mail: proj1390@hc-sc.gc.ca).

Persons making representations should identify any of those representations the disclosure of which should be refused

under the *Access to Information Act*, in particular under sections 19 and 20 of that Act, and should indicate the reasons why and the period during which the representations should not be disclosed. They should also identify any representations for which there is consent to disclosure for the purposes of that Act.

Ottawa, December 6, 2004

EILEEN BOYD  
*Assistant Clerk of the Privy Council*

**REGULATIONS AMENDING THE FOOD AND DRUG  
REGULATIONS (1390 — DATA PROTECTION)**

AMENDMENT

**1. Section C.08.004.1 of the *Food and Drug Regulations* ([see footnote 2](#)) is replaced by the following:**

**C.08.004.1** (1) The following definitions apply in this section and in section C.08.004.2.

"innovative drug" means a drug in respect of which an innovator has received a notice of compliance and includes a drug referred to in paragraph (a) of the definition "Canadian reference product" in section C.08.001.1. (*drogue innovante*)

"pediatric age groups" means the following groups: premature babies born before the 37th week of gestation; full-term babies from 0 to 27 days of age; and all children from 28 days to 2 years of age, 2 years plus 1 day to 11 years of age and 11 years plus 1 day to 18 years of age. (*groupes d'âge pédiatrique*)

(2) This section and section C.08.004.2 apply to the implementation of Article 1711 of the North American Free Trade Agreement, within the meaning given to the word "Agreement" by subsection 2(1) of the *North American Free Trade Agreement Implementation Act*, and paragraph 3 of Article 39 of the Agreement on Trade-related Aspects of Intellectual Property Rights set out in Annex 1C to the WTO Agreement, within the meaning given to the word "Agreement" by subsection 2(1) of the *World Trade Organization Agreement Implementation Act*.

(3) The Minister shall not issue a notice of compliance to a manufacturer, in respect of a new drug that the manufacturer compares to an innovative drug, before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug if

(a) the manufacturer, in its new drug submission, abbreviated new drug submission, supplement to a new drug submission or supplement to an abbreviated new drug submission, directly or indirectly, compares the new drug to the innovative drug and the innovative drug contains a medicinal ingredient that had not been approved in Canada before the first notice of compliance was issued to the innovator;

(b) the comparison forms the basis on which the manufacturer seeks the issuance of a notice of compliance; and

(c) the medicinal ingredient in the new drug is identical to the medicinal ingredient in the innovative drug.

(4) For the purpose of subsection (3), if the first notice of compliance was issued to the innovator in respect of a submission that contained pediatric studies relating to pediatric age groups for which the drug may be used and the Minister determines that the studies were designed and conducted for the purpose of increasing knowledge of the use of the drug in those groups and thereby providing health benefits to the members of those groups, the period specified in that subsection shall be eight years and six months.

(5) Subsection (3) does not apply if the assignment of a drug identification number for the innovative drug has been cancelled under paragraph C.01.014.6(1)(a).

(6) Subsection (3) does not apply if the innovator consents to the issuance of a notice of compliance to the manufacturer referred to in that subsection before the end of the period specified in that subsection.

(7) Nothing in this section prevents any manufacturer from filing a submission or supplement with the Minister before the end of the period specified in subsection (3).

**C.08.004.2** Despite subsection C.08.004.1(3), if the innovator's new drug submission for the innovative drug referred to in that subsection was filed before the coming into force of this

section, only section C.08.004.1, as it read immediately before the coming into force of this section, applies to the issuance of a notice of compliance in respect of the manufacturer's submission or supplement referred to in subsection C.08.004.1(3).

## COMING INTO FORCE

**2. These Regulations come into force on the day on which they are registered.**

[50-1-o]

### [Footnote 1](#)

Although the NAFTA and TRIPS agreements use the term "new chemical en-tity," "new medicinal ingredients" is used here to correspond to the terminology already used in the Food and Drugs Regulations.

### [Footnote a](#)

S.C. 1994, c. 47, s. 117

### [Footnote 2](#)

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.

  
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