

# **Notice of Proposed Regulations to Amend Ontario Regulation 935 under the Drug Interchangeability and Dispensing Fee Act and Ontario Regulation 201/96 under the Ontario Drug Benefit Act**

## **Introduction**

The Minister of Health and Long-Term Care [Minister] on behalf of the Government of Ontario invites public comments on proposed regulations to amend Ontario Regulation 935 [Reg. 935] made under the *Drug Interchangeability and Dispensing Fee* [DIDFA] and Ontario Regulation 201/96 [O. Reg. 201/96] made under the *Ontario Drug Benefit Act* [ODBA].

The DIDFA and the ODBA require that the Minister publish a notice on the ministry's web site concerning certain proposed regulations under the ODBA and DIDFA. This notice pertains to two proposed amending regulations: one which proposes to amend Reg. 935 and the other which proposes to amend O. Reg. 201/96.

The content of the final regulations are at the discretion of the Lieutenant Governor in Council, who may make the regulations with any changes that the Lieutenant Governor in Council considers appropriate.

## **Content of Proposed Regulations**

The proposed regulations would amend O. Reg. 201/96 and Reg. 935 in the following way.

### **Summary of proposed regulation amending Reg. 935 under the DIDFA**

Section 1(1) would

- Amend section 6(1) of the regulation to add a condition for each strength and dosage form of a drug product to be designated as interchangeable with other products that the manufacturer of the drug product submit to the executive officer proof in writing that no rebate (as defined in the Act) has been provided with respect to the product from the time that Health Canada approved the product for sale in Canada.

Section 1(2) would

- Amend section 6(5.1) of the regulation to provide that if one of the types of drug products specified in subsection (5) (e.g. aqueous solution, oral solution, etc.) has been designated by Health Canada on or after February 15, 2005 as equivalent to the original product or to another listed interchangeable product with which it would be designated as interchangeable, the drug product is

deemed to be pharmaceutically equivalent to the original product and to demonstrate the same physicochemical properties of the original product.

#### Section 2 would

- Amend section 8 (Conditions to Continue to be Designated as Interchangeable) of the regulation to add a new paragraph 5.2 to provide an exception to the rule that if the product is a listed drug product under the ODBA, the drug benefit price of the product may not be more than the price that could be proposed to the executive officer under subsection 7 (2). The exception, which would only be in force until July 12, 2007, would provide that the rule does not apply where there is evidence satisfactory to the executive officer that:
  - the product was designated as a listed drug product under the *Ontario Drug Benefit Act* on or before April 1, 1994,
  - the product is one of no more than two drug products that has been designated as interchangeable with an original product and is a listed drug product,
  - the manufacturer is unable to supply the drug product at the drug benefit price due to increased manufacturing costs, including raw material costs, but not due to professional allowances, sales and marketing expenses, or legal costs, which evidence must be supported by the certification of two officers of the manufacturer, and
  - removing the product's listing would result in significant patient safety or access concerns, or significant increased costs to the Government of Ontario.
- Amend section 8 to add a new paragraph 8 which would provide that it is a condition for each strength and dosage form of a drug product to continue to be designated as interchangeable with other products that the manufacturer of the drug product must not have provided a rebate (as defined in the Act) with respect to the product from the time that Health Canada approved the product for sale in Canada.
- Amend section 8(3) to provide that, if the above noted exception applies, the executive officer may, in the executive officer's sole discretion, negotiate an agreement with the manufacturer for any drug benefit price that is not higher than the original product price.

#### Section 3 would

- Provide that the Regulation comes into force on the day it is filed.
- Provide that the amendment to section 8(5.2) (as described under Section 2 above) shall be repealed on July 12, 2007.

## Summary of proposed regulation amending O. Reg. 201/96 under the ODBA

### Section 1 would

- Amend section 12 of the regulation to add a condition for each strength and dosage form of a drug product to be listed as a listed drug product that the manufacturer of the drug product submit to the executive officer certification in writing that no rebate (as defined in the Act) has been provided with respect to the product from the time that Health Canada approved the product for sale in Canada.
- Amend section 12 to add a new subsection (8.1) which would provide that it is a condition of being listed as a listed drug product that the manufacturer must not have provided a rebate (as defined in the Act) with respect to the product from the time that Health Canada approved the product for sale in Canada.

