Patented Medicine Prices Review Board

PMPRB NEWSletter

Volume 11, Issue No. 1
January 2007

Inside...

Board Members

The PMPRB is an independent quasi-judicial body with a dual mandate.

Regulatory - To protect consumers and contribute to Canadian health care by ensuring that prices charged by patentees for patented medicines are not excessive.

Reporting - To contribute to informed decisions and policy making, by reporting on pharmaceutical trends and on the R&D spending by pharmaceutical patentees.

Since our last issue...

Here are some of the key events that occurred since the end of October 2006.

November 2 (Edmonton), 8 (Montréal), 16 (Toronto), 28 (Halifax), 30 (Ottawa)	**Board's Consultations on its Excessive Price Guidelines**
November 15:	Paul De Civita and Ginette Tognet briefed officials of the Taiwanese Bureau of National Health Insurance on the role of the PMPRB
November 20:	The Human Drug Advisory Panel held a quarterly meeting by teleconference
November 27-28:	The Board resumed its public hearing in the matter of Janssen-Ortho Inc. and its medicine Risperdal Consta
December 4-5:	The Board held the first session in its public hearing in the matter of Janssen-Ortho Inc. and its medicine Concerta
December 13:	The Board held its last meeting of the year. A summary of the Minutes is available on page 4
January 22-23:	Dr. Benoit, Mary Catherine Lindberg, Sylvie Dupont, and Béatrice Mullington, Compliance Manager, attended the *Running a Fair Hearing* Conference, hosted by the Canadian Institute, in Ottawa
January 22:	Ron Corvari gave a lecture on the role and responsibilities of the PMPRB to the Faculty of Pharmacy, University of Alberta, in Edmonton
January 17, 18: 24 and 31:	The Board resumed its hearing into the matter of Shire BioChem Inc. and its medicine Adderall XR
February 5-7:	The Board resumed its hearing in the matter of Teva Neuroscience G.P.-S.E.N.C. and its medicine Copaxone. ■

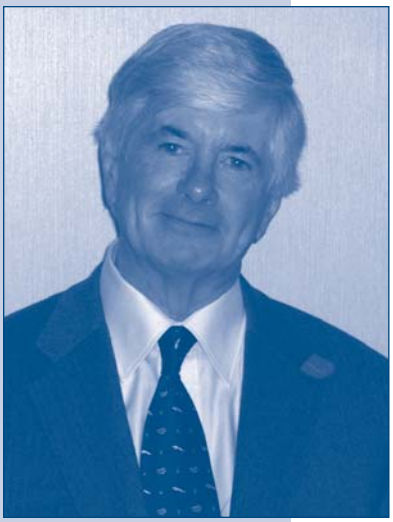
Comings and Goings

- Christine McKennirey, formerly from Health Canada, Pharmaceutical Policy Division, joined the Policy and Economic Analysis Branch.
- Aaron Baillie, formerly from Industry Canada, has joined the Compliance and Enforcement Branch.
- Candice Popkie has joined the Corporate Services Branch.
- Suzanne Paré, Policy and Economic Analysis Branch, accepted a one-year assignment with Health Canada. ■

News from the Chairperson

2006 Wrap-up

2006 was an extremely important and intensive year for the Patented Medicine Prices Review Board. The quasi-judicial activity of the Board saw a significant increase in the number of hearings, we undertook various consultations on the Board's Excessive Price Guidelines (Guidelines), and we initiated our reporting on non-patented prescription drug prices, as per the new responsibility given to the PMPRB by the Minister



Brien G. Benoit, M.D.
Chairperson of the PMPRB

Senior Staff

Executive Director:
Barbara Ouellet

Secretary of the Board:
Sylvie Dupont

Director of Policy
and Economic Analysis:
Ron Corvari

Director of Compliance
and Enforcement:
Ginette Tognet

Director of Corporate Services:
Ravinder Dhillon

Senior Counsel:
Martine Richard

of Health at the end of 2005. I was also pleased to have been appointed Chairperson and that Mary Catherine Lindberg was appointed the new Vice-Chairperson.

