

# **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] under the *Drug Interchangeability and Dispensing Fee Act* [DIDFA] and Ontario Regulation 201/96 [O. Reg. 201/96] 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 regulations: one which proposes to amend Reg. 935 [the "DIDFA Regulation"] and the other which proposes to amend O. Reg. 201/96 [the "ODBA Regulation"].

This notice includes proposed regulation amendments that require consultation, as well as proposed regulation amendments that do not require consultation and that are included for information purposes to provide a more complete description of the proposed changes. These later regulation amendments are provided in the background section of the document.

**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 the DIDFA Regulation and the ODBA Regulation as follows:

### **Summary of proposed regulation amending the DIDFA Regulation**

Section 1 of the proposed regulation to amend the DIDFA Regulation:

- would add a new subsection (6) to section 7 of the DIDFA Regulation to clarify that the manufacturers of products that were listed as benefits on the Formulary before December 31, 2007, but which were delisted in Formulary Update 8 (published on January 15, 2008) or Formulary Update 8A (published on January 17, 2008), may apply for re-listing under the New Exception (introduced by Section 2 of the proposed regulation, as described below). If a manufacturer applies to have a qualifying product re-listed, the product: (i) will be deemed to have met the conditions for listing under s. 6(1) of the DIDFA Regulation; (ii)

must meet the conditions for continued listing under section 8 of the DIDFA Regulation; and (iii) must meet the price increase criteria posted by the Executive Officer on the Ministry website.

Section 2 of the proposed regulation to amend the DIDFA Regulation:

- subsection (1) is a related technical change.
- subsection (2) would amend s.8(1), paragraph 5 of the DIDFA Regulation to make clear that this provision applies only to the Formulary update Edition No. 39, published on October 23, 2006.
- subsection (3) would create a new exception to paragraph 4 of s.8(1) of the DIDFA Regulation (i.e. the 50% pricing rule for interchangeable products that are listed benefits).

The **New Exception** would provide that:

1. if a manufacturer submits evidence satisfactory to the Executive Officer of substantial raw material cost increases for a drug product; and
  2. the manufacturer meets the criteria published by the Executive Officer on the Ministry website establishing that it is in the public interest that the drug product be listed at a higher drug benefit price,
- then the Executive Officer may, in the Executive Officer's sole discretion, negotiate an agreement with the manufacturer of the drug product for any drug benefit price, but in no case may the product be priced higher than the original product [*Refer to Background section for policy related to price increases*].

- subsection (4) is a related technical change.

Section 3 of the proposed regulation to amend the DIDFA Regulation provides that the proposed regulations would come into force on the day they are filed

## **Summary of proposed regulation amending the ODBA Regulation**

Section 1 of the proposed regulation to amend the ODBA Regulation:

- subsection (1) is a technical change which would amend paragraph 2 of s.11(1) of the ODBA Regulation (Conditions for Designation of Listed Drug Products) to make this paragraph consistent with the language in the corresponding paragraph of s.7(2) of the DIDFA Regulation.
- subsection (2) would add a new subsection (5) to s.11 of the ODBA Regulation to clarify that the manufacturers of products that were listed as benefits on the Formulary before December 31, 2007, but which were delisted in Formulary Update 8 (published on January 15, 2008) or Formulary Update 8A (published on January 17, 2008), may apply for re-listing under the New Exception (introduced

by Section 2 of the proposed regulation, as described below). If a manufacturer applies to have a qualifying product re-listed, the product: (i) will be deemed to have met the conditions for listing under s. 6(1) of the DIDFA Regulation; (ii) must meet the conditions for continued listing under section 8 of the DIDFA Regulation; and (iii) must meet the price increase criteria posted by the Executive Officer on the Ministry website.

Section 2 of the proposed regulation to amend the ODBA Regulation:

- would amend s.12(6) of the ODBA Regulation to make it clear that products that are proposed for designation as an interchangeable drug product do not have to comply with submission requirements in s.12(1) of the ODBA Regulation, as they would already have to comply with similar requirements under s.6(1) of the DIDFA Regulation.

