Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada

Patented Medicine Prices Review Board

Outreach Sessions 2012

Montreal February 28, 2012

Toronto, February 29, 2012

Overview

- **DIP Methodology update**
  - Experience during one-year pilot & Working Group review
- **Areas in Guidelines identified for further assessment (January 2011 NEWSletter**
  - Investigation thresholds; requirement for a Voluntary Compliance Undertaking (VCU) after three years of offset; “any market” review for existing patented drug products
- **Priorities 2012-2013**
- **Form 2 Block 5**
  - Filing requirements
  - Verification of foreign patented drug prices
- **PMPRB website**

Experience during Pilot

- **"Simplified" DIP Methodology**
  - 27 cases (Investigations & Does Not Trigger)
  - Simple to understand and apply
  - Minimal evidentiary requirements
  - Linked to Introductory Benchmark Price
- **"Regular" DIP Methodology**
  - 13 cases (Investigations & Does Not Trigger)
  - Less straightforward
  - More evidence required
  - Linked to list prices and increases in CPI

Technical Issues Raised by Working Group

- **Subsequent patentee maintains benefits of previous patentee**
  - Patentee A first sells product XYZ in 2001 and its price of $20.00 is within the Guidelines (the IBP would be $20.00)
    - provides benefits to hospitals in 2004 and by 2007 its ATP is $12.00
  - Patentee B acquires and starts to sell product XYZ in 2008 and provides the same benefits to hospitals, such that its ATP is $12.00 (the IBP is $12.00)
    - in 2010, Patentee B terminates all benefits and the ATP is $20.00
- **<u>RECOMMENDATION</u>: Patentee B to obtain IBP from Patentee A**

Technical Issues Raised by Working Group

- **Benefits offered in first period of sale**
- **RECOMMENDATION:**
  - Two independent approaches depending on the circumstances
    - During first period of sale, patentee to report value of benefits as separate item in Form 2, Block 4 data
      - This will be the case where sales and benefits are offered within the same class of customer
    - Board Staff to review Form 2, Block 4 data in first period of sale to identify a class of customer where no benefits were offered
      - This will be the case where sales occur in one class of customer and benefit are offered to another class of customer

Technical Issues Raised by Working Group

- **Calculation of IBP* in the context of the Regular DIP Methodology where there is a decrease in the list price**

- **<u>RECOMMENDATION</u>:**
  - IBP* is based on list price increases that are within the Guidelines and any actual decreases in the list price taken by patentee

Technical Issues Raised by Working Group

- **CPI-Adjustment Methodology following application of the DIP Methodology**

- **RECOMMENDATION:**
  - Reset the CPI clock to zero the year the DIP Methodology is applied
    - Result is that the benchmark year for the CPI-Adjustment Methodology is reset to the year the DIP Methodology is applied
  - Simple, easily applied and represents a fresh start using an existing concept (i.e., benchmark year)

Recommendations and Next Steps

- **Working Group report presented to Board on February 16th**
  - Recommendation: adopt Pilot on a permanent basis, including recommendations to address technical issues
- **Board agreed with recommendations**
- **Next Steps**
  - Working Group report to be finalized and posted on PMPRB website in coming weeks

Guidelines - Areas of further assessment

- **Thresholds for Opening an Investigation**
  - For existing drug products, eliminate 5% trigger at the national level.

    - The National ATP or any Market-Specific ATP of a new drug product exceeds the Maximum Average Potential Price during the introductory period by more than 5%.
    - ~~The National ATP of an existing drug product exceeds the national Non-Excessive Average price by more than 5%.~~
    - Excess revenues for a new or existing drug product are $50,000 or more.
    - PMPRB receives a complaint.