The PMPRB remains conscious of the evolving and fundamental role of pharmaceuticals in Canadian health care, and of its responsibility to protect consumers by ensuring that the prices of patented medicines sold in Canada are not excessive.

The Board continues to hope that the transparency of the price review process, as facilitated by the Guidelines, will encourage voluntary compliance on the part of patentees. Nevertheless, six Notices of Hearing were issued in 2006 and the proceedings are ongoing.

During the year, considerable effort was devoted to the identification of potential aspects of the Guidelines themselves that might be informed by clarification or modernization, in order to keep pace with developments occurring in the pharmaceutical sector and the health care environment in general. Consultations held in 2005 pointed out a variety of concerns among patentees, consumers, governments and others, about the introductory prices of patented medicines. The Board has acted on these concerns by issuing a Discussion Guide in May 2006, and holding five multi-stakeholder consultation sessions in November to better understand perceived problems and how these might be addressed. The Board is continuing to reflect on what it heard in 2006, and will be communicating further, in the coming months, on how it intends to proceed with the Guidelines review.

With respect to the *Patented Medicines Regulations, 1994*, the Board had identified several amendments which would enable a more efficient and timely price review process. In 2006, stakeholders commented on proposed amendments published in December 2005 in the *Canada Gazette*, Part I. All of the comments received by the Board were considered, and in some cases have resulted in further changes to the proposed amendments.

Finally, in regard to the PMPRB's reporting mandate, under the National Prescription Drug Utilization Information System (NPDUIS) a new report on Pharmaceutical Trends was released in 2006, and considerable progress was made on two new projects aimed at developing Budget Impact Assessment Guidelines and monitoring the New Drug Pipeline. In addition, in support of the F/P/T National Pharmaceuticals Strategy's interest in international price parity for non-patented medicines, in the fall of 2005 the Minister of Health directed the Board to begin reporting on non-patented prescription drug prices. In 2006, two reports were published providing an analysis of Canadian and foreign price trends and of the structure of the Canadian non-patented drug market.

The Board is committed to continuing to carry out its mandate in a manner that is fair, transparent and expeditious. I can assure all interested stakeholders that any future effort to revise the Guidelines will engage their views. The PMPRB will also work diligently to ensure that its analytical studies are objective, of high quality, and relevant both to the interests of the broader pharmaceutical environment and that they address the challenges facing Canada's health care system. ■

Brien G. Benoit, M.D.,
Chairperson

Update on Process relating to the Amendments to the *Patented Medicines Regulations, 1994*

As reported in our October NEWSletter, a revised regulatory package is in the final stages of moving forward to Treasury Board Cabinet Committee for publication in the *Canada Gazette*, Part II. When the Regulations come into force, patentees will be informed of all changes to the filing requirements. Also, updated forms will be posted on our Web site as needed to ensure appropriate implementation of the new Regulations. ■

Hearings – *Updates*

The PMPRB's regulatory mandate is to limit patentees' prices of patented medicines to ensure that they are not excessive and hence protect consumer interests. In the event that the price of a patented medicine appears to be excessive, the Board can hold a public hearing and, if it finds that the price is excessive, it may issue an Order to reduce the price and to offset the excess revenues.

There are currently six ongoing hearings. The purpose of these hearings is to determine whether, under sections 83 and 85 of the *Patent Act*, the patentees are selling or have sold the medicines in question in any market in Canada at a price that, in the Board's opinion, are or were excessive, and if so, what Order if any, should be made.

Adderall XR, Shire BioChem Inc. (Shire)

On December 18, 2006, the Board issued a decision in this matter regarding its jurisdiction during the patent period once the patent issues. Shire BioChem had made a motion to the Board on February 22, 2006, for an order that the Board amend its Notice of Hearing to limit the Board's inquiry to the period following the date of issuance of patent 2,348,090, namely, April 13, 2004. The Board dismissed Shire's motion. Shire filed an application for judicial review in this matter with the Federal Court of Canada on January 16. The Board's decision on pre-patent is available on its Web site (Regulatory; Hearings; Adderall XR; Decisions; Pre-Patent Motion – PMPRB-06-D1-ADDERALL XR).