### Section 2 would

- Amend section 12.1 of the regulation to add a new paragraph 5.2 to provide an exception to the rule that if the product is a listed drug product under the ODBA, the drug benefit price of the product may not be more than the price that could be proposed to the executive officer under subsection 7 (2). The exception, which would only be in force until July 12, 2007, would provide that the rule does not apply where there is evidence satisfactory to the executive officer that:
  - the product was designated as a listed drug product under the ODBA on or before April 1, 1994;
  - the product is one of no more than two drug products that has been designated as interchangeable with an original product and is a listed drug product;
  - the original product was not designated as a listed drug product on October 23, 2006;
  - the manufacturer is unable to supply the drug product at the drug benefit price due to increased manufacturing costs, including raw material costs, but not due to professional allowances, sales and marketing expenses, or legal costs, which evidence must be supported by the certification of two officers of the manufacturer, and
  - removing the product's designation would result in significant patient safety or access concerns, or significant increased costs to the Government of Ontario.
- Amend 12.1(3) to provide that, if the above noted exception applies, the executive officer may, in the executive officer's sole discretion, negotiate an

agreement with the manufacturer for any drug benefit price that is not higher than the original product price.

Section 3 would

- Provide that the Regulation comes into force on the day it is filed.
- Provide that the amendment to s. 12.1(5.2) (as described under Section 2 above) is repealed on July 12, 2007.

### **Invitation to Provide Written Comments**

While the DIDFA and the ODBA require at least 30 days from the date of the publication of the notice during which the public may submit written comments on the proposed regulations, the legislation authorizes the Minister to shorten the time period for public comment if the Minister is of the opinion that the urgency of the situation requires it or the proposed regulations clarify the intent or operation of the DIDFA, the ODBA or their regulations.

As there is urgency to the matters addressed in the proposed regulations and they clarify the intent and operation of the regulations they propose to amend, the time period for members of the public to make written submissions on the proposed regulations has been accordingly shortened and interested parties are invited to provide written comments on the proposed regulations to amend Reg. 935 and O. Reg. 201/96 on or before **5 p.m. on Tuesday June 12<sup>th</sup>, 2007** [comment period].

When preparing your response, please consider whether you agree with the proposed regulations to amend Reg. 935 under the DIDFA and O. Reg. 201/96 under the ODBA and/or whether the proposed regulations should be changed. Please provide any other relevant comments you think might be useful. Please be as specific as possible and provide a full rationale for any suggested changes or additions.

### **Submission of Written Comments**

Please submit your written comments to:

Helen Stevenson  
Executive Lead, Drug System Secretariat  
Ontario Ministry of Health and Long-Term Care  
415 Yonge Street, Suite 1601  
Toronto, Ontario M5B 2E7  
Fax: (416) 325-6647  
E-mail: [helen.stevenson@moh.gov.on.ca](mailto:helen.stevenson@moh.gov.on.ca)

All comments and submissions received during the comment period will be considered during the preparation of the final regulations. Comments and submissions received after

the comment period will not be considered. The content, structure, and form of the proposed regulations may be changed as a result of the comment process in the discretion of the Lieutenant Governor in Council, who has the final decision on the contents of any final regulations. The final amending regulations may, therefore, be different from those posted in this notice.

Copies of the DIDFA, the ODBA, Reg. 935 and O. Reg. 201/96 are available from Publications Ontario, 50 Grosvenor St., Toronto, Ontario, M7A 1N8, (416) 326-5300. They are also available from [www.e-Laws.gov.on.ca](http://www.e-Laws.gov.on.ca).

The content of the final regulations amending Reg. 935 and O. Reg. 201/96 would be published in the Ontario Gazette at [www.ontariogazette.gov.on.ca](http://www.ontariogazette.gov.on.ca) and on e-laws at [www.e-Laws.gov.on.ca](http://www.e-Laws.gov.on.ca).

### **Statement about Comments**

Please note that unless requested and agreed otherwise by the ministry, all materials or comments received from organizations in response to this notice will be considered public information and may be used and disclosed by the ministry to assist in evaluating and revising the proposed regulations. This may involve disclosing materials or comments, or summaries of them, to other interested parties during and after the comment period.

An individual who provides materials or comments and who indicates an affiliation with an organization will be considered to have submitted those comments or materials on behalf of the organization so identified.

Materials or comments received from individuals who do not indicate an affiliation with an organization will not be considered public information unless expressly stated otherwise by the individual. However, the ministry may use and disclose materials or comments provided by individuals to assist the ministry in evaluating and revising the proposed regulations. The ministry will not disclose personal information of those who do not specify an organizational affiliation, such as an individual's name and contact details, without the individual's consent unless required by law.

If you have any questions about the collection of this information, you can contact the ministry's Freedom of Information and Privacy Coordinator at (416) 327-7040.

