



The *Apothecary* is a newsletter of the Newfoundland & Labrador Pharmacy Board and may contain important Association regulatory information that all pharmacists in the province of Newfoundland & Labrador are expected to be aware of. All pharmacies in the province are required to keep at least two years' issues of *The Apothecary* on file as a part of the pharmacy's required reference materials.

PHARMACY BOARD ELECTION RESULTS

The election of members to the Newfoundland and Labrador Pharmacy Board was completed on April 11th. A total of 305 ballots were returned out of 588 ballots sent out, a 51.9% participation rate. The results of the balloting, which will be officially announced at the Annual General Meeting, are as follows:

Elected in Zone 1	Jason Druken of Mount Parl
Elected in Zone 2	David Jenkins of Old Perlican (elected by acclamation)
Elected in Zone 3	Roy Green of Grand Falls/Windsor
Elected in Zone 4	Joanne Howlett of Stephenville
Elected At-Large	Dr. Linda Hensman of St. John's Jerry Young of Manuels, Conception Bay South Brian Healy of St. John's

The new Board will commence its term of office at the NLPB Annual General Meeting. We offer our congratulations to the newly elected Board, and also to those other candidates who offered their names for election. The success of the Board depends on the willingness of pharmacists to offer their time and talents for the assurance to the public of the highest standards of pharmacy professional practice.

DATE OF NLPB ANNUAL GENERAL MEETING REVISED AS A RESULT OF BOARD ELECTION

In accordance with the transitional clauses of the revised Pharmacy Act, the election of the Board, which normally would have been held in August, was moved ahead to late March.

In recent years the Annual General Meeting of NPhA has been held in mid-September, and for the past two years it has been held in the first weekend of October to coincide with the PANL Annual Conference. The NPhA By-Laws, which were recently amended to make them consistent with the requirements of the revised Act, provide that the newly elected Board would assume office at the NLPB Annual General Meeting.

Following consultation with the Board's legal counsel, and with officials of the Department of Health and Community Services, the Board decided at a specially called meeting that the most reasonable solution would be to reschedule the Annual General Meeting of the Board to an earlier date. This would allow for a reasonable and orderly transfer from the old to new Board and ensure that the process was conducted in accordance with the provisions of the By-laws.

Consequently, the Board has decided that the Annual General Meeting of the Board will be held on Monday, July 4th., at a time and place to be announced.

CHANGES TO SCHEDULING OF KETAMINE BY HEALTH CANADA

The office of Controlled Substances (OCS) has indicated that Health Canada plans to remove ketamine from Schedule F of the Food and Drug Regulations (FDR) and explicitly list it in Schedule 1 to the Controlled Drugs and Substances Act (CDSA) and the schedule to the Narcotic Control Regulations (NCR).

Ketamine is an analogue of phencyclidine (PCP) and is therefore captured as Item 14 in Schedule 1 of the CDSA and Item 14 in the NCR which lists "Phencyclidine (1—(1—phenylcyclohexyl)piperidine), its salts, derivatives and analogues and salts of derivatives and analogues."

According to the OCS, all offences and penalties associated with Schedule 1 of CDS are applicable to the drug. These offences include possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production.

All practitioners, pharmacists and hospitals must comply with the Narcotic Control Regulations with respect to any products containing ketamine. Effective immediately, pharmacists must apply the security measures and record keeping requirements of the NCR to ketamine.

Please note that verbal prescriptions for ketamine are no longer permitted.

Ketamine is a non-barbiturate anaesthetic approved for use in both humans and animals. It has been listed in Schedule F of the Food and Drug Regulations since at least 1995. Ketamine has become popular as a party or club drug due to its dissociative effects; it creates the illusion of an out of body experience. It is also used as a date rape drug.