The Board resumed its hearing in this matter on January 17, 18, 24 and 31. The next hearing date is March 2, 2007. A date for closing arguments will be determined and posted on our Web site in the next few weeks.

Airomir, 3M Canada Company (3M Canada)

The Board's hearing in the matter of 3M Canada and its medicine Airomir, scheduled to have started on October 16, 2006, was postponed. In light of the recent sale by 3M of its pharmaceutical section to Graceway Pharmaceuticals, the matter has been suspended for a few weeks to enable Graceway's legal counsel to review the matter. Hearing dates will be announced shortly and posted on our Web site.

Concerta, Janssen-Ortho Inc.

The Board held the first session of its hearing in the matter of Janssen-Ortho Inc. and its medicine Concerta December 4 and 5, 2006.

Additional sessions have been scheduled for March 21 and April 18-20, 2007.

Copaxone, Teva Neuroscience G.P.-S.E.N.C.

The Board's public hearing in this matter of Teva Neuroscience and its medicine Copaxone resumed February 5 for three days. Additional dates to complete this proceeding will be announced shortly.

Risperdal Consta, Janssen-Ortho Inc.

The Board continued hearing arguments in the matter of Janssen-Ortho Inc. and its medicine Risperdal Consta November 27-29, 2006. This hearing will resume on February 28.

Strattera, Eli Lilly Canada Inc.

A Notice of Hearing in the matter of Eli Lilly Canada Inc. and the price of Strattera was issued on December 15, 2006. A pre-hearing conference had been scheduled for February 22, 2007, and the hearing was to have commenced on April 11, 2007. However, following Eli Lilly's Motion for Adjournment of the Strattera matter pending determinations in the Adderall XR and Concerta proceedings, the Board has ruled that it will hear submissions on the Motion on February 22. A revised Schedule will be issued shortly thereafter.

Dovobet, LEO Pharma Inc.

With the release of its decision on the merits of this case on April 19, 2006, the Board requested that Board Staff and LEO Pharma draft, for the Board's consideration, an order. This proposed order was to implement the Board's findings based on the most current sales and pricing information available, thereby allowing the Board to establish a MNE price and calculate the excess revenues to be paid to the Crown. The Hearing Panel heard arguments on the proposed Board Order on December 1 and is expected to issue its order and reasons in the next few weeks.

LEO Pharma Inc. filed an application for judicial review in this matter which was heard by the Federal Court on February 12, 2007. ■

Adderall XR is a medicine indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Airomir is used for the treatment of asthma, chronic bronchitis, and other breathing disorders.

Concerta is indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

Copaxone 20 mg/1.0 mL syringe is a new formulation of an existing compound (*glatiramer acetate*) indicated for use in ambulatory patients with Relapsing-Remitting Multiple Sclerosis to reduce the frequency of relapses.

Risperdal Consta is a new formulation of an existing compound (*risperidone*) indicated for the management of the manifestations of schizophrenia and related psychotic disorders.

Strattera is for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in children 6 years of age and over, adolescents and adults.

Dovobet is a dermatological drug administered for bringing psoriasis under control.

Further information on these hearings is available on our Web site under Regulatory; Hearings. All requests for information on hearings can also be addressed to the Secretary of the Board:

Sylvie Dupont
Secretary of the Patented Medicine Prices Review Board

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Board's Direction on Scheduling of Public Hearing Dates

The Board's Direction is posted on our Web site under Regulatory; Hearings; Board Directions.

On January 31, 2007, the Board issued a Direction addressed to Board Staff and to patentees whose medicines are, or become, the subject of a public hearing pursuant to section 83 of the *Patent Act* ("parties").

