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April 27, 2009

Ms. Sylvie Dupont,
Secretary, Patented Medicine Prices Review Board
Box L40, Standard Life Centre
333 Laurier Avenue West, Suite 1400
Ottawa, Ontario K1P 1C1

Re: PMPRB Notice & Comment on March 26, 2009 Draft Revised Excessive Price Guidelines

Dear Ms. Dupont:

Thank you for the opportunity to review and provide comments on the March 26, 2009 Draft Revised Excessive Price Guidelines.

Procter & Gamble Pharmaceuticals Canada Inc. recognizes the significant effort made by the Board and its staff to address the multitude of comments and concerns received from stakeholders as a result of the previous Notice and Comment issued in relation to the August 2008 version of the draft revised Guidelines. The adjustments made to the Reasonable Relationship Test methodology, allowing for level pricing per unit for multiple strengths of a patented drug product and providing guidance for a negative Y-intercept in the linear relationship test are examples of the improvements contained in the March 2009 version of the draft revised Guidelines. We are appreciative of the consideration afforded to our comments expressed in that regard.

In reviewing the latest version of the draft revised Guidelines, Procter & Gamble Pharmaceuticals Canada Inc. offers this letter and accompanying technical appendix which outlines its concerns with the following aspects of the Guidelines:

1. Dip Methodology: The proposed Dip Methodology, in its current construct, does not recognize allowable CPI increases in its rebound calculation. A company should be allowed to rebound to the pre-benefit price plus the CPI allowable increase. A post-benefit price should not be considered excessive if it is at or below a non-excessive price in another market; otherwise, the price would be "frozen" by providing a benefit. Unless CPI-adjustment is consistently applied in all markets, the Dip Methodology will create a disincentive for companies to offer benefits.

2. Therapeutic Class Comparison (TCC) and Reasonable Relationship (RR) Tests: The PMPRB is proposing two distinctly different practices for the comparator pricing source in the introductory pricing tests, depending upon whether you are the same patentee or a new patentee introducing a new product into the Canadian market. The proposed practice will result in an unfair and inequitable application of the Therapeutic Class Comparison and Reasonable Relationship tests. The impact of the proposed practice will serve to discourage manufacturers from introducing new innovations or line extensions to the Canadian health care system and is not in the interest of consumers. It also represents a disincentive for manufacturers to offer benefits to stakeholders for currently marketed patented products.

PMPRB should use a common public source for any introductory price test so that it is predictable, transparent and fair to all manufacturers. This would be consistent with the preamble in the draft revised Guidelines' ..."the principles of fairness, transparency, openness and predictability." P&GP suggest that the only source that offers predictability, fairness and transparency across the industry is a comparator medicine's published list price and it should be used for all new medicine price tests (i.e. the Reasonable Relationship and Therapeutic Class Comparison tests). In this regard, with a view to certainty and predictability, the PMPRB needs to specify in the Guidelines (as it does now), which published list price source it will use as a general rule, as well as secondary published sources when a comparator price is not available in the primary source.

The use of a specified published list price source would provide greater clarity to patentees and to Board Staff, is consistent with the excessive price standards of the Act, and is consistent with the recent decision of the Board in the *Adderall XR* case as it relates to the published price to be used for the comparator, Dexedrine.

We hope that these comments, provided in the context of the PMPRB's key principles of fairness, transparency, openness and predictability of the Guidelines, will assist the Board in reaching a decision on the final version of the revised Excessive Price Guidelines. As a member of Rx&D, these comments should be considered as a supplement to the response provided by this association on behalf of its member companies.

Yours truly,

Andy McClenaghan
Country Manager
Procter & Gamble Pharmaceuticals Canada Inc.

Appendix: Procter & Gamble Pharmaceuticals Canada Inc. Technical Submission to PMPRB

The following technical submission expands upon Procter & Gamble Pharmaceutical Canada Inc.'s comments, provided in the accompanying cover letter, related to the Dip Methodology and the Therapeutic Class Comparison and Reasonable Relationship introductory prices tests.

1. Dip Methodology

Comments:

Procter & Gamble Pharmaceuticals Canada Inc. recognizes that the Dip Methodology presented in the March 2009 draft revised Guidelines has been simplified in comparison with its previously complex and confusing predecessor. The explanation of its application provides improved clarity and is a welcome addition. We do, however, continue to have a fundamental concern with the proposed Dip Methodology's lack of recognition of allowable CPI increases in the "rebound" calculation.