Guidelines - Areas of further assessment

- Offset of *de minimus* Excess Revenues (i.e. less than $50,000)
  - Replace 3-year period to offset *de minimus* excess revenues through a Voluntary Compliance Undertaking (VCU) with requirement to offset in a timely manner
- No change to status that is reported - will continue to be reported as "Does Not Trigger"

Guidelines - Areas of further assessment

- **"Any market" review**
  - Apply the "any market" Price Review policy only to patented drug products introduced on or after January 1, 2010
- **What this means:**
  - "Any market" review for new patented drug products first sold on or after January 1, 2010
    - Once these patented drug products become existing patented drug products, any market review will be conducted if investigation criteria are triggered
  - "Any market" not conducted for patented drug products which were existing patented drug products on January 1, 2010 (i.e. first sold and patented prior to January 1, 2010)

Guidelines - Areas of further assessment

- **Next Steps**
  - Notice & Comment to be issued in mid to late March
  - Board Meeting May 11, 2012 to review comments and make decisions on changes
  - Changes adopted to be incorporated in consolidated Guidelines released every June

Priorities 2012-2013

- **Board has adopted two new priorities for coming year**
  - Explore possibilities relating to alternative dispute resolution (ADR) as a means to enhance compliance with the Board's Guidelines
  - Consider options to decrease regulatory burden and make effective use of Board Staff resources

Form 2 Block 5

Form 2 Block 5 Publicly Available Ex-Factory Prices for Canada and Other Countries

Patented Medicines Regulations

Subsection 4(1):

For the purposes of paragraphs 80(1)(*b*) and (2)(*b*) of the Act, information identifying the medicine and concerning the price of the medicine shall indicate:

(f) (iii) if the medicine is being sold in one or more of the countries set out in the schedule, the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold to each class of customer in each of those countries.

Subsection 4(9):

For the purposes of this section, “publicly available ex-factory price” includes any price of a patented medicine that is agreed on by the patentee or former patentee and the appropriate regulatory authority of the country in which the medicine is sold by the patentee.

Form 2 Block 5 Publicly Available Ex-Factory Prices for Canada and Other Countries

- Publicly available ex-factory prices in **Canada** and in the **seven countries** listed in the *Regulations.*
- **For all patented drug products in the final dosage form** that the Canadian patentee sells in Canada
- **Even if the Canadian patentee itself does not sell** the product in any of the seven foreign countries
- Information must pertain to **same patented drug product (same patent**)

Form 2 Block 5 Publicly Available Ex-Factory Prices for Canada and Other Countries

- **Ex-factory price:** price at which a drug product is first sold to wholesalers, hospitals, pharmacies, or others. This price excludes sales taxes and wholesale mark-ups.

- If there is more than one ex-factory price for a particular country/province and class of customer for a reporting period, report the **most recent price for the reporting period**.

- Report **in the currency of the country** in which the drug product was sold.

Form 2 Block 5 Publicly Available Ex-Factory Prices for Canada and Other Countries

- Block 5 prices are used :
  - At introduction: Median International Price Comparison test
  - Every year (including intro): Highest International Price Comparison test
  - When applying the DIP methodology: Canadian Block 5

- Block 5 prices are verified at introduction, when the pivotal test is the Median International Price or the Highest International Price.

  A patentee will be asked to provide copies of sources for any discrepancies found between Block 5 and Board Staff prices.

Form 2 Block 5 Prices from International Formularies

Country (code)	Formulary	Hospital	Pharmacy	Wholesale	Other
France (16)	Vidal		X	X	
Germany (15)	Röte Liste		X	X	
Italy (17)	L'Informatore Farmaceutico		X	X	
Sweden (18)	Prislista		X	X	
Switzerland (19)	Medwin			X	
United Kingdom (20)	Monthly Index of Medical Specialties (MIMS)		X	X	
United States (21)	Thompson PDR- Red Book - Direct Price (DP) - Wholesale Acquisition Cost (WAC) Federal Supply Schedule	X	X	X[(a)] X	 X 4-FSS

(a) Report only one Wholesale price unless the DP and WAC prices are different.

Verification of Foreign Patented Drug Prices

- The PMPRB document "**Verification of Foreign Patented Drug Prices (2000)**" describes the original methodology used by Board Staff to verify publicly available ex-factory prices.

- Consult PMPRB website (under **Are you a Patentee?**) for 2011 and 2012 methodology and markups for each foreign country under the Regulations.

- NEWSletter January 2012 : Annual revisions to the formulas will be published every January for the coming year.

