Ontario

Ministry of Health

OHIP, Pharmaceuticals and Devices Division

Executive Officer Notice: Updates to the Ontario Guidelines for Drug Submission and Evaluation

The OHIP, Pharmaceuticals and Devices Division is working to improve efficiencies and to simplify 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 OHIP, Pharmaceuticals and Devices Division.

The Guidelines were last updated in September 2016. Since then, the ministry introduced a number of changes to streamline submission requirements for various submission types. These changes are posted separately, as Addenda, on the ministry's website.

The ministry has recently updated the Guidelines to reflect and consolidate the previous changes. In an effort to reduce complexity and simplify this policy document, specific guidelines aiming to address individual product types are now available.

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

Specific guidelines for different types of products are posted on the ministry's website.

- Ontario Guidelines for Single Source Drug Products.
- Ontario Guidelines for Biosimilar Products.
- Ontario Guidelines for Multiple Source Drug Products.
- Ontario Guidelines for Nutrition Products.
- Ontario Guidelines for Diabetic Testing Agents.
- Ontario Guidelines for Valved Holding Chambers.
- Ontario Guidelines for Flash Glucose Monitoring.

- Ontario Guidelines for Transitioning Unlisted Single Source Drug Products from Exceptional Access Program (EAP) to the Ontario Drug Benefit Formulary/ Comparative Drug Index.
- Ontario Guidelines for Transitioning Generic Drug Products from Exceptional Access Program (EAP) to the Ontario Drug Benefit Formulary/ Comparative Drug Index.
- Ontario Guidelines for Notification of Change to Brand Drug Products.
- Ontario Guidelines for Notification of Change to Generic 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