Ontario Public Drug Programs Division

Proposal to amend Ontario Regulation 201/96 under the *Ontario Drug Benefit Act* and Regulation 935 under the *Drug Interchangeability and Dispensing Fee Act* to optimize appropriate access to unlisted, non-Formulary drug products and further streamline submission requirements for generic drug products

June 1, 2016

As outlined in the *Patients First: Action Plan for Health Care*, the Ministry of Health and Long-Term Care (the "ministry") is committed to building a health care system that is patient-centered and more efficient.

As part of its continuing efforts to strengthen the Ontario Public Drug Programs (the "OPDP"), the ministry is proposing regulatory amendments to Ontario Regulation 201/96 made under the *Ontario Drug Benefit Act* and Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act* that would enable the OPDP to optimize patient access to drug products as well as further streamline and improve the generic drug listing process.

The proposed amendments, if approved, would:

- Enable more appropriate access to certain drugs through Formulary listing, which are currently only available under the Exceptional Access Program;
- Remove a submission barrier for new strengths of a generic product that do not have a comparable reference product (known as a "generic line extension"); and
- Allow for the remaining generic products with a Declaration of Equivalence designation from Health Canada to be reviewed under the faster, streamlined drug submission process.

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

http://www.ontariocanada.com/registry/view.do?postingId=21743&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 changes to the regulations as part of the review. The ministry will consider comments received on or before

July 18, 2016 at midnight EST (“comment period.”). Please be advised that submissions received after the comment period may not be considered.

Please submit your written comments to:

Executive Officer, Ontario Public Drug Programs

Ministry of Health and Long-Term Care

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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.