

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

---

May 20, 2015

The purpose of this notice is to provide you with information regarding recent amendments to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* (“ODBA Regulation”) that will support implementation of the tiered generic pricing framework. The amendments have been approved by the Ontario Government and come into force **retroactively as of April 1, 2013**.

A notice was posted on the ministry’s website on November 5, 2014 that provided stakeholders with information on the proposed amendments to the ODBA Regulation. Stakeholders were given a 45-day period to comment on the proposed regulatory amendments.

I would like to thank all those who submitted comments and participated in the consultation process. As a result of the comments we received, the draft regulations were changed to clarify that for sole source generic products, the 85% price tier only applies if no provincial or territorial authority (including the Executive Officer) has a volume discount agreement with the manufacturer of the relevant brand reference product. The draft regulation was also revised to authorize the Executive Officer to adjust a brand reference price based on Consumer Price Index (CPI) by a factor of more than 10 years, where it is in the public interest to do so.

The amendments to the ODBA Regulation establish a pricing framework for certain generic drug products approved for listing on the Ontario Drug Benefit (ODB) Formulary/Comparative Drug Index on or after April 1, 2013, based on the number of competitor generic products available in the interchangeable group in the Canadian market.

The regulation amendment also addresses the pricing of old drug products, allowing a higher brand reference price to be used to determine the price for single and dual source generic products where the brand name reference product has been discontinued for 10 years or more. The brand reference price would be the product’s highest price when it was listed as a benefit and may be adjusted based on the Ontario all-items CPI to a maximum of 10 years. In exceptional cases, the Executive Officer would be able to adjust the brand reference price beyond 10 years, where it is in the public interest.

For the authoritative text of the regulations, please visit the e-Laws website at:  
<http://www.ontario.ca/laws/regulation/960201>.

Implementation of the framework will provide increased transparency in pricing policy, and will promote stability and predictability in the generic marketplace, while supporting the Government's commitment to protect Ontario's universal health care system as part of the *Patients First: Ontario's Action Plan for Health Care*.

Any questions regarding the tiered generic pricing framework can be directed to:

Executive Officer, Ontario Public Drug Programs  
Ministry of Health and Long-Term Care  
80 Grosvenor Street, 9th Floor  
Hepburn Block, Queen's Park  
Toronto ON  
M7A 1R3  
Fax: 416-325-6647  
E-mail: [PublicDrugPrgrms.moh@ontario.ca](mailto:PublicDrugPrgrms.moh@ontario.ca)