Specifically, while the proposed Dip Methodology allows for an average price depressed by benefits to bounce back to pre-benefit levels without being considered excessive, the methodology still fails to recognize that prices to the non-benefit customers within that market may be increasing by allowable limits during the period in which the benefit was offered.

Limiting the "bounce back" to the previous highest non-excessive average selling price places non-benefit pricing within that market in limbo for several years even though the PMPRB's guidelines allow CPI increases over that period. If the allowable CPI increases have been implemented, pricing at the end of the benefit period will automatically be considered excessive.

Unless CPI-adjustment is consistently applied in all markets, the Dip Methodology will create a disincentive for companies to offer benefits

Proposed Solution:

An approach more representative of market reality is to allow the Dip bounce back to be at the highest previous average transaction price in that market free of benefits, adjusted for CPI. The following example details this approach:

Dip Methodology – Proposed Versus CPI-Adjusted Approach				
	Pharmacy (ATP)	**Wholesale (ATP)**	**PMPRB Proposed Hospital (ATP)**	**CPI-Adjusted Hospital (ATP)**
2007	$5.00	$5.00	$5.00	$5.00
2008	$5.10	$5.10	$4.00	$4.00
2009	$5.20	$5.20	$4.10	$4.10
2010	$5.30	$5.30	$5.00	$5.30
Non-Excessive Average Price (NEAP) – 2010				
2010	**$5.30**	**$5.30**	**$5.00**	**$5.30**

In this example, a benefit was provided to the hospital market in 2008 and 2009 and discontinued in 2010. As noted, according to the approach proposed in the draft revised Guidelines, the allowable price in the hospital sector in 2010 is frozen at the 2007 level of $5.00 while the allowable prices in the other markets are allowed to increase by the change in CPI. In this example, the hospital average transaction price of $5.30 in the 2010 post-benefit period will be considered excessive merely because allowable increases to non-benefit customers in that class were implemented during the benefit period.

Applying CPI adjustment to the market in which the benefit was offered (hospital in this example) recognizes that the non-benefit sector (either within the same market or in other markets) is not stagnant during the benefit period. It also reflects consistency with PMPRB's allowance of CPI adjustment in the other markets (pharmacy and wholesale in this example) during the benefit period.

2. Therapeutic Class Comparison (TCC) and Reasonable Relationship (RR) Tests

Comments:

The preamble to the draft revised Guidelines' refers to "the principles of fairness, transparency, openness and predictability". The pricing sources being proposed for comparison purposes for both the Therapeutic Class Comparison (TCC) and Reasonable Relationship (RR) tests do not ascribe to these principles.

In the conduct of these two introductory price tests, the PMPRB is proposing two distinctly different practices for the comparator pricing source depending on whether it is sold by the same patentee introducing the new product or by a different patentee introducing the new product into the Canadian market.

This proposed practice will result in an unfair, illogical and inequitable application of the Therapeutic Class Comparison and Reasonable Relationship tests. The impact of the proposed practice will serve to discourage manufacturers from introducing new innovations or line extensions to the Canadian health care system and is not in the interests of consumers. It also represents a disincentive for manufacturers to offer benefits to stakeholders for currently marketed patented products.

To illustrate the unfair and inequitable application of the TCC and RR introductory pricing tests, presented below are three constructed scenarios developed from a base case where a patentee, Company One, sells Drug A. These scenarios highlight that two companies introducing a new product within the same ATC class and for the same indication will be assigned two distinctly different Maximum Average Potential Prices, based solely on whether the comparator product is sold by the same patentee or by a different patentee introducing the innovation.

Base Case: Company One, Drug A

Company One sells Drug A in 4 Canadian markets. The introductory Maximum Average Potential Price for Company One's existing Drug A is $20.00. A temporary benefit is offered in Market C, which represents 60% of the national sales-volume mix.

