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

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PMPRB NEWSletter

Message from the Executive Director

Good Tidings for 2014

As the PMPRB's newly minted Executive Director, I thought it fitting to mark both my arrival and that of the New Year with a few words to the readers of our new and improved *NEWSletter*.

Although I am new to the PMPRB, as a former director of patent policy with Industry Canada, I should not be new to any of our readers who played a part in the development of Canadian pharmaceutical patent policy over the past decade. While my knowledge of pharmaceutical industry issues may be slightly dated for the moment, my enthusiasm for the subject matter is undiminished, as no other industry holds out the promise of technologies to not only extend life but to improve its quality in doing so.

These are challenging times for industry and pricing and reimbursement authorities alike. Canada's recent commitment under the Comprehensive Economic and Trade Agreement (CETA) to amend the *Patent Act* to extend the terms of pharmaceutical patents by up to two years has given fresh impetus to the debate over the appropriate balance between intellectual property and consumer protection. While sales of patented medicines in Canada have stabilized in recent years, Canadians still spend more per capita, and as a percentage of GDP, on patented and non-patented pharmaceuticals, than many of our OECD partners. Accordingly, public and private payers in Canada are increasingly looking at new drug cost containment measures, as are their counterparts in many other countries. At the PMPRB, it is important that we keep a close eye on these developments and their impact, both at home and abroad, to ensure that our regulations, guidelines and operating procedures remain relevant and effective.

In the year ahead, I look forward to continuing to collaborate with our industry stakeholders on ways to reduce the regulatory burden on patentees and to streamline and simplify our processes in a cost effective manner. Similarly, in the context of our reporting mandate, I look forward to further assisting the efforts of our F/P/T partners and private insurers with timely and topical reports and studies which will enable them to make

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Notice to Readers

Updates

- The Monitoring and Evaluation Plan for the Major Changes in the Guidelines (GMEP) has been updated for 2013

Upcoming Events

- Doug Clark and Tanya Potashnik are attending the Pharma Pricing & Market Outlook Europe 2014 in London
- Doug Clark is attending the TIP Conference to be held at the University of Toronto on April 6–8

informed reimbursement decisions in real time. Finally, as the debate surrounding the CETA unfolds, I look forward to supporting policy makers with any information and analysis they require to ensure that the aforementioned balance continues to work to the optimal benefit of both industry and consumers.

Douglas Clark
Executive Director

Catherine Lombardo Retires

On January 3, 2014, Catherine Lombardo, Manager of the Scientific Review and Introductory Prices Unit, retired from the public service of Canada.

After having participated in the elaboration of draft amendments to the pharmaceutical provisions of the Patent Act, Catherine was one of the first to join the new organization established in December 1987. Throughout her years at the PMPRB, Catherine participated in policy development and in all aspects of regulatory activities, starting with the Guidelines in 1988.

Catherine's dedication and exceptional contribution to the PMPRB will long be felt.

We thank you Catherine and wish you the very best in retirement.

Submissions by Patentees on Level of Therapeutic Improvement

Schedule 1 of the *Compendium of Policies, Guidelines and Procedures* (Guidelines) sets out that patentees are to file 10 copies of any submission along with all supporting references. The number of required copies has since been reduced to 8, as announced in the July 2013 *NEWSletter* and defined in the 2014 HDAP Schedule.

Proposal for Electronic Submissions

The PMPRB is now proposing that submissions be filed in electronic format only. For the **May 12, 2014**, HDAP meeting, patentees can file their submissions in either **paper or electronic formats**. Starting with the **September 15, 2014**, HDAP meeting, patentees will be required to file all submissions in **electronic format only**.

For submission deadlines, see the HDAP schedule.

Requirements for Electronic Submissions

If you choose to file an electronic submission for the May 12 HDAP meeting, the following requirements apply. They will be reviewed and finalized for subsequent submissions:

- Eight CDs or memory sticks must be filed within the HDAP submission deadlines (see HDAP schedule).
- The CDs or memory sticks should be labelled with the name of the drug product under review.

- NPDUIS staff are presenting studies at the 2014 CADTH Symposium in Gatineau

Reminders

- The deadline for filing Form 3 is March 3, 2014
- Patentee submissions for the May 12, 2014, HDAP meeting are due on February 18

Presentations
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- Documents must be provided in Microsoft Word or in a PDF format that is unlocked, searchable and printable to enable users to extract information or combine documents.
- Documents should be labelled as follows:
    - **Proposal of the Patentee** – refer to Schedule 1 of the *Compendium of Policies, Guidelines and Procedures* for details on the required contents of the proposal.
    - **Patentee's price justification/pricing details** – this document must be submitted as a separate file, as the information is not shared with the members of HDAP.
    - **References** – this file must be easily identifiable and must match the list of references included in the Proposal of the Patentee. See example below:

      A product monograph for Drug XX dated November 15, 2013, a clinical trial by Smith et al. in 2008 and NICE Guidelines from 2010:
        - Ref 1 – Drug XX, PM, November 15, 2013
        - Ref 2 – Smith 2008
        - Ref 3 – NICE 2010
- The CDs or memory sticks should be mailed or couriered to:

  Regulatory Affairs and Outreach Branch
  Patented Medicine Prices Review
  Box L40, 333 Laurier Avenue West, Suite 1400
  Ottawa, ON, K1P 1C1

Next steps

Based on the experience with the filing of electronic submissions for the May 2014 HDAP meeting, adjustments may be made to the requirements. The final requirements will be published in the April 2014 issue of the *NEWSletter* and will be incorporated into the yearly update of the Guidelines in June 2014. Any questions or comments should be referred to Amber MacPherson of the Regulatory Affairs and Outreach Branch of the PMPRB.

2013 CPI-Based Price-Adjustment Factors

Preliminary Price-Adjustment Factors (Based on Forecast Inflation Rates)

Table 1 reproduces preliminary price-adjustment factors for 2013 published in the April 2012 *NEWSletter*. These factors were based on forecasted annual CPI-inflation rates of 2.1% and 2.0% for 2012 and 2013, respectively.

Forecast 2013 Price-Adjustment Factors for Patented Drug Products

Benchmark Year:	(1) 2010	(2) 2011	(3) 2012
Price-Adjustment Factor	1.072	1.041	1.020

These figures imply (1) a maximum allowable cumulative price increase between 2010 and 2013 of 7.2% for patented drug products with Canadian sales in 2010 (that is, products whose "benchmark year" is 2010); (2) a maximum allowable cumulative price increase between 2011 and 2013 of 4.1% for products whose first Canadian sales occurred in 2011; and (3) a maximum allowable cumulative price increase between 2012 and 2013 of 2.0% for products whose first Canadian sales occurred in 2012.

In addition, the forecast inflation rate of 2.0% for 2013 implies a year-over-year price increase cap (applicable to all drug products, regardless of benchmark year) of 3.0% (= 1.5 x 2.0%) for 2013.

Final Price-Adjustment Factors
(Based on Actual Inflation Rates)

The actual rate of CPI inflation for 2012 of 1.5% was published in the January 2013 *NEWSletter*. The actual rate of CPI inflation for 2013 is now available and was 0.9%. These rates (along with the actual 2011 CPI-inflation rate of 2.9%) yield the following final price-adjustment factors.

Final 2013 Price-Adjustment Factors for Patented Drug Products (Based on Actual CPI-Inflation Rates for 2012 and 2013)

Benchmark Year:	(1) 2010	(2) 2011	(3) 2012
Price-Adjustment Factor	1.055	1.025	1.009

The final year-over-year price increase cap for 2013 is 1.4% (= 1.5 x 0.9%).

New Lagged CPI-Adjustment Methodology Initiative – 2015 Implementation

As part of the Board´s commitment to ensure that the Guidelines respond to relevant developments in an appropriate timeframe, a change to the Consumer Price Index (CPI)-Adjustment Methodology was proposed. This change was initiated to reduce the regulatory burden on patentees and to make effective use of Board Staff resources without adversely affecting the PMPRB mandate to protect consumers.

The proposal recommended replacing the forecast CPI with the actual CPI when calculating the CPI-Adjustment Factor for the forecast period. A consultation process was launched and interested parties were invited to submit their comments on the new initiative.

Based on the feedback received from the consultation, the Board has approved implementation of the new Lagged CPI-Adjustment Methodology Initiative.

The new CPI initiative will be implemented for 2015. The Actual 2013 CPI, representing the 12-month period ending in December 2013, will be used to determine the CPI-Based

Price-Adjustment Factors for 2015. The CPI-Based Price-Adjustment Factors provided below will establish the maximum allowed price increase. CPI-Based Price-Adjustment Factors will be announced in the January issue of the *NEWSletter*.

Calculating the CPI-Adjustment Factors for 2015 Using the Actual 2013 CPI

Forecast Year: 2015

Benchmark Year:	2012	2013	2014
Base CPI*	2010 (116.47)	2011 (119.86)	2012 (121.86)
2015 CPI Adjustment Factor	Actual 2013 CPI / 2010 Base CPI	Actual 2013 CPI / 2011 Base CPI	Actual 2013 CPI / 2012 Base CPI

* Base CPI = Benchmark Year – 2
Actual 2013 CPI = 122.82
Cap = 1.5 x Actual Inflation for 2013

Since the date of implementation is 2015, there is no need for any transitional measures to be put in place. Price increases for 2013 and 2014 will be assessed using the current CPI-Adjustment Methodology. Note that the Final 2013 CPI-Based Price-Adjustment Factors based on actual inflation rates are included in this issue of the *NEWSletter*. Similarly, the January 2015 *NEWSletter* will provide the relevant actual 2014 CPI-Based Price-Adjustment Factors. As has been the practice, the 2014 CPI-Based Price-Adjustment Factors based on forecast changes in the CPI have already been announced in the April 2013 *NEWSletter*.

