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

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PMPRB NEWSletter

Anna Chodos and Béatrice Mullington Retire

We would like to thank Anna and Béatrice for their dedication during their time at the PMPRB. After 15 and 7 years, respectively, with the Regulatory Affairs and Outreach Branch, and many more in the public service, Anna and Béatrice have taken a well-deserved retirement.

We wish them all the very best in their new endeavours.

Final Requirements for HDAP Submissions

Based on our experience with the filing of electronic submissions for the May 2014 HDAP meeting, we have established the following requirements.

For patentees seeking to have a medicine considered by HDAP in the future:

- One CD or memory stick must be filed within the HDAP submission deadlines (see HDAP schedule).
- The CD or memory stick should be labelled with the name of the drug product under review.
- 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.
    - **References** – this file must be easily identifiable and must match the list of references included in the Proposal of the Patentee. See example below:

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Notice to Readers

Updates

- The format of the Are you a Patentee page on our website was updated; it now includes links to the presentations and webinars and a list of topics of interest

Upcoming Events

- NPDUIS staff are participating in the CAHSPR Conference in Toronto from May 12 to 15:

Oral Presentation
Elena Lungu and Greg McComb are introducing the *PDPEx Report,* a new annual NPDUIS publication

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 CD or memory stick should be mailed or couriered to:

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

Submissions to the HDAP should **not** be filed at compliance@pmprb-cepmb.gc.ca.

Price justifications or pricing details are **not to be included** in the submission for HDAP. HDAP does not consider this information. If such information is included in the HDAP submission, the entire submission will be returned to the patentee.

The patentee must include in its submission the name of the person it selects to be its primary point of contact in communications with Board Staff during the scientific review process, such as inquiries about documentation or acknowledgements of receipt. This will also be the person to whom the final report from HDAP will be sent.

Submissions will be accepted from other sources, including consulting companies, but subsequent communication regarding the scientific review process will only take place between Board Staff and the company contact.

If a patentee does not clearly identify a contact person in its submission, Board Staff will direct all communications regarding the scientific review process to the individual identified as the primary company contact for the price review process.

Any questions or comments regarding the above should be referred to Amber MacPherson of the Regulatory Affairs and Outreach Branch of the PMPRB.

Online Filing of Form 2 – Project Update

We have developed an online tool to increase the efficiency and ease of filing of Form 2 information. This tool will enable patentees to access a secure portal, load their Form 2 data into the verification tool, correct for any errors and then automatically submit the information to our database.

This tool will be operational for the upcoming January–June 2014 filing, due Wednesday, July 30, 2014. Patentees will be invited to attend a training session (Montreal and Toronto) in June. Invitations will be emailed to patentees the week of May 12.

Poster Presentations

Elena Lungu is presenting her analysis of Private Drug Plans
Greg McComb is presenting the most recent edition of the *New Drug Pipeline Monitor*

- Kirk Stanley, Senior Regulatory Officer, is speaking at the TELUS Health Vancouver drug conference on May 14
- Doug Clark and Tanya Potashnik are attending the Pharmaceutical Pricing and Reimbursement Information (PPRI) network meeting in Paris, France, on May 16
- The PMPRB will be attending the annual conference of the Council of Canadian Administrative Tribunals in Gatineau on June 1–3
- Doug Clark will be speaking at Norton Rose Fulbright in Montreal and Toronto on June 17 and 19, respectively

Reminders

- Product monograph and patentee submissions for the September 15, 2014, HDAP meeting are due on May 26 and June 25, respectively
- The deadline for filing Form 2 is July 30, 2014

CPI-Based Price-Adjustment Factors for 2015

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.

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 implemented. For more details about the new **Lagged CPI-Adjustment Methodology Initiative**, see the January 2014 issue of the *NEWSletter*.

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 iInflation for 2013).

The Hearing Panel Approved a VCU in the Teva Canada Innovation G.P-S.E.N.C. and the Medicine Copaxone Matter

A Voluntary Compliance Undertaking (VCU) is a written undertaking by a patentee to adjust its price to conform to the Board's Guidelines. Under the Guidelines, patentees are given an opportunity to submit a VCU when Board Staff concludes, following an investigation, that the price set forth by the patentee

for a patented drug product sold in Canada appears to have exceeded the Guidelines. A VCU can also be submitted by a patentee after a Notice of Hearing is issued as in this case.

In the 2013 redetermination of the matter of Teva Canada Innovation G.P-S.E.N.C. and the medicine Copaxone

On February 14, 2014, the Hearing Panel in the 2013 Copaxone redetermination matter accepted a VCU, concluding this hearing.

On January 31, 2014, Teva Canada Innovation G.P-S.E.N.C. and Board Staff filed a Joint Submission proposing a VCU to resolve the issues that were raised in the proceedings.

On February 13, 2014, Teva and Board Staff filed a Supplementary Joint Submission at the Board's request. The purpose of the Supplementary Joint Submission was to clarify the methodology used by the parties to appropriately balance the factors in subsection 85(1) of the *Patent Act* and to determine a payment by way of a VCU.

In its Order, the Panel underscored that the acceptance of the VCU was premised on the specific and unique facts presented in this case and that the parties accept the approach and methodology set out in the Board's February 23, 2012, decision.

The Panel further indicated that the acceptance of the VCU was not to be interpreted as a policy change in how the Board applies the Guidelines.

Under the terms of the VCU, Teva made a payment of $248,222.32 to the government of Canada. It also agreed that the national average transaction price of the Copaxone 20 mg/1.0 mL syringe would remain within the Guidelines while under the PMPRB's jurisdiction.

New Publication – NPDUIS Research Study

NPDUIS released a new analytical study in April:
Utilization of Prescription Opioids in Canada's Public Drug Plans, 2006/07 to 2012/13

This study focuses on the use of opioids by beneficiaries of selected public drug plans in Canada. It reports on trends in the number of claims, drug cost and morphine equivalence from fiscal year 2006/07 to 2012/13.

A stratification based on claimant intensity of use is included in the study for a more in depth and targeted analysis. Due to their high volume of use in treating pain, special analysis was prepared on two of the more potent opioids, oxycodone and hydromorphone.

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

Summary of the Board's April 23, 2014 Meeting

As part of the Board's strategic planning process, the Executive Director presented a comprehensive environmental scan to assist the Board in prioritizing its strategic objectives and in identifying specific area of focus within each priority.

The Board's next meeting is scheduled for May 8, 2014, to review and approve the Annual Report for 2013. The Report will be submitted to the Minister of Health on May 30, 2014 for tabling in Parliament.