

## Template Letter of Authorization to Collect and Disclose Pre-NOC Information

[Manufacturer's letterhead]

[Date]

Director  
Drug Programs Policy and Strategy Branch  
Drugs and Devices Division  
Ministry of Health and Long-Term Care  
3rd Floor, 5700 Yonge Street  
Toronto, ON M2M 4K5

Dear Director:

**RE: Rapid Review of <product name/generic name, strength, and dosage form > (the “Product”) manufactured by <name of manufacturer> (“the Manufacturer”).**

Background:

- i. The Manufacturer has made a submission to Health Canada seeking authorization to market and sell the Product in Canada (“Drug Submission”) but has not, as of yet, been issued a Notice of Compliance (“NOC”) in respect of the Product;
- ii. The Manufacturer has also submitted the Product for designation as a listed drug product on the Ontario Formulary under the expedited review process established by s.12(1)(a)(ii) of O. Reg 201/96 made under the Ontario Drug Benefit Act (the “Rapid Review Process”), which permits Her Majesty the Queen in right of Ontario as represented by the Executive Officer for Ontario Public Drug Programs (“Ontario”) to commence review of drug products prior to the issuance by Health Canada of a NOC;
- iii. As a condition of being considered for designation as a listed drug product on the Ontario Formulary through the Rapid Review Process, the Manufacturer must authorize Ontario to obtain information in respect of the Product from Health Canada prior to the potential issuance by Health Canada of a NOC for the Product (“Pre-NOC Information”).

For the purposes of this Letter of Authorization, Pre-NOC Information: Includes:

- i. information provided to Health Canada by the Manufacturer as part of the Drug Submission and any other information obtained by Health Canada in connection with the Drug Submission;
- ii. any information, documents or reports, including reviewer reports, created by Health Canada in the course of its review of the Drug Submission; and
- iii. any information pertaining to the Product or the Manufacturer in the possession of the government of any province or territory in Canada, the Patented Medicine Prices Review Board (PMPRB), the Canadian Agency for Drugs and Technology in Health (CADTH), or Cancer Care Ontario (the “Public Organizations”).

Excludes:

- i. third party proprietary information in the possession of Health Canada which Health Canada has agreed with that third party to hold in confidence; and
- ii. any pricing information in respect to the Product which the Manufacturer has supplied to Ontario as confidential information.

Authorization of Manufacturer:

The Manufacturer, both during and after the Rapid Review Process, authorizes Ontario to:

- i. collect and use any and all Pre-NOC Information in the possession of Health Canada, the government of any province or territory in Canada, the PMPRB, the CADTH, or Cancer Care Ontario (the “Public Organizations”);
- ii. disclose in confidence any and all Pre-NOC Information in the possession of Ontario to Health Canada, the government of a province or territory in Canada, the PMPRB, the CADTH, or Cancer Care Ontario (the “Public Organizations”); and
- iii. if the Product is a cancer drug, disclose in confidence any pricing information in respect of the Product to Cancer Care Ontario, or CADTH (the “Public Organizations”).

The Manufacturer further authorizes Health Canada to:

- i. disclose in confidence any and all Pre-NOC Information in its possession to Ontario for use by Ontario, and
- ii. respond to any inquiries made by Ontario in respect of Pre-NOC Information disclosed to Ontario pursuant to this Letter of Authorization.

*[Signature]*

*[Name and Title of Senior Company Official]*

I have authority to bind the Manufacturer