  Ex. Formulas for January-December 2012 were published in January 2012

Example

- Drug ABC, DIN 01234567, Strength/unit: 100 mg/tab
- Prescription drug product sold in package sizes 28, 30, 50, 90
- Introduced to the Canadian market in March 2011
- Sold in Canada (all provinces), Germany (15), France (16) and U.S.A. (21)
- At introduction, the MIPC is the pivotal test . As a result, Board Staff will do a verification of the prices reported by the patentee in its Form 2 Block 5 for March-June 2011.

Example: Form 2 Block 5 for Drug ABC March-June 2011

5 PUBLICLY AVAILABLE EX-FACTORY PRICES FOR CANADA AND OTHER COUNTRIES

Generic name of medicine	DIN	Strength/Unit	Dosage Form	Package Size	Ex-Factory Price	Country	Customer Class
ABC	1234567	100 MG/TAB	S1	28	40.0400	15	1
ABC	1234567	100 MG/TAB	S1	28	42.1000	15	2
ABC	1234567	100 MG/TAB	S1	28	40.0400	15	3
ABC	1234567	100 MG/TAB	S1	28	36.2200	16	2
ABC	1234567	100 MG/TAB	S1	28	33.3200	16	3
ABC	1234567	100 MG/TAB	S1	30	76.5000	5	1
ABC	1234567	100 MG/TAB	S1	30	84.1500	13	1
ABC	1234567	100 MG/TAB	S1	30	203.0000	21	1
ABC	1234567	100 MG/TAB	S1	30	76.5000	5	2
ABC	1234567	100 MG/TAB	S1	30	84.1500	13	2
ABC	1234567	100 MG/TAB	S1	30	203.0000	21	2
ABC	1234567	100 MG/TAB	S1	30	76.5000	5	3
ABC	1234567	100 MG/TAB	S1	30	84.1500	13	3
ABC	1234567	100 MG/TAB	S1	30	203.0000	21	3
ABC	1234567	100 MG/TAB	S1	30	167.2400	21	4-FSS
ABC	1234567	100 MG/TAB	S1	50	59.5000	16	1
ABC	1234567	100 MG/TAB	S1	90	608.9600	21	1
ABC	1234567	100 MG/TAB	S1	90	608.9600	21	2
ABC	1234567	100 MG/TAB	S1	90	608.9600	21	3
ABC	1234567	100 MG/TAB	S1	90	501.7100	21	4-FSS

Example: International Price Verification Report for Drug ABC, March-June 2011

ABC 100 mg/tab (DIN 01234567)
International Price Verification
January-June 2011

Country	Company Submission Prices (Local Currency)			Company Submission Prices (Canadian Currency)	Publicly Available International Prices			International Ex-Factory Prices Backed Out From Public Sources (Local Currency)			International Ex-Factory Prices Backed Out From Public Sources (Canadian Currency)
Canada	(30) (30) (30) (30) (30) (30)	76.5000 84.1500 76.5000 84.1500 76.5000 84.1500	(CDN$)(H) (CDN$)(H) (CDN$)(P) (CDN$)(P) (CDN$)(W) (CDN$)(W)	$2.6775	(30) (30)	76.5000 84.1500	(CDN$) (CDN$)				$2.6775
Germany	(28) (28) (28)	40.0400 42.1000 40.0400	(€)(H) (€)(P) (€)(W)	$2.1463	(28)	61.2400	(€)	(28) (28)	42.1000 39.7200	(€)(P) (€)(W)	$2.1561
France	(28) (28) (50)	36.2200 33.3200 59.5000	(€)(P) (€)(W) (€)(H)	$1.8069	(28)	36.2200	(€)	(28) (28)	36.2200 33.4000	(€)(P) (€)(W)	$1.8346
US	(30) (30) (30) (30) (90) (90) (90) (90)	203.0000 203.0000 203.0000 167.2400 608.9600 608.9600 608.9600 501.7100	(US$)(H) (US$)(P) (US$)(W) (US$)(FSS) (US$)(H) (US$)(P) (US$)(W) (US$)(FSS)	$6.9589	(30) (30) (90) (90)	165.3400 188.8400 496.0400 566.4700	(US$)(FSS) (US$)(WAC) (US$)(FSS) (US$)(WAC)	N/A			$6.3429
Median				$2.1463							$2.1561