For a summary of the changes to the Guidelines arising from this policy decision (Part C, subsection C.12; and Schedule 9, subsections 1.2, 2.5, 2.6, 2.7, 2.9 and 2.10), please see the side-by-side comparison of current and new text now available on the website. The change will be reflected in the annual June update of the *Compendium of Policies, Guidelines and Procedure* once it comes into effect.

2015 CPI-Based Price-Adjustment Factors for Patented Drug Products

The *Patent Act* specifies the factors to be used by the PMPRB in determining whether the price of a patented drug product sold in Canada is excessive. One of these factors is the Consumer Price Index (CPI). The Board´s *Compendium of Policies, Guidelines and Procedures* requires the cumulative increase in a product´s price over any three-year period be no more than the increase in the CPI over the same period. The Compendium also sets a cap on year-over-year price increases equal to one and one-half times the CPI-inflation rate for the year in question.

The following table provides the CPI-Based Price-Adjustment factors for 2015. The factors were based on the actual rate of CPI inflation of 1.8% for 2010, 2.9% for 2011, 1.5% for 2012 and 0.9% for 2013.

Benchmark Year:	2012	2013	2014
Price-Adjustment Factor	1.055	1.025	1.009

Using the calculated 2015 CPI-Adjustment Factors, one can derive:

- Maximum allowable cumulative price increase between 2012 and 2015 of 5.5% for patented drug products with Canadian sales in 2012.
- Maximum allowable cumulative price increase between 2013 and 2015 of 2.5% for products whose first Canadian sales occurred in 2013.
- Maximum allowable cumulative price increase between 2014 and 2015 of 0.9% for products whose first Canadian sales occurred in 2014.

The final year-over-year price increase cap for 2015 is 1.4% (= 1.5 x Actual Inflation for 2013).

Note that the Final 2013 CPI-Based Price-Adjustment Factors are the same as the 2015 CPI-Based Price-Adjustment Factors. This is because the new lagged CPI-Adjustment Methodology will apply the actual 2013 CPI in calculating the CPI-Based Price-Adjustment Factors for 2015.

Patentees Reporting on R&D and Sales

Patentees are reminded that the deadline for filing Form 3 information on revenues and R&D expenditures is March 3, 2014.

Under the *Patented Medicines Regulations* (Regulations), all patentees are required to file information on revenues and R&D expenditures (Form 3).

Failure to File

If a patentee fails to file complete information by March 3, 2014, the patentee will be advised in writing that the information required to be filed under the Regulations has not been received by the PMPRB and will be given a further seven (7) days to provide the information. Should the patentee not file within the further period, Board Staff shall request that the Board issue an order pursuant to section 88 of the Act requiring that the patentee file the required information. Orders issued by the Board are reported in the PMPRB´s publications and posted on the website.

For more information on Licensees, Revenues and Expenditures, see the *Patentee's Guide to Reporting*.

Form 3 should be filed at:
compliance@pmprb-cepmb.gc.ca

Publications – Two New NPDUIS Research Studies

NPDUIS released two new analytical studies in December: *The Drivers of Prescription Drug Expenditures – A Methodological Report* and *The New Drug Pipeline Monitor – Fifth Edition*.

See the NPDUIS Research Agenda for a complete list of NPDUIS research priorities and upcoming publications.

Summary of the Board's December 4, 2013 Meeting

At its final meeting of 2013, the Board welcomed the PMPRB's new Executive Director, Doug Clark.

The Chair formally tabled the revised Guidelines for the Conduct of Board Members. As of January 2014, Board Members will submit a Declaration of Familiarization, both upon appointment and annually, indicating that they have reviewed the Chair's Guidelines, and the related legislation and codes, and understand their obligation to comply with the requirements therein.

The Board finalized the results of its September Strategic Planning Session, reviewed its priorities and discussed its upcoming policy development agenda. As well, the Board reviewed comments submitted on the October 2013 Notice and Comment on the CPI-Adjustment Methodology initiative. The Board approved a lagged CPI-Adjustment Methodology, replacing a forecast CPI methodology with actual when calculating the CPI-Adjustment Factor for the forecast period. This New Lagged CPI-Adjustment Methodology will be implemented on January 1, 2015.

Board members were briefed on several issues and given progress reports on a number of initiatives including the Guidelines Monitoring and Evaluation Plan, the Regulatory Burden Reduction initiative and NPDUIS studies.

The Board's next quarterly meeting will be scheduled in mid-March.
