

**- Final Report -**

**FOLLOW-UP RECOMMENDATIONS ON IMPLEMENTATION OF  
THE DIP METHODOLOGY**

*DIP METHODOLOGY TECHNICAL WORKING GROUP*

April 2012

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## **INTRODUCTION**

The DIP Working Group (DIP-WG), originally struck in the first quarter of 2011, reconvened for two days at the PMPRB's offices to discuss experiences to date and the perspectives of industry and the PMPRB alike on the pilot application of the DIP Methodology.

This report summarizes the DIP WG's assessment of the pilot experience, application-related issues identified during the pilot, proposed options to address these issues, and the DIP-WG's recommendation to the Board to adopt the DIP Methodology on a permanent basis.

## **BACKGROUND**

The *Compendium of Policies, Guidelines and Procedures* (Guidelines) implemented January 1, 2010, included the DIP Methodology which patentees could request in certain circumstances as an alternative to the CPI-Adjustment Methodology. The Board's intent with the DIP Methodology was not to create disincentives to the offering of "benefits" to customers. Schedule 10 of the Guidelines defines a benefit as "any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature."<sup>1</sup>

In December 2010, in response to concerns on the application of the DIP Methodology (e.g. onerous evidence requirements), the Board decided to establish the DIP-WG to develop possible solutions that would make the DIP Methodology more workable. The DIP-WG consisted of representatives of the innovative pharmaceutical industry, the biotechnology industry, the generic pharmaceutical industry, and members of Board Staff. The DIP-WG submitted its Final Report to the Board on March 4, 2011. The DIP-WG's recommendations consisted of:

- (i) Two processes for the DIP Methodology : the Simplified DIP or the Regular DIP<sup>2,3</sup>

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<sup>1</sup> *Compendium of Policies, Guidelines and Procedures*, 2010; Schedule 10, Section 1.2

<sup>2</sup> The Simplified DIP is a simplified approach for the DIP Methodology in situations where the National Average Transaction Price (N-ATP) of the patented drug product is less than or equal to the Introductory Benchmark Price (IBP) for that patented drug product. The Regular DIP applies where the N-ATP of the patented drug product is greater than the IBP, but not more than the IBP adjusted by actual list price increases taken by a patentee where these list price increases are within the Guidelines (referred to as IBP\*).

<sup>3</sup> The DIP-WG's final report stated on page 7 "The DIP Methodology would not automatically apply in cases where the National Average Transaction Price is greater than the IBP\*. Further investigation would be required." For the

- (ii) Adopting feasible and manageable information requirements; and,
- (iii) Establishing clear processes to request and invoke the DIP.

A copy of the DIP-WG Final Report is included at Annex A.

At its March 2011 meeting, the Board accepted that the recommendations of the DIP-WG be applied on a one-year pilot basis. Board Staff developed the necessary forms for use by patentees when invoking the Simplified DIP and the Regular DIP. These are reproduced at Annex B and are available on the PMPRB's Website<sup>4</sup>.

The Board decided to reconvene the DIP-WG at the end of the one-year pilot. In January 2012, available original members of the DIP WG (see Annex B for the list of attendees to the January 2012 meeting) reconvened to review experiences and issues arising from the pilot application of the DIP for the purpose of providing the Board with possible further recommendations.

### **THE DIP METHODOLOGY PILOT EXPERIENCE**

To date, the pilot application of the DIP Methodology has been invoked a total of 40 times: 27 cases as a Simplified DIP and 13 cases as a Regular DIP. Of the 40 times the DIP Methodology has been invoked: 22 cases (i.e., 55%) were investigations opened prior to 2010; 12 cases (i.e., 30%) were investigations opened during or after 2010; and 6 cases (i.e., 15%) that had not triggered an investigation.

The DIP-WG found that the pilot application has generally been a positive experience for both patentees and Board Staff alike owing to the:

- i. Less onerous process to request and invoke the DIP Methodology;
- ii. Standardized means to report required evidence; and,
- iii. Manageable and operationally available evidence requirements.

The procedural and information requirements of the pilot application of the DIP Methodology have also been readily available to patentees on the PMPRB's Website, which industry representatives on the DIP-WG found to be in clear and concise language that is easy to understand.

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purpose of clarification, the DIP Methodology does not apply in instances when the N-ATP is greater than the IBP\*; instead, the evidence and procedural requirements of Board investigations apply.

<sup>4</sup> <http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1490&mid=1249>

The DIP-WG ultimately found that the pilot DIP Methodology proved to be an effective solution to address and resolve investigations arising from the reduction or termination of the provision of benefits.

#### Application-Related Issues Identified

While the pilot application of the DIP Methodology was viewed by the DIP-WG as a positive experience, four issues arising from the actual application of the pilot were identified. These issues were identified solely to clarify the application of the methodology, without affecting the DIP Methodology on a policy level, and to advance integrating its application into the regulatory framework on the whole.

The four issues identified by the DIP-WG are presented below as questions and for each issue the DIP-WG provides a recommended solution, including instances when more than one option is identified.