The Board makes a reasonable effort to schedule its public hearings on dates that accommodate the interests of parties to the proceedings. However, certain recent and ongoing hearings have been delayed to an unacceptable degree by the failure of parties to make their witnesses available in a reasonably timely manner and to fully utilize the hearing days that the Board has set aside for its public hearings.

The Board has a public interest mandate to conduct its hearings as expeditiously as the paramount need for fairness permits. This is especially important when the hearing concerns an allegation that a medicine is being sold at excessive prices at the time of the hearing.

Parties are advised that, while the Board will continue to attempt to consult with parties when practicable regarding the scheduling of its public hearings, parties are expected to retain counsel and witnesses who can make themselves available on the hearing days that are scheduled by the Board. Parties are also required to make full use of scheduled hearing days by having witnesses ready to testify throughout those days, standing-by where required in order to avoid delays or unutilized scheduled time. ■

Patented Medicine Prices Review Board – December 13, 2006 Meeting

For additional information, please contact the Secretary of the Board at: 1 877 861-2350, or (613) 954-8299, or at sdupont@pmprb-cepmb.gc.ca.

Summary of Board Meetings are available on our Web site under About the PMPRB.

At its meeting, the Board:

- Discussed:
  - The November consultations on its Excessive Price Guidelines and possible next steps.
- Was briefed on:
  - The future PMPRB activities related to NPDUIS;
  - The ongoing process for the publication of the third quarterly report on Non-Patented Prescription Drug Prices; and
  - The results of the compliance and investigation reports.

The next Board meeting will be held March 1, 2007. ■

Patentees' Reporting on Research and Development (R&D) and Sales

Detailed information on the reporting requirements for Form 3 is set out in the Patentees' Guide to Reporting and the *Patented Medicines Regulations, 1994* (Regulations). The Patentees' Guide and Regulations are available on our Web site under Legislation, Regulations and Guidelines.

Further to the October 2006 article on *Patentees' Reporting on R&D/Sales – Licensee issues*, the purpose of this article is to provide additional guidance on patentees' requirements, under the *Patented Medicines Regulations, 1994* (Regulations), for the upcoming filing date of March 1, 2007. Please note that this clarification pertains to current filing requirements and is unrelated to any proposed amendments to the Regulations currently under consideration.

As defined in the article in this issue of the NEWSletter on "PMPRB Jurisdiction: Definition of a Patentee", the *Patent Act* defines a patentee as the person for the time being entitled to the benefit of a patent and includes both the patent holder and any other person with a license or other agreement that enables the rights under the patent to be exercised.

As a result, all patentees (patent holders, licensees or others) are required to file Form 3 information on Revenues and R&D Expenditures. Subsection 5(1)(c) of the Regulations specifies that patentees shall indicate total gross revenues from all sales (i.e., of patented and non-patented drugs) in Canada during the year by the patentee. If a patentee has a license or other agreement with a person related to the sale of medicines in Canada, it must also report total revenues received from all licensees/others, including royalties or any other revenues as prescribed by the license/other agreement.

Subsection 5(1)(d) of the Regulations requires that the patentee provide a summary of all expenditures made during the year by the patentee towards the cost of R&D relating to medicines for human or veterinary use carried out in Canada by or on behalf of the patentee. These expenditures are not limited to R&D related to patented medicines under the Board's jurisdiction.

Form 3, the template created by the PMPRB in order to help patentees file this information, has been updated to facilitate the implementation of this clarification. The updated Form 3 is now available on our Web site and may also be used to file electronically. ■

PMPRB Jurisdiction: Definition of a Patentee

A "patentee" is defined in subsection 79(1) of the *Patent Act* as follows:

> "patentee", in respect of an invention pertaining to a medicine, means the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a license continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, that other person in respect of those rights;

The above definition of "patentee" is not limited to the patent holder; and includes any person entitled to exercise any rights in relation to the patent; that is a person that has an agreement, which entitles them to exercise rights under a patent and that, pursuant to the agreement, sells the medicine to which the patent pertains, is considered a patentee for purposes of the PMPRB. The *Patented Medicines Regulations, 1994* (Regulations) establish the data reporting requirements of a patentee as well as the time frame within which a patentee is to submit its information to the PMPRB.

