Ministry of Health

Drugs and Devices Division

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

The Drugs 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 Drugs and Devices Division.

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

1. Simplified requirements for *Notification of Change* submissions.
2. Simplified requirements for *Off-Formulary Interchangeability* (OFI) submissions.
3. Removal of the *Template Letter of Confirmation of Same Formulation for Clinical and Commercial Lot* for submissions under the *Ontario Drug Benefit Act (ODBA).*
4. The ministry will accept the clinical evidence and pharmacoeconomic evidence submitted to the Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (pCODR) for submissions under the ODBA. The information will be accepted and will not be subject to further screening or adjudication for quality.
5. Removal of the ODB Financial Impact Analysis - Assumptions and Estimates Template for submissions under the ODBA.
6. Removal of the Certified Product Information Document (CPID) or Master Formulation for submissions under the ODBA where the drug product that is the subject of the submission was reviewed by the Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (pCODR).
7. Remove the Submission Summary Template for submissions under the ODBA.

8. Reminder that the Clinical Data Checklist for submissions under the ODBA where the drug product that is the subject of the submission was reviewed by the Common Drug Review (CDR) or the pan-Canadian Oncology Drug Review (pCODR) is not required.

Manufacturers must continue to make submissions to the Drugs and Devices Division to have their products considered by the Executive Officer for listing and funding, in accordance with Regulation 201/96 of the *Ontario Drug Benefit Act* and Regulation 935 of the *Drug Interchangeability and Dispensing Fee Act*

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