Section 3 of the proposed regulation to amend the ODBA Regulation:

- subsection (1) is a related technical change.
- subsection (2) would amend s.12.1(1), paragraph 6 of the ODBA Regulation to make clear that this provision applies only to the Formulary update Edition No. 39, published on October 23, 2006.
- subsection (3) would create a new exception to paragraph 5 of s.12.1(1) of the ODBA Regulation (i.e. the 50% pricing rule for interchangeable products that are listed benefits).

The **New Exception** would provide that:

1. if a manufacturer submits evidence satisfactory to the Executive Officer of substantial raw material cost increases for a drug product; and
  2. the manufacturer meets the criteria published by the Executive Officer on the Ministry website establishing that it is in the public interest that the drug product be listed at a higher drug benefit price,
- then the Executive Officer may, in the Executive Officer's sole discretion, negotiate an agreement with the manufacturer of the drug product for any drug benefit price, but in no case may the product be priced higher than the original product [*Refer to Background section for policy related to price increases*].

- subsection (4) is a related technical change.

Section 4 of the proposed regulation to amend the ODBA Regulation:

- subsection (1) would create a power for the Executive Officer to establish criteria that must be met for the purpose of the New Exceptions (described in Section 3 above) in order to establish that it is in the public interest to list a drug product at a higher drug benefit price, and provide that the Executive Officer must publish

the criteria on the Ministry's website [*refer to Background section for policy related to price increases*].

- subsection (2) is a related technical change.

Section 5 of the proposed regulation to amend the ODBA Regulation:

- would add a new subsection (7) under s.18 of the ODBA Regulation to specify that the Executive Officer is not required to pay a dispensing fee for the dispensing of a drug to an eligible person in a quantity that is sufficient for less than a 30-day course of treatment, unless: (a) the eligible person is a resident of a long-term care home; or (b) the prescriber has indicated on the prescription that a lower quantity is to be dispensed.

Section 6 of the proposed regulation to amend the ODBA Regulation provides that the proposed regulations would come into force on the day they are filed.

## **Background**

### **Proposed Criteria for Price Increases for Brand and Generic Drugs**

The following section is not required as part of this Notice of Proposed Regulations, however, in the interests of transparency, the Executive Officer is proposing to publish the following criteria on the Ministry website pertaining to price increase requests for both **brand and generic** products listed on the Formulary. The proposed regulation amendments (required to allow price increases for qualifying generic products) are contained in Section 2 of the proposed regulation to amend the DIDFA Regulation and Section 3 of the proposed regulation to amend the ODBA Regulation. No regulation amendment is required in order to accept brand product price increases.

Note that the Executive Officer reserves the right, in the Executive Officer's sole discretion, to amend or modify any of the criteria noted below prior to publication on the Ministry's website, or to amend the criteria at any time after publication.

Price increase requests may be considered for brand and generic products listed on the Formulary for at least three years where there has been a substantial increase in the raw material costs directly related to that product.

Manufacturers will be required to submit relevant cost information to support a price increase request based on material cost increases, plus two years of historical data to assess growth rates. Templates will be posted on the ministry's website that will outline the requested information. Requests will be reviewed as they are received.

## Invitation to Provide Written Comments

The DIDFA and the ODBA require a 30-day consultation period from the date of the publication of the notice during which the public may submit written comments on the proposed regulations.

Interested parties are invited to provide written comments on the proposed regulations to amend Reg. 935 under the DIDFA and O. Reg. 201/96 under the ODBA **before 5 p.m. on Friday May 30, 2008.**

When preparing your response, please consider whether you agree with the proposed regulations to amend the DIDFA Regulation and the ODBA Regulation 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  
Assistant Deputy Minister and  
Executive Officer, Ontario Public Drug Programs  
Ministry of Health and Long-Term Care  
80 Grosvenor Street, 9<sup>th</sup> Floor  
Hepburn Block, Queen's Park  
Toronto ON  
M7A 1R3  
Fax: 416-325-6647  
E-mail: [helen.stevenson@ontario.ca](mailto:helen.stevenson@ontario.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. Section 7 of Regulation 935 of the Revised Regulations of Ontario, 1990 is amended by adding the following subsection:**

(6) For greater certainty, upon the application of the manufacturer, the Executive Officer may re-designate a drug product as a benefit under the *Ontario Drug Benefit Act* that was designated on the Formulary before December 31, 2007, and whose designation was removed by either of the amendments to the Formulary known as Update 8 to Edition 40, effective January 15, 2008, or Update 8A to Edition 40, effective January 17, 2008, subject to the following:

1. The submission requirements set out in subsection 6 (1) shall be deemed to have been met with respect to the product.

2. The conditions for continued listing set out in section 8 must be met with respect to the product.
3. The criteria established by the Executive Officer under section 12.2 of Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* must be met with respect to the product.