The table below summarizes the obligations and the time frames for submission of the information.

Form 1	Medicine Identification	The earlier of: (a) 30 days after the issuance of the first Notice of Compliance, or (b) 30 days after date of first sale in Canada
Form 2	Price & sales data for the medicine sold by province and by class of customer (Block 4) Publicly available ex-factory price for the medicine sold by province and by class of customer (Block 5) Publicly available ex-factory price sold to each class of customer in France, Germany, Italy, Sweden, Switzerland, United Kingdom and United States (Block 5)	All Form 2 information: On or before 30 days following the first 30-day period of sale Thereafter; On or before July 30 for the January 1 to June 30 reporting period) and On or before January 30 for the July 1 to December 31 reporting period
Form 3	Revenues from the sale of all medicines and expenditures on R&D	On or before March 1 of each year ■

For additional information on filing requirements, patentees are encouraged to contact the Compliance Officer assigned to their company.

Detailed information on the reporting requirements for Forms 1, 2 and 3 are set out in the *Patented Medicines Regulations, 1994* and the Patentees' Guide to Reporting, both available on our Web site under Legislation, Regulations and Guidelines.

2006 CPI-Adjustment Factors

CPI-Adjustment Factors Based on Inflation Forecasts

The 2006 CPI-adjustment factors included in Table 1 were published in the April 2005 NEWSletter. These factors are based on forecasts of annual CPI-inflation rates for 2005 and 2006. The Base-CPI is the average of the monthly CPI figures, as published by Statistics Canada, for the benchmark year.

Table 1 2006 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2003	(2) 2004	(3) 2005
Base-CPI	122.32	124.56	n/a
2006 Forecast CPI	129.47	129.47	129.47
2006 CPI-Adjustment Factor	1.058	1.039	1.020

The 2006 Forecast CPI was 129.47 (1992=100) and was based on the actual CPI figures for 2004 (124.56), as published by Statistics Canada, and the latest available inflation projections (1.9% for 2005 and 2.0% for 2006) from the federal Department of Finance.

Cap for 2006 = 3.0% (1.5 x 2.0)

CPI-Adjustment Factors Based on Actuals

As of January 2007, Statistics Canada reports annual average CPI values of 127.34 and 129.90 for 2005 and 2006, respectively. Table 2 gives revised CPI-adjustment factors incorporating these actuals.

Table 2 2006 CPI-Adjustment Factors for All Patented Drug Products (CPI 1992=100)

	Benchmark Year		
	(1) 2003	(2) 2004	(3) 2005
Base-CPI	122.32	124.56	127.34
2006 Actual CPI	129.90	129.90	129.90
2006 CPI-Adjustment Factor	1.062	1.043	1.020

The actual 2006-over-2005 CPI-inflation rate was 2.0% and equal to the forecast. This implies a 2006-over-2005 price increase cap of 3.0% (= 1.5 x 2.0%). ■

Public Consultations on the Board's Excessive Price Guidelines – Update

The Board's consultations included a series of targeted meetings that took place across Canada with key stakeholders during November 2006. Meetings were held in Edmonton, Montréal, Toronto, Halifax and Ottawa. Their purpose was to further engage stakeholders both to better understand the issues with the current Guidelines and to explore potential options for change.

In total, close to 140 people attended the sessions, drawn from patient and consumer groups; the pharmaceutical industry; government; health care; academic research; private insurance; and other interested groups.

The sessions followed a written submission process that began in May 2006. The *Discussion Guide on the Excessive Price Guidelines* asked stakeholders for their views on three issues: the categorization of new drugs; introductory price tests used to determine if a drug's price is excessive; and how the Board addresses the "any market" clause of the *Patent Act* (currently, drug prices are generally reviewed at the level of the Canadian Average Transaction Price).