**The Honourable George Smitherman**  
**Minister of Health and Long-Term Care**

## **PROPOSED REGULATION AMENDING REG. 935 UNDER THE DIDFA**

**1. (1) Subsection 6 (1) of Regulation 935 of the Revised Regulations of Ontario, 1990 is amended by adding the following clause:**

- (f) certification in writing that no rebate as defined in subsection 12.1 (14) of the Act has been provided to a person listed in subsection 12.1 (1) of the Act with respect to the product contrary to the Act since Health Canada approved the product for sale in Canada;

**(2) Subsection 6 (5.1) of the Regulation is amended by adding “on or after February 15, 2005” after “Health Canada”.**

**2. (1) Paragraph 4 of subsection 8 (1) of the Regulation is amended by striking out “5 and 5.1” and substituting “5, 5.1 and 5.2”.**

**(2) Paragraph 4 of subsection 8 (1) of the Regulation, as amended by subsection (1), is amended by striking out “5, 5.1 and 5.2” and substituting “5 and 5.1”.**

**(3) Subsection 8 (1) of the Regulation is amended by adding the following paragraphs:**

- 5.2 Paragraph 4 does not apply with respect to a product that has been designated as interchangeable with an original product where there is evidence satisfactory to the executive officer that:
  - i. the product was designated as a listed drug product under the *Ontario Drug Benefit Act* on or before April 1, 1994,
  - ii. the product is one of no more than two drug products that has been designated as interchangeable with an original product and is a listed drug product,
  - iii. the manufacturer is unable to supply the drug product at the drug benefit price due to increased manufacturing costs, including raw material costs, but not due to professional allowances, sales and marketing expenses, or legal costs, which evidence must be supported by the certification of two officers of the manufacturer, and
  - iv. removing the product’s listing would result in significant patient safety or access concerns, or significant increased costs to the Government of Ontario.

. . . . .

8. The manufacturer must not have provided a rebate as defined in subsection 12.1 (14) of the Act to a person listed in subsection 12.1 (1) of the Act with respect to the product contrary to the Act since Health Canada approved the product for sale in Canada.

**(4) Paragraph 5.2 of subsection 8 (1) of the Regulation, as made by subsection (3), is revoked.**

**(5) Subsection 8 (3) of the Regulation is amended by striking out “5 or 5.1” and substituting “5, 5.1 or 5.2”.**

**(6) Subsection 8 (3) of the Regulation, as amended by subsection (5), is amended by striking out “5, 5.1 or 5.2” and substituting “5 or 5.1”**

**3. (1) Subject to subsection (2), this Regulation comes into force on the day it is filed.**

**(2) Subsections 2 (2), (4) and (6) come into force on July 12, 2007.**

#### **PROPOSED REGULATION AMENDING O. REG. 201/96 UNDER THE ODBA**

**1. (1) Subsection 12 (1) of the Regulation is amended by adding the following clause:**

- (f) certification in writing that no rebate as defined in subsection 11.5 (18) of the Act has been provided to a person listed in subsection 11.5 (1) of the Act with respect to the product contrary to the Act since Health Canada approved the product for sale in Canada;

**(2) Section 12 of the Regulation is amended by adding the following subsection:**

(8.1) It is a condition of being listed as a listed drug product that the manufacturer must not have provided a rebate as defined in subsection 11.5 (18) of the Act to a person listed in subsection 11.5 (1) of the Act with respect to the product contrary to the Act since Health Canada approved the product for sale in Canada..

**2. (1) Paragraph 5 of subsection 12.1 (1) of the Regulation is amended by striking out “6 and 6.1” and substituting “6, 6.1 and 6.2”.**

**(2) Paragraph 5 of subsection 12.1 (1) of the Regulation, as amended by subsection (1), is amended by striking out “6, 6.1 and 6.2” and substituting “6 and 6.1”.**

**(3) Subsection 12.1 (1) of the Regulation is amended by adding the following paragraph:**

- 6.2 Paragraph 5 does not apply with respect to a product that has been designated as interchangeable with an original product where there is evidence satisfactory to the executive officer that:
- i. the product was designated as a listed drug product on or before April 1, 1994,
  - ii. the product is one of no more than two drug products that has been designated as interchangeable with an original product and is a listed drug product,
  - iii. the manufacturer is unable to supply the drug product at the drug benefit price due to increased manufacturing costs, including raw material costs, but not due to professional allowances, sales and marketing expenses, or legal costs, which evidence must be supported by the certification of two officers of the manufacturer, and
  - iv. removing the product’s listing would result in significant patient safety or access concerns, or significant increased costs to the Government of Ontario.

**(4) Paragraph 6.2 of subsection 12 (1) of the Regulation, as made by subsection (3), is revoked.**

**(5) Subsection 12.1 (3) of the Regulation is amended by striking out “6 or 6.1” and substituting “6, 6.1 or 6.2”.**

**(6) Subsection 12.1 (3) of the Regulation, as amended by subsection (5), is amended by striking out “6, 6.1 or 6.2” and substituting “6 or 6.1”**

**3. (1) Subject to subsection (2), this Regulation comes into force on the day it is filed.**

**(2) Subsections 2 (2), (4) and (6) come into force on July 12, 2007.**

