Ministry of Health
Health Programs and Delivery Division

# Drug Submission: Policy Directive

Health Programs and Delivery Division is working to improve efficiencies and to modernize drug submission requirements.

The purpose of this notice is to provide information regarding changes to the Ontario Guidelines for Drug Submission and Evaluation (Guidelines) to assist manufacturers in making submissions to the Health Programs and Delivery Division.

To modernize the submission requirements for manufacturers of “well-established” brand and generic drug products, the Ontario Government has made amendments to O. Reg. 201/96 under the *Ontario Drug Benefit Act* (ODBA) and Reg. 935 under the *Drug Interchangeability and Dispensing Fee Act* (DIDFA).

Well-established drugs are drug products that are not “new drugs” as defined in the Food and Drug Regulations made under the *Food and Drugs Act* (Canada). In other words, they are drug products containing substances that have been sold in Canada for sufficient time and in sufficient quantity to establish their safety and effectiveness.

Prior to the making of the regulatory amendments described above, Ontario’s submission requirements for brand and generic drugs were not fully aligned with Health Canada’s requirements for approving well-established drugs for sale in Canada. This misalignment may have prevented manufacturers of certain well-established drugs from having their products funded under the Ontario Drug Benefit (ODB) program and/or designated as interchangeable in Ontario.

Manufacturers are asked to take note of the following changes, effective immediately:

The ministry has updated the following guidelines available on the ministry’s website.

- Ontario Guidelines for Single Source Drug Products.
- Ontario Guidelines for Multiple Source Drug Products.

Manufacturers are responsible for monitoring changes made to the Guidelines from time to time.

**For more information, please visit the ministry's website at: Drug Submissions**