

Notice: Proposed Amendments to Regulations under the *Ontario Drug Benefit Act* and the *Drug Interchangeability and Dispensing Fee Act* relating to Private Label Products

October 29, 2018

The purpose of this notice is to provide you with information regarding proposed revocations of section 12.0.2 of Ontario Regulation 201/96 (made under the *Ontario Drug Benefit Act*) and section 9 of Regulation 935 (made under the *Drug Interchangeability and Dispensing Fee Act*) that would, if approved, come into force at a future date.

The proposed regulatory amendments would allow private label products to be designated as listed drug products under the *Ontario Drug Benefit Act*, or interchangeable products under the *Drug Interchangeability and Dispensing Fee Act*, if other existing conditions in the regulations are met.

The proposed regulatory amendments would reduce the regulatory burden on companies that wish to develop and sell private label products, and ensure that Ontario's position on private label products is aligned with the other provinces and territories in Canada.

A summary and draft of the proposed amendments to the regulations are available on the Regulatory Registry website at:

<https://www.ontariocanada.com/registry/view.do?postingId=27986&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.

The MOHLTC is also seeking feedback on two other potential regulatory initiatives relating to private label products. Please visit the Regulatory Registry at the above link to see a description of those potential initiatives.

Interested parties are invited to provide written comments on the proposed changes to the regulations as part of the review. The ministry will consider comments received on or before **November 27, 2018 at midnight EST**. Please be advised that submissions received after this date may not be considered.

Please submit your written comments to:

Drugs and Devices Division
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

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.