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

**(2) Paragraph 5 of subsection 8 (1) of the Regulation is amended by adding the following sentence at the end:**

This paragraph applies only with respect to the version of Formulary known as Edition No. 39, published on October 23, 2006.

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

- 5.2 Paragraph 4 does not apply with respect to a product that has been designated as interchangeable with an original product where the manufacturer of the interchangeable product has submitted evidence satisfactory to the Executive Officer of substantial raw material cost increases, and the Executive Officer is satisfied that the criteria established under section 12.2 of Ontario Regulation 201/96 (General) made under the *Ontario Drug Benefit Act* have been met establishing that it is in the public interest that the interchangeable product be listed at a higher drug benefit price, but in no case may the interchangeable product be priced higher than the original product.

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

**3. This Regulation comes into force on the day it is filed.**

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

**1. (1) Paragraph 2 of subsection 11 (1) of Ontario Regulation 201/96 is amended by striking out “if the product is an original product that was but is no longer a listed drug product” and substituting “if the original product was but is no longer a listed drug product”.**

**(2) Section 11 of the Regulation is amended by adding the following subsection:**

(5) Upon the application of the manufacturer, the Executive Officer may re-designate a drug product that was designated on the Formulary before December 31,

2007, and whose designation was removed by either of the amendments to the Formulary known as Update 8 to Edition 40, effective January 15, 2008, or Update 8A to Edition 40, effective January 17, 2008, subject to the following:

1. The submission requirements set out in subsection 12 (1) shall be deemed to have been met with respect to the product.
2. The conditions for continued listing set out in section 12.1 must be met with respect to the product.
3. The criteria established by the Executive Officer under section 12.2 must be met with respect to the product.

**2. Subsection 12 (6) of the Regulation is amended by striking out “that is designated” and substituting “that is proposed to be designated”.**

**3. (1) Paragraph 5 of subsection 12. 1 (1) of the Regulation is amended by striking out “paragraphs 6 and 6.1” and substituting “paragraphs 6, 6.1, and 6.2”.**

**(2) Paragraph 6 of subsection 12.1 (1) of the Regulation is amended by adding the following sentence at the end:**

This paragraph applies only with respect to the version of the Formulary known as Edition No. 39, published on October 23, 2006.

**(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 the manufacturer of the interchangeable product has submitted evidence satisfactory to the Executive Officer of substantial raw material cost increases, and the Executive Officer is satisfied that the criteria established under section 12.2 have been met establishing that it is in the public interest that the interchangeable product be listed at a higher drug benefit price, but in no case may the interchangeable product be priced higher than the original product.

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

**4. The Regulation is amended by adding the following section:**

ESTABLISHING CRITERIA

**12.2** Pursuant to subsection 1.1 (9) of the Act, it is provided that,

- (a) the Executive Officer has the power to establish criteria that must be met for the purposes of paragraph 6.2 of subsection 12.1 in order to establish that it is in the public interest to list a drug product at a higher drug benefit price; and
- (b) the Executive Officer shall publish those criteria on the Ministry website.

**5. Section 18 of the Regulation is amended by adding the following subsection:**

(7) Despite subsections 13 (4) and 17 (2), the dispensing fee payable by the Executive Officer for the dispensing of a drug to an eligible person with respect to a quantity of the drug that is sufficient for less than a 30-day course of treatment is nil unless,

- (a) the eligible person is a resident of a long-term care home; or
- (b) the prescriber has indicated on the prescription that a lower quantity is to be dispensed.

**6. This Regulation comes into force on the day it is filed.**