Example: Verification – Canada (Drug ABC, March-June 2011)

Company Submission & Verification

Company Submission				Publicly Available Price [1]		
Pack Size	Price CDN$	Customer Class	Average Price/ Unit in CDN $	Pack Size	Price CDN$	Ex-factory price per unit
(30)	76.50	(H)	[(76.50/30) + (84.15/30) + (76.50/30) + (84.15/30) + (76.50/30) + (84.15/30)] /6 = **$2.6775**	(30) (30)	76.5000 84.1500	[(76.50/30) + (84.15/30)] /2 = **$2.6775**
(30)	84.15	(H)				
(30)	76.50	(P)				
(30)	84.15	(P)				
(30)	76.50	(W)				
(30)	84.15	(W)				

(1) Source for Publicly Available Price: RAMQ June 2011; ODB June 2011

Example: Verification – Germany (Drug ABC, March-June 2011)

Company Submission

Pack Size	Price €	Customer Class	Average Price / Unit in €	Average Price/ Unit in CDN $
(28)	40.04	(H)	[(40.04/28) +(42.10/28) + (40.04/28)] / 3 = **1.4545 €**	1.4545 x 1.47565833 = **CDN $ 2.1463**
(28)	42.10	(P)		
(28)	40.04	(W)		

Company would be requested to provide evidence that € 40.04 is the publicly available ex-factory price of ABC for hospitals in Germany.

Exchange rate for Germany: 1.47565833

Verification Methodology - Germany (prescription products) - 2011

- Formulary Price (FP) stated in euros in Röte Liste
- FP includes 19% Value Added Tax (VAT)
- No price comparable to ex-factory hospital price reported by patentee

- Step 1: Remove VAT: FP net (FPN) = FP / 1.19
- Step 2: Calculate ex-factory pharmacy price (PP)

  PP = (FPN-8.10) / 1.03
- Step 3: Derive ex-factory wholesale price (WP)

Verification Methodology - Germany (prescription products) - 2011

- **Ex-factory wholesale price (WP) is derived as follows:**

If :	0	< PP ≤	3.45	WP = PP / 1.15
	3.46	< PP ≤	4.19	WP = PP - 0.45
	4.20	< PP ≤	5.60	WP = PP / 1.12
	5.61	< PP ≤	7.26	WP = PP - 0.60
	7.27	< PP ≤	9.81	WP = PP / 1.09
	9.82	< PP ≤	12.37	WP = PP - 0.81
	12.38	< PP ≤	24.61	WP = PP / 1.07
	24.62	< PP ≤	28.43	WP = PP - 1.61
	28.44	< PP ≤	1,272.00	WP = PP / 1.06
		PP >	1,272.00	WP = PP – 72

Example: Verification – Germany (Drug ABC, March-June 2011)

Verification

Publicly Available Price[1]		Backing out			Average Price/ Unit in €	Average Price/ Unit in CDN $
Pck Size	Price €	Pck Size	Price €	Cust. Class		
(28)	61.2400	(28)	42.10	(P)	[42.10/28 + 39.72/28]/2 = **1.4611 €**	1.4611 x 1.47565833 = **CDN $ 2.1561**
		(28)	39.72	(W)		

(1) Source of Publicly Available Ex-Factory Price in Germany: Röte Liste Jan. 1, 2011

Explanation of second column

Prescription drug

Step 1 remove VAT FPN = 61.24/1.19= 51.46

Step 2 PP = (FPN-8.10) /1.03 = (51.46 – 8.10) /1.03= 42.10

Step 3 WP = 42.10/1.06 = 39.72

Exchange rate for Germany based on 36-month ending June 2011: 1.47565833

Example: Verification – France (Drug ABC, March-June 2011)

Company Submission

Pack Size	Price €	Customer Class	Average Price / Unit in €	Average Price/ Unit in CDN $
(28)	36.22	(P)	[36.22/28 + 33.32/28 + 59.50/50] / 3 = **1.2245 €**	1.2245 x 1.47565833 = **CDN $ 1.8069**
(28)	33.32	(W)		
(50)	59.50	(H)		

Company would be requested to provide evidence that € 59.50 is the publicly available ex-factory price of ABC for hospitals in France.

