Ministry of Health

Drugs and Devices Division

PART XIII. Guideline for Biosimilar Products

ODBA Regulation

12(2.2) Clauses (1) (h) and (i) do not apply to the manufacturer of a biosimilar product if the executive officer is satisfied that the product is safe, therapeutically effective or efficacious, and appropriate for public funding, having regard to,

(a) its approval for sale in Canada by Health Canada;

(b) the availability or funding of other drug products that treat the same or similar indications, including the original biologic product; and

(c) any other information available to the executive officer.

A "biosimilar product" means a biologic drug product that has been approved for sale in Canada by Health Canada based on information comparing the biosimilar product to an original biologic product.

A "biologic drug product" means a drug derived from living organisms or their cells.

An "original biologic product" means the original source of a biologic drug product in a particular strength and dosage form.

Submission Requirements

For biosimilar products to be considered for funding under the Ontario Drug Benefit (ODB) program, the manufacturer must provide a complete submission that satisfies the following requirements:

1. Cover letter.
2. Evidence that Health Canada has approved the product for sale in Canada, including:
    - A copy of the Notice of Compliance (NOC), if applicable;
    - A copy of the most recent Product Monograph approved by Health Canada.

3. A letter authorizing the Executive Officer to gain access to all information with respect to the Drug Product in the possession of Health Canada, the Patented Medicines Pricing Review Board established under section 91 of the *Patent Act* (Canada), the government of any province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health and authorizing the Executive Officer to disclose any information with respect to the Drug Product in the possession of the Ministry to Health Canada, the Patented Medicine Prices Review Board, the government of a province or territory in Canada or the Canadian Agency for Drugs and Technologies in Health.
   The ministry's template letter is available on the ministry's website.
4. An estimate of the net costs to the ODB Program in three-year period including:
   - Budget Impact Analysis (report and model; must include an estimate of the net costs to the ODB Program in a three-year period);
   - ODB Financial Impact Analysis Summary Sheet.

   The Summary Sheet template is available on the ministry's website.

5. Submit a proposed drug benefit price for the Drug Product.
6. Confirmation that the manufacturer is able to supply the Drug Product at the proposed drug benefit price in a quantity sufficient to meet the anticipated demand for the Drug Product. The ministry's template letter is available on the ministry's website.
7. The manufacturer must certify in writing that no rebates were provided to persons listed under subsection 11.5(1) of the ODBA with respect to the Drug Product from the time that Health Canada approved the Drug Product for sale in Canada. The ministry's template letter is available on the ministry's website.
8. Certification confirming that the Drug Product is not a private label product. The ministry's template letter is available on the ministry's website.

Third Party Authorization/Business Agreement:

Where a third party is involved with a submission, a letter should be submitted from **both** the NOC/DIN holder and the third party confirming the business arrangement between the submitting party and the NOC/DIN holder. Depending on the nature of the relationship, the letter from the NOC/DIN holder must provide an authorization to the third party to assume responsibility for the submission or authorization to submit the product on the NOC/DIN holder's behalf. All parties that have information on file with Health Canada, other provinces and other affiliated groups relating to the product must provide a consent letter allowing communication with these bodies as outlined in paragraph 3 above.

Format and Organization of Submissions:

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.

Filing of Drug 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 ministry expects manufacturers to follow the Guidelines when preparing submissions. The onus is on a manufacturer to provide the ministry with a submission that is complete, accurate and complies with applicable legislative, regulatory and policy requirements. Also, the ministry reserves the right to request additional information at any time during the review process.

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