Insert as a new section in Ontario Guidelines for Drug Submission and Evaluation
PART XII – Other Listed Substances

PART XII.2. Guidelines for Flash Glucose Monitoring (FGM)

For the purpose of this document, the ministry interprets "listed substance" to mean a product, other than a drug, that is approved and funded by the Executive Officer for ODB eligible recipients. This includes, but is not limited to, diabetic testing agents, nutrition products and valved holding chambers (VHCs). As a result, a submission for these products will undergo a similar review process as a drug product.

Flash Glucose Monitoring (FGM)

The ministry funds Flash Glucose Monitoring products through the ODB program. If an FGM product is listed on the Formulary, the FGM product would be eligible for reimbursement when it is prescribed for ODB-eligible recipients.

Submission Requirements

A manufacturer may satisfy the submission requirements by submitting one electronic copy (CDs, DVDs or USB keys) of the following:

(a) Cover Letter

The letter should include a subject heading that adheres to the following format:

RE: <insert full product name > (the "Product") manufactured by <insert name of manufacturer> ("the Manufacturer")

(b) Evidence that Health Canada has issued an authorization (i.e. a copy of the Medical Device Licence and Medical Device Establishment Licence, as applicable) for the sale or importation of the product in Canada;

(c) A letter authorizing the Executive Officer of Ontario Public Drug Programs (Executive Officer) to gain access to all information with respect to the product in the possession of Health Canada or of the government of any province or territory in Canada and authorizing the Executive Officer to disclose any information with respect to the product in the possession of the ministry to Health Canada or of the government of any province or territory in Canada (template can be found on the ministry website:

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

(d) Clearly indicate the manufacturer list price: the lowest price per package size and per FGM sensor to four decimal places sold to wholesalers or pharmacies (if direct distribution to pharmacies).

In cases where the cost per FGM sensor is different from the cost per pack divided by the number of FGM sensor in each package, the lowest price will be used.

(e) A letter dated and signed by a senior company official confirming the ability to supply product at the submitted price for distribution in a quantity sufficient to meet the anticipated demand. The template can be found on the ministry website:

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

(f) Certification that no rebates were provided to a person listed under in section 11.5(1) of the *Ontario Drug Benefit Act* since Health Canada approved the product for sale in Canada. The template can be found on the ministry website:

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

(g) Certification confirming that the FGM products are not private label products, as defined in section 12.02 of O. Reg. 201/96 made under the *Ontario Drug Benefit Act*, with necessary modifications. The template can be found on the ministry website:

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

(h) A copy of the device label.

(i) Evidence of safety and effectiveness of the submitted product:

- A copy of the completed, dated, and signed New Class II Medical Device Licence Application Form approved by Health Canada.

- A summary of objective evidence to establish that the submitted product is compliant with the safety and effectiveness requirements in accordance with section 10, subsections 11(1) and 12(1) and sections 13 to 20 of the *Medical Devices Regulations*.

If any of this information was not a requirement for filing the regulatory submission with Health Canada, please include a statement confirming this on the cover letter of the submission to OPDP. Should questions arise, it may be necessary to provide further information in order to complete a submission.

(j) ODB market share penetration and a Business Impact Analysis on ODB expenditure, including the underlying assumptions for the calculations.

(k) A Pharmacoeconomic Analysis (summary, report and model).

The submission will be deemed incomplete if any of the above components are missing.

If certain information or data are not provided in the submission, an adequate justification must be given by the manufacturer or the submission will be deemed incomplete and will not proceed further in the review process.

Points of Clarification

It is important to note that the ministry reserves the right to request additional information or material, or defined conditions not specifically described in the Guidelines, in order to allow the ministry to adequately assess the safety, efficacy, quality, costs and cost-effectiveness of the product.

Establishment License

No manufacturer shall import or sell a Flash Glucose Monitoring System unless Health Canada has issued an authorization for its sale or importation. These medical devices must meet the safety and effectiveness requirements established by Health Canada.

Format and Organization of Submissions

The manufacturer must submit one electronic copy (CDs, DVDs or USB keys) of the submission, and any material responding to any deficiency from the Ministry's Notice of Drug Submission Status (NDSS).

The electronic copy:

- The documents must be provided in MS Word 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. Please 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 Drugs and Devices Division.

Notification of Change

The ministry must be notified of changes to the license, ownership of the product, including any change in the medical conditions, purposes or uses for which the device is manufactured, sold or represented where the changes may affect the quality or performance of the product. The manufacturer must provide evidence to support the change, including where applicable, evidence of Health Canada's approval.

For any type of changes not discussed above, please contact the ministry for guidance about documentation requirements.