Exchange rate for France : 1.47565833

Verification Methodology - France 2011

- **Formulary price (FP) stated in euros in Vidal**
- **No price comparable to ex-factory hospital price reported by patentee**
- **Ex-factory pharmacy price (PP) directly comparable to FP** (Px-Achat)
- **Ex-factory wholesale price (WP) is derived as follows:**

If FP ≤ 22.90	**WP = FP / 1.0993**
22.90 < FP ≤ 150.00	$\mathrm{WP} = 20.83 + \frac{\mathrm{FP\text{-}22.90}}{1.06}$
FP > 150.00	$\mathrm{WP} = 140.73 + \frac{\mathrm{FP\text{-}150}}{1.02}$

Example: Verification – France (Drug ABC, March-June 2011)

Verification

Publicly Available Price (1)		Backing out			Average Price/ Unit in €	Average Price/ Unit in CDN $
Pck Size	Price €	Pck Size	Price €	Cust. Class		
(28)	36.2200	(28)	36.22	(P)	[36.22/28 + 33.40/28] /2 = **1.2432 €**	1.24325 x 1.47565833 = **CDN $ 1.8346**
		(28)	33.40	(W)		

(1) Source of Publicly Available Ex-Factory Price in France: Vidal June 2011
Exchange rate for France : 1.47565833

Explanation of second column

PP= FP = 36.22

36.22 is between 22.90 and 150, apply formula: $\mathrm{WP} = 20.83 + \frac{\mathrm{FP\text{-}22.90}}{1.06}$

WP= 20.83 + (36.22 - 22.90)/1.06 = 33.40

Example: Verification – U.S.A (Drug ABC, March-June 2011)

Company Submission

Pack Size	Price US$	Customer Class	Average Price / Unit in US $	Average Price / Unit in CDN $
(30)	203.0000	(H)	[(203.00/30) + (203.00/30) + (203.00/30) + (167.24/30) + (608.96/90) + (608.96/90) + (608.96/90) + (501.71/90)] /8= **US $ 6.4687**	6.4687 x 1.07454444 = **CDN $ 6.9509**
(30)	203.0000	(P)		
(30)	203.0000	(W)		
(30)	167.2400	(FSS)		
(90)	608.9600	(H)		
(90)	608.9600	(P)		
(90)	608.9600	(W)		
(90)	501.7100	(FSS)		

Exchange rate for the U.S.A. : 1.07454444

Company would be requested to provide evidence that US$ 203 and 608.96 are publicly available ex-factory prices of ABC for hospitals and pharmacies in the USA.

Example: Verification – U.S.A. (Drug ABC, March-June 2011)

Verification

Publicly Available Price(1)			Backing out			Average Price/ Unit in US $	Average Price/ Unit in CDN $
Pck Size	Price US $	Source	Pck Size	Price US $	Cust. Class		
(30)	165.34	(FSS)	No backing out as there are no regulated mark-ups in the US			[(165.34/30)+ (188.84/30) + (496.04/90) + (566.47/90)] / 4 = **US $ 5.9029**	**5.9029 x 1.07454444 = CDN $ 6.3429**
(30)	188.84	(WAC)					
(90)	496.04	(FSS)					
(90)	566.47	(WAC)					

(1) Sources of Publicly Available Ex-Factory Prices in the U.S.A. : Thompson PDR - Red Book Wholesale Acquisition Cost and Federal Supply Schedule June 2011

