Patented Medicine Prices Review Board
Conseil d'examen du prix des médicaments brevetés

Canada

Patented Medicine Prices Review Board

Regulatory Affairs and Outreach Branch

DIP Methodology

Ottawa, June 7, 2012

Overview

- **DIP Methodology Technical Working Group (DIP-WG)**
  - Historical Background
- **Pilot Application of the DIP Methodology**
  - General Results
  - Application-Related Issues and Solutions
- **Follow-up recommendations on implementation of the DIP Methodology – April 2012**

DIP-Working Group

- Historical Background

  - WG struck early 2011 to identify challenges in applying the DIP Methodology and develop workable solutions

  - Board accepted WG Final Report in March 4, 2011

  - Recommendations to be applied on a one-year pilot basis:

    - Two processes: Simplified DIP and Regular DIP

    - Feasible and manageable information requirements

    - Clear processes to request and invoke the DIP

  - Reconvened for two days in 2012 to discuss experiences to date with the pilot application of the DIP Methodology

Pilot Application of the DIP Methodology: General Results

- Invoked 40 times: 27 Simplified DIP and 13 Regular DIP
- Of the 40 cases
  - 22 (55%) were investigations opened prior to 2010
  - 12 (30%) were investigations opened during or after 2010
  - 6 (15%) had not triggered an investigation (excess only)
- Less onerous process to request and invoke the DIP Methodology
- Standardized means to report required evidence
- Manageable and operationally available evidence requirements

Pilot Application of the DIP Methodology: Four Application-Related Issues and Solutions

- **Issue 1**

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

Solution

The IBP for the product sold by the second patentee would be equal to the IBP for the product sold by the first patentee provided the second patentee receives this information from the first patentee.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 1 – Example 1

2003: Drug product X is introduced by patentee A to Canadian market. The ATP is $20.00 and within Guidelines.

2005: Patentee A starts giving benefits to hospitals.
ATP becomes $12.00.

2008: Patentee B acquires product X from patentee A and continues providing benefits to hospitals.
ATP remains $12.00.

2010: Patentee B terminates the benefits.
ATP bounces back to $20.00.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 1 – Example 1

	2003	2004	2005	2006	2007	2008	2009	2010
Form 2 Block5 Canada	$20.00	$20.00	$20.00	$20.00	$20.00	$20.00	$20.00	$20.00
ATP	$20.00	$20.00	$12.00	$12.00	$12.00	$12.00	$12.00	**$20.00**
IBP	$20.00					$12.00		

Patentee A Patentee B

To invoke the Simplified DIP in 2010, patentee B must obtain the IBP from patentee A.

Note: Form 2 Block 5 Canada is the publicly available ex-factory price.

It corresponds generally to the list price: a price at which no benefits are offered to any customers and an actual price that is paid by some customers.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 2

How to apply the DIP Methodology when benefits exist at introduction?

Solution:

Report customers with and without benefits as separate lines in the Form 2 Block 4 at introduction and as long as benefits are given

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- **Issue 2 - Example 1 (one class with benefits, one class without)**

2010: Drug product X introduced to Canadian market on September 1
DIN 1234567; strength/unit 1 MG/TAB; dosage form S1; pack size 10;
500 packages sold to wholesale and 500 sold to clinics in Ontario

Price to wholesale: $20.00/tablet

Price to clinics: $15.00/tablet

MAPP is $20.00/tablet

N-ATP is $17.50/tablet

W-ATP and O-ATP are within Guidelines.

2012: 500 packages sold to wholesale and 500 sold to clinics but price is same to everyone: $20.00/tablet

N-ATP is now $20.00/tablet

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- **Issue 2 - Example 1**

Form 2 Block 4 September-December 2010

4 SALES OF THE MEDICINE BY THE REPORTING PATENTEE IN FINAL DOSAGE FORM IN CANADA [1]

Drug Identification Number (DIN) or Assigned Number	Strength/Unit	Dosage Form	Package Size	Number of Packages Sold	INDICATE EITHER (6)		Province	Class of Customer
(2)	(3)	(3,4)	(3,5)	(5)	Net Revenue	AVG Price/Package	(4)	(4)
1234567	1 MG/TAB	S1	10.00	500.00	100000.0000		6	3
1234567	1 MG/TAB	S1	10.00	500.00	750000.0000		6	4

