Ontario

Ministry of Health

Drugs and Devices Division

Drug Submission: Policy Directive

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. Requirements for various types of *Notification of Change* submissions are simplified. The following sections have been revised or removed:

    - Changes to the Drug Identification Number (DIN), Ownership, Company Name, and Drug Product Name.
    - Changes to the Master Formulation.
    - Changes to the Product Monograph.
    - Changes Not Approved by Health Canada.
    - Changes in the Container Closure System where the Primary Packaging Component is not affected.

    Manufacturers are requested to replace relevant sections of the Ontario Guidelines for Drug Submission and Evaluation as follows:

    - Replace requirements for Notification of Change to Brand Drug Products (page 127 to page 136) of the current Drug Submission Guidelines with the new section available at the following link:

http://www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/guideline_templates.aspx

- Replace requirements for Notification of Change to Generic Drug Products (page 200 to page 208) of the current Drug Submission Guidelines with the new section available at the following link:

http://www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/guideline_templates.aspx

2. Requirements for *Off-Formulary Interchangeability* (OFI) submissions are simplified. The following Reference Product Requirements have been removed:

- A copy of summary of bioequivalence study final report between the submitted and reference drug products for oral solid dosage forms, non-aqueous, oil-based solutions, suspension and metered dose inhalers. The study final report must contain the product name, generic name, lot number and expiry date of the submitted and reference products.

  When the lot number and expiry date is not found in the protocol, please submit both the bioequivalence study final report and the summary or synopsis of the bioequivalence study.

- For aqueous solutions as classified under the *Health Canada Guidance for Industry: Pharmaceutical Quality of Aqueous Solutions*, the manufacturer must:
  - submit a waiver of comparative bioavailability studies for oral solutions, as applicable;
  - submit a waiver of the requirement to demonstrate in vivo bioequivalence for aqueous solutions, as applicable;
  - provide proof of purchase of Canadian reference product;
  - provide a certificate of analysis, i.e., the results of comparative and non-comparative physiochemical parameter tests with the innovator (reference product) demonstrating pharmaceutical equivalence. This includes product name, Drug Identification Number, strength, dosage form, package format (if applicable) and the expiry date of the test and reference products; and
  - describe any device attributes, as required by Health Canada.

- For pseudogeneric drug product, the manufacturer must provide:

  - The approved and completed clinical study final report, clinical study summary report or synopsis of the clinical study of the innovator (brand) product. This includes product name, strength, dosage form, package format (if applicable) and the expiry date of the brand product.

Manufactures are requested to replace requirements for *Off-Formulary Interchangeability* (OFI) submissions (page 244 to page 248) of the current Drug Submission Guidelines with the new section available at the following link:

http://www.health.gov.on.ca/en/pro/programs/drugs/drug_submissions/guideline_templates.aspx

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. Removal of the Submission Summary Tempalte 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*

Note: In making any submissions to the ministry, manufacturers are to refer to the complete Ontario Guidelines for Drug Submissions and Evaluation together with any updates (i.e., Drug Submissions Policy Directives) for the complete details on requirements and processes.

It is the manufacturer’s responsibility to monitor changes made to the Guidelines from time to time.