	Market A	Market B	Market C	Market D
Public List Price	$15.00	$20.00	$19.00	$19.00
Benefit	$0.00	$0.00	$4.00	$0.00
Benefit Price	$15.00	$20.00	$15.00	$19.00
Sales-Volume Mix	10%	20%	60%	10%
National-ATP (with benefit)				$16.40
National-NEAP (at benefit termination / DIP rebound)				$18.80

Scenario 1: Therapeutic Class Comparison Test - Company One Introduces Drug B

Company One introduces a new chemical entity, Drug B, in Canada. Drug B is within the same ATC class and is approved for the same indication as their existing Drug A. Drug B does not offer an improved therapeutic benefit in comparison to Drug A.

The applicable introductory price test for Company One's new Drug B is the Therapeutic Class Comparison (TCC) Test. As the patentee for the TCC comparator Drug A, the reference price for Drug B, according to the draft revised Guidelines, is the National Average Transaction Price (National-ATP) of Drug A.

Using the above base case for the comparator pricing information, the introductory Maximum Average Potential Price for Company One's new Drug B is $16.40.

Issues:

- The introductory Maximum Average Potential Price for Company One's new Drug B, calculated at $16.40 as per the draft revised Guidelines, is unfairly skewed by the inclusion of the benefit-reduced Market-Specific Average Transaction Price (MS-ATP) for Market C in the calculation of the National-ATP for Company One's existing Drug A.

- As applied, this would force Company One to launch Drug B at $16.40 when it is currently selling its comparator product Drug A at the allowable and non-excessive prices of $20.00 and $19.00, in Markets B and C/D, respectively. It is illogical and unfair that Company One can charge $20.00 for Drug A and only $16.40 for its comparable new Drug B. This represents a disincentive for Company One to offer a benefit on its existing Drug A.

- The draft revised Guidelines seem to assume that a company will offer the same level of benefits for the new product (Drug B) as it does for its comparator product (Drug A). In fact, the Guidelines' proposed approach forces a company to do so or to establish a list price equal to the comparator product's average selling price that includes benefits.

- The draft revised Guidelines also seem to assume that a manufacturer is able to immediately enter into a stakeholder benefit agreement for a new innovation or line extension in the introductory period for the new product. In reality, both the uptake and discontinuation of benefits are variable and require a two-way negotiation from both the manufacturer and the stakeholder. There is no way to predict the timing of the introduction and the termination of a benefit. Similarly, there is no way to predict if a stakeholder will be willing to agree to a benefit for the new product.

- At the termination of the temporary benefit in Market C, the MS-NEAP for Company One's existing Drug A will rebound, as per the Dip Methodology, to $19.00. This will result in a rebound of the National-NEAP to $18.80 (see base case above). Thus, following the termination of the benefit, Company One can sell its existing Drug A at the National-NEAP of $18.80 but is still only allowed to charge $16.40 for its new Drug B.

Scenario 2: Therapeutic Class Comparison Test - Company Two Introduces Drug C

Company Two also introduces a new chemical entity, Drug C, in Canada. Drug C is within the same ATC class and is approved for the same indication as Company One's Drug A. Drug C does not offer an improved therapeutic benefit in comparison to Drug A.

The applicable introductory price test for Company Two's new Drug C is the Therapeutic Class Comparison Test. Company Two is not the patentee for the TCC comparator product, Drug A. As a result, the reference price for Drug C, according to the draft revised Guidelines, is the public list price that most closely reflects Drug A's National-NEAP.

Using the above base case for the comparator pricing information, the introductory Maximum Average Potential Price for Company Two's new Drug C is assumed to be $19.00. This public list price is the closest public price to Drug A's National-NEAP of $16.40.

Issues:

- The PMPRB is proposing to use a published public price that most closely reflects a patented comparator product's National-NEAP. In reality, for the scenario where a different patentee is introducing the innovation, the closest public price is $15.00. During the PMRPB-Industry teleconference on April 6th, 2009 it was implied by the Board that in application they will look for the closest, but not lower than, public list price for the patented comparator medicine ($19.00 for this scenario).

- As applied, the draft revised Guidelines will allow Company Two to launch Drug C at the introductory Maximum Average Potential Price of $19.00. In contrast, Company One is only allowed to introduce their Drug B at the introductory Maximum Average Potential Price of $16.40. Prices should not be deemed excessive merely because the company that is introducing the innovation to the Canadian market also sells the patented critical comparator. This represents an inequitable application of regulatory process.