Form 2 Block 4 January-June and July-December 2012

4 SALES OF THE MEDICINE BY THE REPORTING PATENTEE IN FINAL DOSAGE FORM IN CANADA [1]

Drug Identification Number (DIN) or Assigned Number	Strength/Unit	Dosage Form	Package Size	Number of Packages Sold	INDICATE EITHER (6)		Province	Class of Customer
(2)	(3)	(3,4)	(3,5)	(5)	Net Revenue	AVG Price/Package	(4)	(4)
1234567	1 MG/TAB	S1	10.00	500.00	100000.0000		6	3
1234567	1 MG/TAB	S1	10.00	500.00	100000.0000		6	4

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 2 - Example 2 (customers with and without benefits within the same class)

2010: Drug product X introduced to Canadian market on September 1
DIN 1234567; strength/unit 1 MG/TAB; dosage form S1; pack size 10;
1000 packages sold only to hospitals, in Ontario

Price to some hospitals: $20.00/tablet

Price to other hospitals: $15.00/tablet (contract).

MAPP is 20.00/tablet

N-ATP is $17.50/tablet H-ATP is $17.50/tablet

2012: Contract ends. Same quantities sold as in 2010 but price is now $20.00 to all hospitals. N-ATP is now $20/tablet

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- **Issue 2- Example 2**

Form 2 Block 4 September-December 2010

4 SALES OF THE MEDICINE BY THE REPORTING PATENTEE IN FINAL DOSAGE FORM IN CANADA [1]

Drug Identification Number (DIN) or Assigned Number	Strength/Unit	Dosage Form	Package Size	Number of Packages Sold	INDICATE EITHER (6)		Province	Class of Customer
(2)	(3)	(3,4)	(3,5)	(5)	Net Revenue	AVG Price/Package	(4)	(4)
1234567	1 MG/TAB	S1	10.00	500.00	75000.0000		6	1
1234567	1 MG/TAB	S1	10.00	500.00	100000.0000		6	1

Form 2 Block 4 January-June and July-December 2012

4 SALES OF THE MEDICINE BY THE REPORTING PATENTEE IN FINAL DOSAGE FORM IN CANADA [1]

Drug Identification Number (DIN) or Assigned Number	Strength/Unit	Dosage Form	Package Size	Number of Packages Sold	INDICATE EITHER (6)		Province	Class of Customer
(2)	(3)	(3,4)	(3,5)	(5)	Net Revenue	AVG Price/Package	(4)	(4)
1234567	1 MG/TAB	S1	10.00	500.00	100000.0000		6	1
1234567	1 MG/TAB	S1	10.00	500.00	100000.0000		6	1

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- **Issue 3**

In cases where the Regular DIP has been invoked (i.e., the N-ATP is above the IBP), how is the IBP* derived when the list price increases following a decrease in the list price?

Solution

Following a decrease in the list price, the IBP* would be based on list price increases within the Guidelines and any actual list price decreases taken by the patentee.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 3 – Example 1 (Regular DIP)

	2003	2004	2005	2006	2007	2008	2009
Form 2 Block 5 Canada	$20.00	$19.00	$19.38	$19.77	$20.16	$20.57	$20.98
N-ATP	$20.00	$12.00	$12.00	$12.00	$12.00	$12.00	**$20.98**
IBP/IBP*	$20.00	$19.00	$19.38	$19.77	$20.16	$20.57	$20.98

Regular DIP can be applied in 2009 as N-ATP is not greater than IBP*.

Note: A 2% CPI is assumed in each example discussed under Issue 3

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 3 – Example 2 (Regular DIP)

	2003	2004	2005	2006	2007	2008	2009
Form 2 Block 5 Canada	$20.00	$19.00	$19.00	$19.50	$19.50	$20.00	$20.00
N-ATP	$20.00	$12.00	$12.00	$12.00	$12.00	$12.00	**$19.50**
IBP/IBP*	$20.00	$19.00	$19.00	$19.38	$19.38	$19.77	$19.77

Regular DIP can be applied in 2009 as N-ATP is not greater than IBP*.

