

**PART IV**

**SUBMISSION GUIDELINES**

**FOR**

**DIABETIC TESTING AGENTS**

A submission for a diabetic testing agent (i.e., blood glucose strip) undergoes a similar review process as a drug product, although the manufacturer must satisfy a different set of requirements to be considered for reimbursement according to the Maximum Allowable Reimbursement (MAR) mechanism and pricing schedule.

A Committee to Evaluate Drugs (CED) consultant reviews the submission first. As with drug products, the CED as a whole is asked to make a final recommendation to the Ministry regarding the reimbursement of diabetic testing agents. Please refer to the Formulary/CDI for more information on MAR and to Part II: Drug Submission Review Process for more detail on the review process.

### **Submission Requirements**

A manufacturer may satisfy the submission requirements by submitting two copies of the following:

- (a) Evidence that Health Canada has issued an authorization (i.e. establishment license) for the sale or importation of a diabetic testing agent in Canada.
- (b) A letter authorizing the Minister 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 Minister to disclose any information with respect to the product in the possession of Health Canada or of the government of any province or territory in Canada [refer to template letter of consent].
- (c) The lowest price per unit sold to pharmacies and wholesalers (with and without the mark-up). Cost of test strips priced above the current MAR price must be justified.
- (d) 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.
- (e) Evidence of the product's effectiveness including precision, linearity, bias, interference, accuracy, variability and reliability over an appropriate range of values, as well as clinical testing in patients.
- (f) Specifications for the finished product.
- (g) A copy of instructions (patient package insert, prescriber information/insert for the therapeutic use of the product).
- (h) A sample of the label of the finished product as it is intended to be sold in Canada.
- (i) ODB market share penetration or impact analysis on ODB expenditure, including the underlying assumptions for the calculations.

The submission will be deemed incomplete if any of the above components are missing without an adequate explanation.

## Points of Clarification

### Establishment License

No manufacturer shall import or sell a blood glucose monitoring in vitro diagnostic devices unless Health Canada has issued an authorization for its sale or importation. These medical devices must meet the safety and effectiveness requirements acceptable by Health Canada.

### Evidence of safety and effectiveness of product

Submissions should include the following data to support the product's precision, accuracy, variability and reliability:

- Within day performance
- Between day performance
- Environmental testing (effect of varying temperature, humidity)
- Dynamic range for glucose
- Comparison of accuracy against a standard YSI glucose analyzer
- Sensor movement testing
- Sample volume (accuracy of glucose concentrations with varying sample volumes)
- Oxygen sensitivity testing
- Interference testing with a battery of at least 15 chemicals which could potentially interfere on the basis of strip chemistry and monitor technology.
- Stability
- Hematocrit testing
- Human Factor Study and Consumer Study Field Testing

Note: Where applicable, raw data and a quantification of deviations between individual samples should be provided.

**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.**

### Pricing

Clearly indicate the following prices:

- (1) the lowest price per strip sold to pharmacies **AND** wholesalers (i.e. direct price without mark up)
- (2) the lowest price including the mark up (indicate percentage), for each package size of the product offered for sale. Include both the cost per strip and the cost per package. Where more than one price is proposed, the lowest price will be used.

Note that the maximum allowable mark-up for diabetic testing agents is identical to that prescribed for purposes of paragraph 3 of subsection 6(1) of the *Ontario Drug Benefit Act*. Refer to Part II of the Formulary for more information.

Where patients are required to pay a co-pay (i.e., the submitted price is above the current MAR price) a justification for this incremental cost must be provided.

### Format and Organization of Submissions

Submissions for diabetic testing agents should follow the same format and organization as described in Part II of the submission guidelines. In order to organize a submission in a manner that will facilitate review, submissions should be clearly tabbed in order, according to the headings of the submission requirements for diabetic testing agents as outlined above. Disorganized or incomplete submissions may be returned at the discretion of the Ministry, at the manufacturer's expense, without prejudice to refileing.