- Company Two is forced to limit the price of their new product, Drug C, to the Introductory Maximum Average Potential Price of $19.00 in all markets when the Comparator product, Drug A, is being sold at the allowable and non-excessive price of $20.00 in some markets.

- Using the published public price that most closely reflects a patented comparator product's National NEAP will reveal some confidential information of Company A's pricing strategy and benefits program to Company Two. Company Two may be able to construct and estimate the potential benefits of a competitor by knowing the approximate National NEAP of its competitor.

Scenario 3: Reasonable Relationship Test - Company One Introduces Drug D

Company One introduces Drug D in Canada. It is a capsule form of the same medicine in the same strength as its own existing Drug A tablet. Company One's Drug D is within the

same ATC class and is approved for the same indication as their existing Drug A. Drug D does not offer an improved therapeutic benefit in comparison to Drug A.
The applicable introductory price test for Company One's new Drug D is the Reasonable Relationship (RR) Test. Since it is the same strength as their existing Drug A, the reference price for the RR as per the draft revised Guidelines is the National Average Transaction Price of Drug A.

Using the above base case for the comparator pricing information, the introductory Maximum Average Potential Price for Company One's new Drug D is $16.40.

Issues:

- The introductory Maximum Average Potential Price for Company One's new Drug D calculated at $16.40 as per the draft revised Guidelines, is unfairly skewed by the inclusion of the benefit-reduced Market-Specific Average Transaction Price (MS-ATP) for Market C in the calculation of the National-ATP for Company One's existing Drug A.

- As applied, this would force Company One to launch Drug D at $16.40 when it is currently selling its comparator product Drug A at the allowable and non-excessive prices of $20.00 and $19.00, in Markets B and C/D, respectively. It is illogical and unfair that Company One can charge $20.00 for Drug A and only $16.40 for its comparable new Drug D. This represents a disincentive for Company One to offer a benefit on its existing Drug A.

- At the termination of the temporary benefit in Market C, the MS-NEAP for Company One's existing Drug A will rebound, as per the Dip Methodology, to $19.00. This will result in a rebound of the National-NEAP to $18.80 (see base case above). Thus, following the termination of the benefit, Company One can sell its comparator Drug A at the National-NEAP of $18.80 but is still limited to $16.40 for Drug D, which is the same medicine and strength, but in a capsule formulation rather than a tablet.

- The draft revised Guidelines seem to assume that a company plans to offer the same level of benefits for the new product (Drug D) as it does for its comparator product (Drug A). In fact, the Guidelines' proposed approach forces a company to do so or to establish a list price equal to the comparator product's average selling price that includes benefits.

- The draft revised Guidelines also seem to assume that a manufacturer is able to enter into a stakeholder benefit agreement for a new innovation or line extension in the introductory period for the new product. In reality, both the uptake and discontinuation of benefits are variable and require a two-way negotiation from both the manufacturer and the stakeholder. There is no way to predict the timing of the introduction and the termination of a benefit. Similarly, there is no way to predict if a stakeholder will be willing to agree to a benefit for the new product.

- The use of Company One's existing products' ATPs for comparison purposes can also have a significant impact on the results of the other Reasonable Relationship testing methods used by the PMPRB (i.e. the different strength test and the linear relationship test). For example, if there are two existing strengths within the company's patented product line, the company's new entry within the product line will be limited by the linear relationship defined by the ATPs of the two existing strengths. This linear relationship is skewed by the impact of benefits supplied to each of the existing strengths, with a high potential for varying results depending upon the specific level of benefits recorded for each existing strength during the introductory period of the new strength within the product line.

Proposed Solution:

To foster the fair, transparent, open and predictable application of the Therapeutic Class Comparison and Reasonable Relationship introductory pricing tests, P&GP suggest that the only source that offers predictability, fairness and transparency across the industry is a comparator medicine's published list price and it should be used for all new medicine price tests (i.e. Reasonable Relationship and Therapeutic Class Comparison tests). In this regard, with a view to certainty and predictability, the PMPRB needs to specify in the Guidelines (as it does now), which published list price source it will use as a general rule, as well as secondary published sources when a comparator price is not available in the primary source.

The use of a specified published list price source would provide greater clarity to patentees and to Board Staff, is consistent with the excessive price standards of the Act, and is consistent with the recent decision of the Board in the *Adderall XR* case as it relates to the published price to be used for the comparator, Dexedrine.