

Proposed Regulation Amendments to Establish a Pricing Framework for Certain Generic Products on the Ontario Drug Benefit (ODB) Formulary

November 5, 2014

As part of ongoing efforts to reduce the cost of drugs, the Health Care Innovation Working Group (HCIWG), through the Council of Federation, announced steps toward achieving better value for generic drugs through the Pan-Canadian Generic Value Price Initiative. The initial phases of this work led to establishing a price point for a total of 10 of the most common drugs at 18% of the equivalent brand name product on April 1st of 2013 and 2014.

The next phase of this work was in response to the Canadian Generic Pharmaceutical Association (CGPA) submitting a proposed tiered pricing model to Provinces and Territories (P/T) for consideration. Through ongoing discussions with P/Ts a final pan-Canadian framework was developed.

Proposed amendments to O. Reg. 201/96 made under the *Ontario Drug Benefit Act* are required to implement the pricing framework for certain generic drug products approved for listing on the Ontario Drug Benefit (ODB) Formulary/Comparative Drug Index. Pricing for generic products listed on the Formulary apply to public and private reimbursement.

As part of the HCIWG commitments, the framework will be reassessed within three years of the effective date for the proposed changes.

The current pricing framework requires manufacturers to set generic prices at 25% of the brand reference product for solid dosage forms (e.g., tablets, capsules) and 35% for non-solid dosage forms (e.g., solutions, creams). The regulations include a number of provisions for the Executive Officer to consider exemptions to the 25/35% price requirements.

The proposed regulations would establish a framework for generic pricing for products listed on the Formulary on or after April 1, 2013 where there are only 1 or 2 generic products available in the Canadian market. The proposed amendments would set the price of a generic product, where there are no other generic products listed on the Formulary and/or available on the Canadian market (“single source generic product”) at 75% of the brand reference product or 85% if the Province does not have a listing agreement with the brand reference product. The price of the generic product that is set at 75/85% may be reviewed by the Executive Officer 120 days before the second anniversary date of listing. The Executive Officer may request additional information to be provided by the manufacturer to support the price of the drug product. The Executive Officer is required to complete her review of the price of the product within prescribed timelines.

Where there are only 2 generic products available on the Canadian market (“dual source generic products”), the price would be set at 50%. If there are 3 or more generic products, then the current 25/35% price rules apply.

The proposed framework is not intended to impact a large number of generic product listings. The P/Ts will be monitoring the impact of these changes as part of the three year reassessment.

The proposed regulation would also include provisions to address potential price increases for Ontario single or dual source generic products listed before 2006. The current regulations state that the price of a generic product may not be higher than the brand reference product, unless stringent public interest criteria are met. In some cases, the brand product may no longer be marketed and, as a result, the reference price may be too low in light of inflation over a long period of time. For single and dual source generic products listed prior to 2006 the brand reference price may be adjusted based on CPI to a maximum of 10 years, for the purpose of adjusting the highest reference price for older generic products. The pricing of older generic products will be discussed as part of the ongoing work of the HCIWG to develop recommendations on a common approach for considering price adjustments. Additional amendments to the regulation may be proposed at that time to reflect the outcome of that work.

A copy of the draft regulation is available on the Regulatory Registry website at:

<http://www.ontariocanada.com/registry/view.do?postingId=16622&language=en>

The content of the final regulations are at the discretion of the Lieutenant Governor in Council (“LGIC”) who may make the regulations with any changes that the LGIC considers appropriate.

Interested parties are invited to provide written comments on the proposed change to the draft regulations as part of the review. The ministry will consider comments received on or before **December 21, 2014 at 5:00 p.m. EST** (“comment period.”). Please be advised that submissions received after the comment period may not be considered.

Please submit your written comments to:

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Statement about Comments

Unless requested and otherwise agreed to by the ministry, all materials or comments received from organizations in response to the notice will be considered public information and may be used and disclosed by the ministry as part of its review. The ministry may disclose materials or comments, or summaries of them, to other interested parties during and after the comment period.

An individual who makes a submission and who indicates an affiliation with an organization in his or her submission will be considered to have made his or her submission on behalf of the affiliated organization.

The ministry will not disclose any personal information contained in a submission of an individual who does not specify an organizational affiliation in his or her submission without the individual's consent unless required by law. However, the ministry may use and disclose the content of the individual's submission to assist the ministry in its review.

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.