

PRICE INCREASE CRITERIA AND REQUEST PROCESS

November 20, 2008

DRUG PRODUCTS ELIGIBLE FOR PRICE INCREASES

The Executive Officer may consider requests for price increases in respect of drug products:

- (a) that have been listed as benefits on the Ontario Drug Benefit (ODB) Formulary for at least five (5) years, and
- (b) which there has been a substantial increase in raw material costs during the previous year.

PRICE INCREASE REQUESTS – APPLICATION REQUIREMENTS

Manufacturers are required to submit the following information in respect of every drug product for which they are requesting a price increase:

- (1) A completed *Application for Price Increase Requests* form (Appendix A). This form includes a product description, proposed price change, details on related costs and other information specific to that product. One Application must be completed for each strength of the drug product for which a price increase is requested. Any price increase request must include information for the previous two 12-month periods based on either the manufacturer's fiscal year or calendar year (for example, a request submitted on November 1, 2008 must include data from 2006 and 2007);
- (2) A budget impact analysis (BIA), which shows the overall impact that the proposed price increase will have on the Ontario Public Drug Programs' budget over the next three (3) fiscal years (NB: the BIA may include all strengths of the drug product for which a price increase is requested); and
- (3) Other factors that are relevant to the price increase application that the manufacturer wants the Executive Officer to consider.

The Executive Officer will consider all of the foregoing information, in addition to the fiscal position of the Ministry and Government of Ontario, before rendering a decision on a price increase request.

MINIMUM THRESHOLD CALCULATION

A drug product may qualify for an increase to its Drug Benefit Price (DBP) if the increase in the raw material costs compared to the previous year is sufficiently large to justify at least a 1% price increase ("Minimum Threshold"). To determine whether a drug product meets the Minimum Threshold, the following calculation must be performed:

$$\text{[Percent Increase in Raw Material Costs]} \times \text{[Raw Material Cost-to-Price Ratio]} \geq \text{Minimum Threshold (1\%)}$$

(i) Percent Increase in Raw Material Costs

The Percent Increase in Raw Material Costs is equal to the per cent increase in average per unit raw material costs compared to the previous year. All costs are to be expressed in per unit terms (e.g. per tablet, per mL).

The following shall NOT be included as part of the raw material costs:

- Marketing/selling expenses
- Administrative expenses
- Research and development expenses
- Expenses related to government regulation
- Litigation expenses

(ii) Raw Material Cost-to-Price Ratio

The Raw Material Cost-to-Price Ratio is the ratio of raw material costs to the product's DBP as listed in the Formulary as of the date on which the application for a price increase is submitted.

(iii) Sample Calculation

Drug Product X has:

- a DBP of \$1.0000 per tablet;
- a Percent Increase in Raw Material Costs of 40% - i.e., increase from \$0.20 (2006 12-month period) to \$0.28 (2007 12-month period); and
- Raw Material Cost-to-Price Ratio is 0.20 (\$0.20/\$1.00).

[Percent increase in raw material costs]	X	[Raw Material Cost-to-Price Ratio]	≥	Minimum Threshold (1%)
40%	X	0.20	=	8%

The 8% result exceeds the Minimum Threshold of 1%. Accordingly, Drug Product X may be eligible for a DBP increase of up to 8%.

FUTURE PRICE INCREASE REQUESTS

Subsequent price increase requests in respect of the same drug product will be based on the increase in raw material costs compared to the previous application. Manufacturers will be required to submit cost data for the previous two 12-month periods.

METHOD AND FREQUENCY OF PRICE REVIEW

Completed applications for price increases will be reviewed in the order that they are received by the Ministry in accordance with the criteria and process outlined above. Upon completion of the review, the Executive Officer will notify the manufacturer as to whether or not the price increase request was accepted ("Notice of Decision"). The Ministry will endeavour to publish the revised DBP in the Formulary with the first update following the date of the Notice of Decision. Any required listing agreement amendments must be finalized and executed before the revised DBP can be published in the Formulary. Be reminded that manufacturers are legally prohibited from increasing the price of a listed drug product unless an increase to the DBP has been effected in accordance with the legislation and published in the Formulary..

CONFIDENTIALITY

All information contained within a manufacturer's price increase application that is not in the public domain will be treated by the Ministry as confidential information ("Confidential Information") and will not be disclosed by the Ministry unless such disclosure has been previously authorized by the manufacturer or is required by applicable law. In the event that the Ministry is required by law to disclose Confidential Information, the Ministry undertakes to notify the manufacturer prior to such disclosure.

SUBMISSIONS

Manufacturers must submit four (4) copies of each completed application to:

Pharmaceutical Services Coordination
Ontario Public Drug Programs
3rd Floor, 5700 Yonge Street
Toronto ON M2M 4K5

If you have any questions regarding the price increase criteria and request process, please [contact us](#) [hyperlink "contact us" to http://www.health.gov.on.ca/english/providers/program/drugs/drugs_contact.html]

- Appendix A – Application for Price Increase Requests [hyperlink to pdf document]