For purposes of calculating IBP*, increases in list price in 2006 (2.6%) and 2008 (2.6%) not used as greater than the assumed 2% CPI, the IBP* calculated based on assumed 2% CPI for each year.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- **Issue 3 – Example 3 (Regular DIP)**

	2003	2004	2005	2006	2007	2008	2009
Form 2 Block 5 Canada	$20.00	$19.50	$19.50	$19.50	$19.50	$20.00	$20.00
N-ATP	$20.00	$12.00	$12.00	$12.00	$12.00	$12.00	**$20.00**
IBP/IBP*	$20.00	$19.50	$19.50	$19.50	$19.50	$19.89	$19.89

Regular DIP cannot be applied in 2009 as N-ATP is greater than IBP*.

For purposes of calculating IBP*, increase in list price in 2008 (2.6%) not used as greater than the assumed 2% CPI, the IBP* calculated based on assumed 2% CPI.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 3 - Example 4 (Simplified DIP)

	2003	2004	2005	2006
Form 2 Block 5 Canada	$20.00	$16.00	$16.00	$16.00
N-ATP	$20.00	$12.00	$12.00	**$20.00**
IBP/IBP*	$20.00	$16.00	$16.00	$16.00

Simplified DIP cannot be applied in 2006. Even though N-ATP in 2006 is equal to IBP, because of list price decrease, the rebound is limited to $16.00.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 3 - Example 5 (Simplified DIP)

	2003	2004	2005	2006
Form 2 Block 5 Canada	$20.00	$16.00	$16.00	$20.00
N-ATP	$20.00	$12.00	$12.00	**$20.00**
IBP/IBP*	$20.00	$16.00	$16.00	$16.32

Simplified DIP cannot be applied in this case in 2006.

Furthermore, Regular DIP cannot be applied. For purposes of calculating IBP*, increase in list price in 2006 (25%) not used as greater than the assumed 2% CPI, the IBP* calculated based on assumed 2% CPI.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 3 – Example 6 (Simplified DIP)

	2003	2004	2005	2006	2007
Form 2 Block 5 Canada	$20.00	$19.00	$19.38	$19.76	$20.15
N-ATP	$20.00	$12.00	$12.00	$12.00	**$20.00**
IBP/IBP*	$20.00	$19.00	$19.38	$19.76	$20.15

Simplified DIP can be applied in this case in 2007.

Even though the IBP* is not used in the context of the Simplified DIP, as there is a list price decrease it is reviewed to ensure that the correct rebound price is established.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 4

How to avoid unnecessary investigations in years subsequent to the application of DIP because of the application of the CPI-Adjustment Methodology?

Solution:

Change the benchmark year for the CPI-Adjustment Methodology to the year the DIP Methodology is applied.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 4 – Example 1

2006: Introductory Benchmark Price of drug product X is $15.

2008: The ATP is $10 due to benefits provided to some customers.

2009: Some benefits end in 2009. ATP increases to $13 triggering the opening of an investigation. Form 2 Block 5 Canada has been $15 since introduction.

Simplified DIP Methodology can be applied.

2009 N-NEAP = 2009 N-ATP = $13

The 2010 N-NEAP will be: $13 x 1.018 = $13.234

Benchmark year is now 2009 and 1.018 is the CPI-Adjustment Factor for that year in 2010.

Pilot Application of the DIP Methodology
Four Application-Related Issues and Solutions

- Issue 4 – Example 1 (Cont'd)

2010: All benefits are eliminated

ATP increases to $15 triggering the opening of an investigation.

Form 2 Block 5 is still $15.

Simplified DIP can be applied.

2010 N-NEAP = 2010 N-ATP = $15

2011 N-NEAP = $15 x 1.029 = $15.425

Benchmark year is now 2010 and 1.029 is the CPI-Adjustment Factor for that year in 2011.

Final Report

Board accepted recommendations from DIP Working Group at its May 16, 2012 meeting.

The DIP Methodology is now fully implemented.

DIP-WG Final Report is on the PMPRB website.