In the November consultations, stakeholders worked in breakout groups to discuss drug categorization and the "any market" topic. They also deliberated on two new subjects: whether and when an introductory price of a drug should be "re-benched" (re-evaluated), and potential principles that could guide how the price factors in the *Patent Act* are operationalized into a process for carrying out price reviews.

The agenda did not include introductory price tests, as the tests are linked to the current drug categorization system, and the written submission process had revealed that stakeholder views about this system needed more exploration before price tests could be further discussed.

At least one Board member was present at each consultation, and at their December meeting, they shared their perspectives with each other on what they had heard from stakeholders. Board members also discussed several other Guideline-related topics, including introductory price tests, which were not covered in the sessions.

At their upcoming meeting, the Board will finalize and approve a work plan for the next phase of analysis in the review of the Guidelines. ■

Summary reports of the consultations will soon be available on our Web site under Consultations; Consultations on the Board's Excessive Price Guidelines.

NPDUIS – *Looking ahead*

The NPDUIS Steering Committee's biannual meeting was held in Ottawa on November 17 and 18, 2006. The PMPRB presented progress reports on projects currently underway. Following is a status update on these projects.

- *Budget Impact Analysis (BIA) Guidelines* – This project has two components. The first is a report that summarizes current practices, existing guidelines and templates for performing BIAs. The second is a spreadsheet model for conducting a BIA structured in accordance with the guidelines. The report is expected to be published early this spring.
- *Pharmaceutical Trends Overview* – Analyses of pharmaceutical trends have been updated to include recent data. DIN-level aggregate data is provided by seven provincial drug plans (Alberta, Saskatchewan, Manitoba, Ontario, New Brunswick, Nova Scotia and Prince Edward Island) and the Pharmacy Program of the Non-Insured Health Benefits, Health Canada.
- *New Drug Pipeline Monitor* (NDPM) – The NDPM is in the process of being developed. It will be available on the PMPRB Web site as a resource on new drugs expected to be launched in Canada within the next two to five years. The purpose of the report is to assist drug plans and others by identifying pharmaceuticals which are in the latter phases of research and have potential to be important therapeutically.
- *Forecasting Pharmaceutical Costs* – A methodology is being developed to forecast future (mid-term) drug expenditures. ■

For further information on NPDUIS projects, please consult our Web site under Reporting; National Prescription Drug Utilization Information System (NPDUIS); Analytical Study Series.

Monitoring and Reporting of Non-Patented Prescription Drug Prices

The first report (*Canadian and Foreign Price Trends*), released in July 2006, provided an overview of non-patented prescription drug sales and price trends, including international price comparisons and notable price changes. The second report (*Trends in Canadian Sales and Market Structure*), released in October 2006, examined annual growth rates in sales, sources of growth, market shares, sales concentration, and international price comparisons by level of concentration.

The third quarterly report will examine new leading products that have gone off-patent between the years 2000 and 2004. This analysis will cover issues such as the degree and timing of entry of generic drug products, trends in prices and market shares for the off-patent drugs – both with and without generic competition – and for generic entrants.

It was expected that this third quarterly report would be published in January 2007. However, given the complexity in establishing the basket of newly off-patent drugs, more time is needed to ensure that the methodologies including the definitions used to conduct the analysis are sound and the results validated. ■

In October 2005, the federal, provincial and territorial (FPT) Ministers of Health announced the endorsement of the PMPRB to monitor and report on the prices of non-patented prescription drugs. In November 2005, the PMPRB received direction from the federal Minister of Health, on behalf of himself and his Provincial/Territorial colleagues, to monitor and report on the prices of non-patented prescription drugs.

The latest report will be available at the end of March 2007 on our Web site under Reporting; Non-Patented Prescription Drug Prices. We invite readers to forward their comments and or questions to pmprb@pmprb-cepmb.gc.ca.

