Ontario Public Drug Programs, Ministry of Health and Long-Term Care

Executive Officer Notice

Drug Submission – Ontario Guidelines for Drug Submission and Evaluation 2016

To help drug manufacturers prepare drug submissions, the Ministry of Health and Long-Term Care has updated its Ontario Guidelines for Drug Submission and Evaluation (Guidelines).

The Guidelines take effect on October 6, 2016. All submissions received on or after this date must comply.

The updated Guidelines reflect current regulatory and policy requirements for manufacturer submissions.

Highlights include:

- Compilation of previously stand-alone submission guideline documents, such as
  - Submission Guidelines for Diabetic Testing Agents (with additional guidance on studies and standards)
  - Submission Guidelines for Nutritional Products, and
  - Submission Guidelines for Long-Acting Oxycodone Products in a Solid Oral Dosage Form
- New section to describe policies that relate to drug submissions evaluation
- All templates required for submissions, including two new template letters:
  - Certification Confirming Product is not a Private Label Product
  - Confirmation of Same Formulation for Clinical and Commercial Lot

The updated Guidelines are also available on the ministry's website as of September 16, 2016.

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