

Ministry of Health

Drugs and Devices Division

PART VI

**OFF-FORMULARY INTERCHANGEABILITY
MULTIPLE SOURCE DRUG PRODUCTS
SUBMISSION REQUIREMENTS**

**DRUG INTERCHANGEABILITY AND DISPENSING FEE ACT
(DIDFA)
REG. 935**

Implementation of Off-Formulary Interchangeability (OFI)

OFI means designating a drug product as interchangeable with an original product but not as a listed drug product (benefit) under the ODB i.e., original product is not listed on the Formulary. The ministry interprets **original product** to mean a brand name product (typically the innovator product) that has not been listed as a benefit on the Formulary.

For clarity and consistency, “original/innovator” will be used throughout the Guidelines.

A submission for an OFI interchangeable product must meet the regulatory requirements as prescribed in Regulation 935 made under the *Drug Interchangeability and Dispensing Fee Act* (the “DIDFA Regulation”) and the applicable regulation and policy requirements set out in Part III-B of the Guidelines. A submission must also include all applicable supporting documentation as applicable.

The ministry endeavours to process the OFI submissions two weeks after the cut-off date of [submission deadline](#). All complete and incomplete Notice of Drug Submission Status (NDSS) letters are usually faxed by 5p.m. three weeks after the new submission deadline.

If the submission is complete, the manufacturers will only be asked to respond to the Branch if the data (product description, Drug Identification Number (DIN) or price, etc.) provided in the letter is incorrect. Any changes/clarification must be provided in writing to the Manager, Benefits Administration one business day from the date of the fax. You may wish to fax your written response; however, the original date document must also be forwarded to the Branch. If there is no response from the manufacturer, the product(s) will go forward for consideration by the Executive Officer with no changes. If the manufacturer responds with a correction in one business day timeframe, the ministry will make the appropriate changes so that the product(s) will go forward for consideration by the Executive Officer.

In addition to meeting the requirements as set out in Part III-B, the manufacturers must submit the following information in respect of the OFI reference product to facilitate the listing of OFI products.

Reference Product Requirements:

1. Drug Identification Number (DIN);
2. Brand Name;
3. Medicinal Ingredient Name (generic name);
4. Strength;
5. Dosage Form;
6. Manufacturer Name.

Over-the-Counter (OTC) Drug Product or Natural Health Product (NHP)

The ministry will not accept or consider any submissions for OTC drug products or NHP drug product for considerations of OFI listing.

Discontinued Reference (Innovator) Product

The ministry will not consider generic-to-generic comparisons for interchangeability unless the generic reference product is designated and listed as OFI interchangeable with the original/innovator product.

Policy on Receipt and Format of Submissions

All submissions and any additional related information must be sent to:

Senior Manager
Drug Benefits Management
Drug Programs Policy and Strategy Branch
Drugs and Devices Division
Ministry of Health
3rd Floor, 5700 Yonge Street
Toronto, ON M2M 4K5

The manufacturer must submit one electronic copy of the submission. For electronic submissions, the ministry will accept CDs, DVDs or USB keys, and they must fulfill the following requirements:

- The documents must be provided in MS Word, Excel or PDF format that is unlocked, searchable and printable.
- Users must have the ability to extract information or combine documents.

Manufacturers may wish to password protect any electronic submissions (i.e., CD, DVD or USB key) made to the ministry. Send the password needed to access the files to the email DrugSubmissions.MOH@ontario.ca ahead of the arrival of the electronic drug submission to the ministry.

All submissions must be organized and indexed. Refer to Part II-A.1 for organization of information in submissions. The ministry will not accept faxed submissions. All submissions must be delivered by either courier services or in person by the manufacturer to the address indicated above by 3:00p.m. on the scheduled new submission deadline.

To facilitate the review of the clinical/bioequivalence data, as required, the manufacturers should not submit analytical raw data (e.g. laboratory analytical test preparation, LC/GLC chromatograms) for review.

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