#### **Issue 1: In cases involving the acquisition of a patented drug product prior to January 1, 2010, what is the appropriate IBP where a patentee acquires a DIN(s) that had been previously sold by another patentee?**

This is an issue where a previous patentee provided benefits and the subsequent patentee continues to provide those benefits when it begins to sell the patented drug product.

Illustration - Patentee A first sells product XYZ in 2001 and its price of \$20.00 is within the Guidelines (i.e., the IBP would be \$20.00). Patentee A starts to provide benefits to hospitals in 2004 and by 2007 its ATP is \$12.00. In 2008, Patentee B acquires and starts to sell product XYZ; at which time Patentee B provides the same benefits to the hospitals when it sells, such that its ATP is also \$12.00. In 2010, Patentee B terminates the benefits and the non-benefit price increases to \$20.00.

Question: should the IBP of patentee B be equal to its IBP (i.e., the non-excessive average price for the first six months it sells the drug (i.e., \$12.00)), or should it be equal to the IBP of Patentee A (i.e., \$20.00).

Recommended Option: The IBP for Patentee B would be set equal to the IBP of Patentee A (i.e., \$20.00) provided Patentee B receives this information from Patentee A.

This option places responsibility on the patentee who wants to invoke the DIP to obtain the IBP. The patentee could consult with Board Staff when it has difficulty obtaining the

IBP from the previous patentee. The working group recommends, as part of this option, that this issue could be raised in the context of the outreach sessions with patentees.

**Issue 2: How to apply the DIP Methodology when benefits exist at introduction?**

Recommended Option: Use a two-step process whereby: (i) patentees report the value of benefits as a separate line item in the Form 2, Block 4 data at introduction; and (ii) when this approach is not feasible, to use Block 4 data to identify a class of customer where no benefits exist for the patented drug product.

Step (i) of this option will provide absolute data clarity on the value of benefits at introduction, though some additional effort will be required by patentees to quantify and report the value of benefits at introduction. Step (ii) will provide a fall back procedure for establishing the value of benefits at introduction when step (i) is not feasible, while representing additional work for Board Staff.

In relation to the above recommended option, the working group also recommends that this subject be included in items brought to patentees' attention during future outreach sessions.

**Issue 3: In cases where the Regular DIP has been invoked (i.e., the N-Average Transaction Price is above the IBP), how is the IBP\* derived when the list price increases following a list price decrease?**

Recommended Option: Following a list price decrease, the IBP\* would be based on list price increases within the Guidelines and any actual list price decreases taken by the patentee.<sup>5</sup> Consider the illustration below.

Table 1: List Price Increases and Decreases		
Year A	Year B	Year C
List Price=\$10.00	List Price=\$10.20	List Price=\$9.50
IBP=\$10.00		
	IBP*=\$10.20	IBP*=\$9.50

<sup>5</sup> In the context of the Simplified DIP, a decrease in the list price below the IBP will impact the application of the Simplified DIP.

- Year A: A new patented drug product is introduced, its ATP of \$10.00 is found to be within the Guidelines such that its IBP is set equal to its ATP. The list price at introduction is \$10.00.
- Year B: The list price increases by an amount within the Guidelines (e.g., 2%) to \$10.20; therefore, IBP\* is equal to \$10.20.
- Year C: The list price decreases by 7.4% to \$9.50; therefore, IBP\* decreases to \$9.50.

(Note: IBP\* is only calculated the year when the ATP exceeds the N-NEAP.)

#### Underlying Principles of Recommended Option

The list price represents:

- i. a price at which no benefits are offered to any customers; and,
- ii. an actual price paid by customers.

#### **Issue 4: How to avoid unnecessary investigations in years subsequent to the application of DIP because of the mathematical application of the CPI-Adjustment Methodology?**

Recommended Option: To avoid either the cumulative CPI change component or the CAP component of the CPI-Adjustment Methodology being triggered in years subsequent to the application of the DIP Methodology, change the benchmark year for the CPI-Adjustment Methodology to the year the DIP Methodology is applied. This option is simple, easily applied and represents a fresh start using a concept (i.e., benchmark year) already present in the CPI-Adjustment Methodology.

#### **OTHER ISSUES IDENTIFIED BY THE DIP-WG**

The experience with the DIP Methodology pilot clearly demonstrated that: (i) price review at the level of “Any Market” introduces unnecessary complexity; and, (ii) the current CPI-Adjustment Methodology fails to provide price increase certainty patentees value in the planning cycle and has an inherent complexity that is compounded by the context/application of the DIP.

Market dynamics have changed sufficiently. The DIP-WG therefore strongly recommends that the Board consider establishment of a working group to investigate possible options for modernizing these policies and streamlining the regulatory process in these two areas.