Exchange rate for the U.S.A. : 1.07454444

Example: International Price Verification Report for Drug ABC, March-June 2011

ABC 100 mg/tab (DIN 01234567)
International Price Verification
January-June 2011

Country	Company Submission Prices (Local Currency)			Company Submission Prices (Canadian Currency)	Publicly Available International Prices			International Ex-Factory Prices Backed Out From Public Sources (Local Currency)			International Ex-Factory Prices Backed Out From Public Sources (Canadian Currency)
Canada	(30) (30) (30) (30) (30) (30)	76.5000 84.1500 76.5000 84.1500 76.5000 84.1500	(CDN$)(H) (CDN$)(H) (CDN$)(P) (CDN$)(P) (CDN$)(W) (CDN$)(W)	$2.6775	(30) (30)	76.5000 84.1500	(CDN$) (CDN$)				$2.6775
Germany	(28) (28) (28)	40.0400 42.1000 40.0400	(€)(H) (€)(P) (€)(W)	$2.1463	(28)	61.2400	(€)	(28) (28)	42.1000 39.7200	(€)(P) (€)(W)	$2.1561
France	(28) (28) (50)	36.2200 33.3200 59.5000	(€)(P) (€)(W) (€)(H)	$1.8069	(28)	36.2200	(€)	(28) (28)	36.2200 33.4000	(€)(P) (€)(W)	$1.8346
US	(30) (30) (30) (30) (90) (90) (90) (90)	203.0000 203.0000 203.0000 167.2400 608.9600 608.9600 608.9600 501.7100	(US$)(H) (US$)(P) (US$)(W) (US$)(FSS) (US$)(H) (US$)(P) (US$)(W) (US$)(FSS)	$6.9589	(30) (30) (90) (90)	165.3400 188.8400 496.0400 566.4700	(US$)(FSS) (US$)(WAC) (US$)(FSS) (US$)(WAC)		N/A		$6.3429
Median				$2.1463							$2.1561

PMPRB Website Overview

Website Reorganization

- **Newly revamped website launched October 1, 2011**

- **Why did we do it?**
  - To reorganize and update content
  - To make it more user friendly
  - To bring more context to the content on our website
  - To ensure that users visiting the website infrequently have the same base knowledge as those who use it on a daily basis.

Information for Patentees

- **One stop shopping for Patentees**
  - Revamped "Are you a Patentee?" section of our website
  - One central hub for all Patentee related materials

- **Information found in "left-hand" menu**
  - *New Patented Medicines Reported to the PMPRB* Module
  - Regulating Prices
  - Legislation, Regulations and Guidelines
  - Analytical Studies
  - NPDUIS Reports

New Medicines Reported to the PMPRB

- **Brand new module launched January 30, 2012**
  - Fully searchable and sortable – works like a search engine
  - Up to date data – user friendly, much more accessible

- **Price Review Records**
  - Records are live for 2010 onward
  - Data for 2011 will be posted incrementally in the coming weeks/months

Other Initiatives

- **PMPRB Twitter feed on March 1, 2012 - @PMPRB_CEPMB**
  - Enhanced accessibility and transparency
  - More immediate, instant access
  - Works in conjunction with the website and our eBulletin service

- **Transitioning toward an "electronic-only" environment**
  - January 2012 NEWSletter
    - First issue of the NEWSletter available as an "electronic-only" document
  - Eventually all publications will move away from print versions
    - Ex. 2012 Annual Report will be web only. 2012 Annual Report in Brief will be available in print.

Communication with Board Staff

- **Query to PMPRB Staff**
  - **Guidelines: Ginette Tognet**
    Tel: (613) 954-8297 E-mail: ginette.tognet@pmprb-cepmb.gc.ca
  - **Scientific and new meds: Catherine Lombardo**
    Tel: (613) 952-7620 E-mail: catherine.lombardo@pmprb-cepmb.gc.ca
  - **Filing Form 1 and 2: Beatrice Mullington**
    Tel: (613) 952-2924 E-mail: beatrice.mullington@pmprb-cepmb.gc.ca
  - **Investigation: Senior Regulatory Officer assigned to Company**
  - **Form 3: Lokanadha Cheruvu**
    Tel: (613) 954-9812 E-mail: lokanadha.cheruvu@pmprb-cepmb.gc.ca
  - **Website Issues: Tom Kloppenburg**
    Tel: (613) 960-4553 E-mail: tom.kloppenburg@pmprb-cepmb.gc.ca

- **All other questions: 1-877-861-2350 pmprb@pmprb-cepmb.gc.ca**