DIP Methodology

Patented Medicine Prices Review Board
Regulatory Affairs and Outreach Branch

Ottawa, Ontario
April 20, 2011

Overview

- **DIP Methodology Technical Working Group (DIP-WG)**
  - Historical Background
  - Issues and Challenges
  - Guiding Principles for a Solution
  - Processes
  - Final report and Next Steps

- **Application Forms**
  - Simplified DIP: Part A
  - Regular DIP: Part A and Part B

DIP-WG Historical Background

- Tasks

  - to identify challenges in applying the DIP Methodology under the Guidelines

  - to develop workable solutions

- Composition

  - 3 representatives of the innovative pharmaceutical industry

  - 2 representatives of the biotechnology industry

  - 1 representative of the generic pharmaceutical industry

  - 4 members of Board Staff

- Four meetings between January 20 and February 23, 2011

DIP Methodology – Issues and Challenges

- Onerous Evidence Requirements
- Any Market
- Increase in ATP due to business conditions beyond the control of patentees
- Refunds and Returns

DIP Methodology – Guiding Principles for a Solution

- Feasible
- Transparency
- Predictability and consistency
- Premise should not be based on price increase
- High level approach
- Investigations should not be conducted for years where the PMPRB has already deemed the ATP compliant
- Apply appropriate terminology

DIP Methodology – Two Processes

- **Simplified DIP Methodology**

  N-ATP ≤ IBP

- **Regular DIP Methodology**

  IBP < N-ATP ≤ IBP*

Underlying assumption - no review at level of "any market"

DIP-WG Final Report and Next Steps

- Final report reviewed by the Board on March 4, 2011
- Board decision:
  - Implement as pilot project for one year
  - Evaluate at the end of July to December 2011 reporting period

Application Forms: Simplified DIP (Part A)

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

Product Information

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

Application Forms: Simplified DIP (Part A)

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

Regular DIP: Part A and Part B

- Part A: as described previously
- Part B

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										

Regular DIP: Example 1

- Patented drug product has been sold to various customers since April 10, 2005. Its price became under investigation in 2010. Patentee believes that Regular DIP Methodology can be applied.
- Only one List Price

  $1/tab in 2005, 2006 and 2007

  $1.10/tab in 2008, 2009 and 2010
- Price increase was effective as of April 1st, 2008
- Maximum selling price to at least one customer:

2005: $1	2006: $1	2007: $1
2008: $1.10	2009: $1.10	2010: $ 1.10

Regular DIP: Example 1

PART A

Drug product information, background and description of benefit to be provided as required in the Form

PART B **Price Increase Chart**

	2005		2006	2007	2008	2009	2010
List Price (price/unit)	1.00	1.00	1.00	1.00	1.10	1.10	1.10
% List Price Increase					10%		
Maximum Selling Price/Unit	1.00	1.00	1.00	1.00	1.10	1.10	1.10
Effective Date of List Price increase					01-Apr-08		

Copies of the List Price to be provided for each year reported in the Price Increase Chart

Regular DIP: Example 2

- Patented drug product has been sold to various customers since April 10, 2005. Its price became under investigation in 2010. Patentee believes that Regular DIP Methodology can be applied.
- Two List Prices: Wholesaler $1/tab in 2005, 2006 and 2007
  $1.10/tab in 2008, 2009 and 2010
  Quebec $0.80/tab in 2005, 2006 and 2007
  $0.85/tab in 2008, 2009 and 2010
- Price increases were effective as of April 1st, 2008
- Maximum selling price to at least one customer:

Wholesaler	2005: $1	2006: $1	2007: $1
	2008: $1.10	2009: $1.10	2010: $1.10
Quebec	2005: $0.80	2006: $0.80	2007: $0.80
	2008: $0.85	2009: $0.85	2010: $0.85

Regular DIP: Example 2

PART A
Drug product information, background and description of benefit to be provided as required in the Form

PART B **Price Increase Chart**

Wholesaler	2005		2006	2007	2008	2009	2010
List Price (price/unit)	1.00	1.00	1.00	1.00	1.10	1.10	1.10
% List Price Increase					10%		
Maximum Selling Price/Unit	1.00	1.00	1.00	1.10	1.10	1.10	1.10
Effective Date of List Price increase					01-Apr-08		

Quebec	2005		2006	2007	2008	2009	2010
List Price (price/unit)	0.80	0.80	0.80	0.80	0.85	0.85	0.85
% List Price Increase					6.25%		
Maximum Selling Price/Unit	0.80	0.80	0.80	0.80	0.85	0.85	0.85
Effective Date of List Price increase					01-Apr-08		

Copies of the List Price to be provided for each year reported in the Price Increase Chart

DIP Methodology

For further information on the application of the DIP Methodology to specific drug products, please contact the Senior Regulatory Affairs Officer assigned to your company.