To better serve our readers,

all PMPRB publications, such as the Annual Report, the NEWSletter, the Non-Patented Prescription Drug Prices Quarterly Reports, and the NPDUIS Analytical Study Series may be obtained by mail by clicking on the appropriate boxes at the bottom of our Web site-Home Page at www.pmprb-cepmb.gc.ca. Those who do not register to receive our publications by mail will be able to access them on our Web site. ■

Questions and Comments

Please forward all subscriptions to the PMPRB e-mail or mailing lists, and requests for publications to Elaine McGillivray at **Elaine@pmprb-cepmb.gc.ca**.

For more information on our Web site, please contact our Communications Officer at **pmprb@pmprb-cepmb.gc.ca**. ■

Human Drug Advisory Panel (HDAP) Process

The HDAP meets four times a year. The meetings or conference calls for 2007 are scheduled as follows: **February 16, June 4, September 10 and December 5**.

The purpose of this article is to advise patentees on prioritization of scheduling of submissions for meetings or conference calls of the Human Drug Advisory Panel (HDAP).

The role of the HDAP is to provide recommendations for the categorization, and the selection of comparable drug products and dosage regimens for all new active substances (NAS). At the request of Board Staff, the HDAP will also provide recommendations for the categorization and selection of comparable drug products and dosage regimens for a medicine which is not a NAS. Recommendations of the HDAP are based on the criteria set out in the PMPRB's *Compendium of Guidelines, Policies and Procedures* (Compendium). The approach is evidence-based and the recommendations reflect medical and scientific knowledge and current clinical practice.

The HDAP is composed of three members who hold qualifications as a physician, pharmacist or other professional designation with recognized expertise in drug therapy and who have experience in clinical research methodology, statistical analysis and the evaluation of new drugs. The current members are Jean Gray, M.D., Mitchell Levine, M.D., and James McCormack, PhD.

The HDAP reviews and evaluates scientific information available to the PMPRB including submissions by patentees, research prepared by a Drug Information Centre, and information obtained by Board Staff. Members of the HDAP may also conduct their own research. Each member of the HDAP conducts an independent review of the drug product which will be discussed during the HDAP meetings or conference calls. The recommendations of the HDAP are based on the majority vote.

In order to provide for fairness to the patentee, assurance that a drug will in fact be scheduled for discussion at a meeting or conference call and to also expedite the process, Board Staff requires that a patentee provide a product monograph or information similar to that included in a product monograph (if the product has not yet been approved for sale in Canada) at least three months prior to an HDAP meeting or conference call.

If a patentee wishes to make a submission with respect to categorization and comparable drugs and dosage regimens, the submission must be made two months prior to an HDAP meeting or conference call. For more details on what should be included in a company submission, please refer to the Compendium, Sections 6 and 7. Board Staff will refer this submission, as well as any additional information that it has collected, to the HDAP at least one month before an HDAP meeting or conference call.

Over the past year, a large number of submissions were received on the deadline dates established for the HDAP meetings or conference calls in 2006. This situation has impacted on the ability of Board Staff to compile the full range of information for the HDAP members, including the research conducted by a Drug Information Centre, for the HDAP meeting or conference call, with the result that several reviews have had to be postponed to a subsequent meeting or conference call. To better streamline the process and to ensure transparency and fairness for all patentees, in the event that a large number of submissions are received for any one meeting or conference call of the HDAP, priority for a particular meeting or conference call will be determined as follows:

(1) drug products that are patented and sold;

(2) drug products that are patented and about to be sold;

(3) drug products for which advisory assistance has been requested

- drug product is patented but is not sold;
- drug product is not patented but is sold;
- drug product is not patented and is not sold.