## **CONCLUSIONS**

Upon examination of the pilot application of the DIP Methodology since its adoption by the Board in March 2011, the DIP-WG concluded that the pilot has proven to be a positive experience, though some fine-tuning of application-related issues is needed. The pilot DIP Methodology demonstrated procedural clarity, manageable and feasible evidence requirements and effectiveness in resolving ongoing investigations arising from the reduction or termination of the provision of benefits. Since being adopted on a pilot basis, the DIP Methodology has been invoked in 40 instances: 27 involving the Simplified DIP and 13 involving the Regular DIP.

The DIP Methodology deals with changes in ATP such that an increase in the ATP does not necessarily imply a price increase to any customer. The DIP-WG recommends that the Board, following consideration of the application-related issues identified in this report, adopt the pilot DIP Methodology on a permanent basis.

**ANNEX A**  
**(See Separate Attachment)**

**DIP-WG Final Report, March 2011**

## Annex B

### Membership for the Reconvened DIP Methodology Technical Working Group (Sorted Alphabetically by Last Name)

Member	Title
Michelle Boudreau <b>Chairperson</b>	Executive Director Patented Medicine Prices Review Board
Peter Giakoumatos <i>Brand Representative</i>	Manager - Strategic Pricing and Contracts Merck
Claudia Neuber <i>Brand Representative</i>	Director of Pricing and Contracting Astra Zeneca
Kimberly Robinson <i>Alternative Brand Representative</i>	Director - Strategic Pricing Janssen Inc.
Janet Thompson Mar <i>Biotech Representative</i>	Director - Contract Operations Talecris Biotherapeutics
Robert Squires	A/Manager – Policy Division Patented Medicine Prices Review Board
Ginette Tognet	Director - Regulatory Affairs and Outreach Patented Medicine Prices Review Board

## Annex C:

### On-Line Information and Forms for Application of the DIP Methodology

#### HOW TO COMPLETE THE FORMS TO INVOKE THE DIP METHODOLOGY

**To invoke the Simplified DIP Methodology** : Please complete **Part A** of the Application Form and send the completed Part A to the PMPRB Senior Regulatory Officer (SRO) assigned to your company.

**To invoke the Regular DIP Methodology** : Please complete **Part A and Part B** of the Application Form and send the completed Part A and B to the SRO assigned to your company.

To complete Part B – Price Increase Chart:

- ✓ Identify each year the patented drug product has been sold on the Canadian market. Add or delete as many columns as necessary.

**Example 1:** Patented drug product A has been sold since 2007. Year 1, 2, 3 and 4 of the template should be replaced by 2007, 2008, 2009 and 2010.

	2007	2008	2009	2010
List Price (price/unit)				
% List Price Increase				
Maximum Selling Price/Unit				
Effective Date of List Price Increase				

- ✓ Enter the List Price for each year the patented drug product was sold. The List Price may or may not be the same as the price previously filed in the Form 2 Block 5. If there is more than one List Price, repeat the above format as many times as needed specifying the class of customer or province to which the List Price applies.

**Example 2:** Patented drug product A had three different List Prices: one for wholesaler, one for pharmacy and one for Ontario. The Price Increase Chart should be completed as follows:

<b>Wholesaler</b>	2007	2008	2009	2010
List Price (price/unit)				
% List Price Increase				
Maximum Selling Price/Unit				
Effective Date of List Price Increase				
<b>Pharmacy</b>	2007	2008	2009	2010
List Price (price/unit)				
% List Price Increase				
Maximum Selling Price/Unit				

Effective Date of List Price Increase					
<b>Ontario</b>	2007	2008	2009	2010	
List Price (price/unit)					
% List Price Increase					
Maximum Selling Price/Unit					
Effective Date of List Price Increase					

- ✓ Complete each cell of every row of the template.
- ✓ Provide documentary evidence for each List Price listed in the template.
- ✓ Once completed send Part A, Part B and the documentary evidence to the SRO assigned to your company.

Further evidence and supporting data may be requested by Board Staff and will be determined on a case by case basis.

For an explanation about the DIP Methodology, please refer to the March 2011 Final Report of the DIP Methodology Technical Working Group:

<http://www.pmprb-cepmb.gc.ca/english/View.asp?x=1486&mp=1485>

## Application form to invoke the Dip Methodology

Which methodology are you invoking: Simplified DIP  (Please complete Part A only)

Regular DIP  (Please complete Part A and Part B)

### PART A

<u>Product Information</u>		
Brand Name:		Generic Name:
DIN:	Strength/Unit:	Period of Review:

**Background Information:** Please describe the circumstances that support the application of the DIP methodology to this DIN

**Description of the benefit:** Please indicate when the benefit commenced and was terminated, the type and value of the benefit, customer classes that received it, whether there are on-going benefits, etc.

**Certified by** I hereby certify that the information presented is true and correct.

Signature of duly authorized person for the reporting patentee:

Name:

Title:

Organization:

Date:

Tel Number: ( )

Fax Number: ( )

E-mail:

**Please send the completed Form to the PMPRB Senior Regulatory Officer assigned to your company**

**Part B**

**Price Increase Chart**

	Year 1		Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9
List Price (price/unit)										
% List Price Increase										
Maximum Selling Price/Unit										
Effective Date of List Price increase										