Summary of remaining meetings/conference calls for 2007 and Information to be submitted

Date of HDAP Meeting/ Conference call	Information	Deadline
June 4, 2007	• 1 copy of product monograph or information similar to that included in a product monograph (if the product has not yet been approved for sale in Canada)	• March 4, 2007
	• 7 copies of company submission	• April 4, 2007
September 10, 2007	• 1 copy of product monograph or information similar to that included in a product monograph (if the product has not yet been approved for sale in Canada)	• June 10, 2007
	• 7 copies of company submission	• July 10, 2007
December 5, 2007	• 1 copy of product monograph or information similar to that included in a product monograph (if the product has not yet been approved for sale in Canada)	• September 5, 2007
	• 7 copies of company submission	• October 5, 2007 ■

List of New Drugs introduced since the publication of the October 2006 NEWSletter

Since the publication of our last NEWSletter, 35 new DINs for human use (representing 24 medicines) were added to the list of New Patented Medicines reported to the PMPRB for the period ending December 31, 2006. Fifteen of these new medicines are new active substances, representing 21 DINS.

The following table presents the new active substances reported to the PMPRB during the period October to December 2006.

As of December 31, 2006

Brand Name	Generic Name	Company
Alvesco (100 mg/dose, 200mg/dose)	*ciclesonide*	Altana Pharma Inc.
Vesicare (5mg/tab, 10mg/tab)	*solifenacin succinate*	Astellas Pharma Canada Inc.
Denavir (10mg/gm)	*penciclovir*	Barrier Therapeutics Canada Inc.
Nutrineal PD4 (11mg/ml)	*amino acids + electrolytes*	Baxter Corporation
Hepsera (10mg/tab)	*adefovir dipivoxil*	Gilead Sciences Inc.
Prezista (300mg/tab)	*darunavir ethanolate*	Janssen-Ortho Inc.
Gardasil (0.5ml/dose)	*papillomavirus recombinant vaccine*	Merck Frosst Canada Ltd.
Rotateq (2ml/dose)	*oral live rotavirus vaccine pentavalent*	Merck Frosst Canada Ltd.
Cubicin (500mg/vial)	*daptomycin*	Oryx Pharmaceuticals Inc.
Vantas (50mg/imp)	*histrelin acetate*	Paladin Labs Inc.
Trelstar (3.75mg/vial)	*triptorelin pamosate*	Paladin Labs Inc.
Trelstar LA (11.25mg/vial)	*triptorelin pamosate*	Paladin Labs Inc.
Stutent (12.5mg/tab, 25mg/tab, 50mg/tab)	*sunitinib malate*	Pfizer Canada Inc.
Arava (10mg/tab, 20mg/tab)	*leflunomide*	Sanofi-Aventis Canada Inc.
Azilect (0.5mg/tab, 1mg/tab)	*rasagiline mesylate*	Teva Neuroscience ■

Upcoming Events

Upcoming Events are available on our Web site under Consultations; Events.

February

5-7 Public Hearing: Copaxone

16 HDAP Teleconference

22 Public Hearing: Strattera – on the Eli Lilly's Motion for Adjournment

28 Public Hearing: Risperdal Consta

March

1 Board Meeting

1 R&D Filings as per *Patented Medicines Regulations*

2 Public Hearing: Adderall XR

21 Public Hearing: Concerta

21 Canadian Pharma Industry Symposium

27 Pharmaceutical and Biotech Regulatory Compliance Summit

To be scheduled in March – Publications: NPDUIS – *Budget Impact Analysis (BIA) Guidelines*; NPPDP 3rd quarterly Report

April

18-20 Public Hearing: Concerta

23-24 Canadian Agency for Drugs and Technologies in Health (CADTH) – *2007 Symposium – Informing Policy, Influence, Practice, Improving Health*

30 Release of the April NEWSletter

30 Public Hearings: Adderall XR; (to be confirmed)

May

6-8 Canadian Council of Administrative Tribunals (CCAT), Vancouver

16-17 Board Meeting

31 PMPRB 2006 Annual Report to the Minister of Health

June

4-5 HDAP Meeting, Ottawa

To be scheduled in June – Tabling of the Board's 2006 Annual Report

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