Questions concerning this notice should be directed to:

by mail: Policy and Regulatory Affairs Division
Office of Controlled Substances, Address Locator: 3403D,
123 Slater Street, Ottawa, ON K1A 1B9

by telephone: (613) 946-0124
by fax: (613) 946-4224
by e-mail: OCS_Policy_and_Regulatory_Affairs@hc-sc.gc.ca

484 WATER STREET SOLD

The property at 484 Water Street, attached to Apothecary Hall, was purchased by the NPhA in March of 2001 with the intent that the property could be renovated to provide additional office space that would permit PANL and the Board to share facilities while operating as separate entities. Subsequently, PANL decided not to pursue that model, but rather chose to move to rented space that was separate from the premises owned by NPhA.

The Pharmacy Board was faced with making a decision of what to do with the 484 Water Street property, which was in need of repairs and maintenance. The decision was made that the best solution at this time was to demolish the building, place an exterior wall on the east side of Apothecary Hall and grass over the area previously occupied by 484 Water Street. Provision was made in the NLPB budget for the cost of financing this project over a five-year period.

In December of last year the Board was approached by Mr. Paul Madden of Patrick Street Holdings with an expression of interest in purchasing that property, and subsequently an offer to purchase was made and accepted by the Board. The sale of the property was concluded on April 4th, for a purchase price of \$50,000. The sale of 484 Water Street has also permitted the Board to avoid the costs of

demolishing the building and rebuilding the east side of Apothecary Hall.

Of the proceeds from the sale of 484 Water Street, \$30,000 has been donated to the School of Pharmacy to support the continuing operation of the Drug Information Centre. This donation was in accordance with a resolution passed at the last Annual General Meeting of NPhA.

UPDATES TO THE PROVINCIAL DRUG SCHEDULES

The Minister of Health and Community Services has approved changes to the provincial Drug Schedules, based on the advice of the Pharmacy Board. The recommendations made by the Board included:

- < the addition to Schedule II of Cholera vaccine (oral, inactivated) when used for prophylaxis against Traveller's Diarrhea due to enterotoxigenic escherichia coli (ETEC). Note that other cholera vaccines remain Schedule I and would require a prescription.
- < the addition to Schedule III of nicotine when sold as an inhalation device delivering 4mg or less of nicotine per dosage unit. Note that the NAPRA Model Drug Schedules recommend that nicotine gum, patches and inhalers be unclassified and eligible for sale

at any retail outlet, however, the Newfoundland and Labrador Pharmacy Board has reviewed this recommendation and continues its recommendation that these nicotine products remain in Schedule III (OTC pharmacy sale)

- < the addition to Schedule II of levonorgestrel 0.75mg (Plan B) when packaged and labelled for emergency contraception.
- < the addition to Schedule I of a list of drugs subject to the requirements of the Tamper Resistant Prescription Drug Pad Program.

A copy of the amendments to the drug schedules is attached to this *Apothecary* and **should be placed in your Pharmacy Manuel for future reference.**

REFERRAL TO RNC BY NLPB RESULTS IN PUBLIC WARNING

In late April, while responding to e-mail messages, NLPB's Administrative Assistant, Joan O'Mara,, detected what appeared to be a scam e-mail purporting to be from the Canadian Imperial Bank of Commerce that asked the recipient to confirm their account number and identification passwords. That same morning a similar message appeared to come from the Royal Bank of Canada.

Joan reported these e-mail messages to a Royal Newfoundland Constabulary site that investigates potential Internet fraud, and was told that this was a new scam that they hadn't encountered in this province before. The RNC later issued a public warning based on this report by Joan.

Pharmacists who detect what appears to be a scam or fraudulent Internet activity can report their concerns to the Police at rarespade@nfld.net.

TAMPER RESISTANT PRESCRIPTION PAD PROGRAM TO BE IMPLEMENTED IN NEAR FUTURE!

Plans are being finalized for the implementation of the use of tamper resistant prescription pads for the prescribing of certain narcotics and controlled drugs that have a potential for abuse and misuse. This program was one of the recommendations that came out of the Report of the OxyContin Task Force.

Under the program physicians must use specific prescription pads that incorporate security features intended to foil forgeries, alterations and photocopying when they prescribe drugs that are listed as being subject to this program. These special pads, which will be personalized to bear the physician's name and contact information, are being prepared and should be circulated to physicians this summer. It is intended that a complete information package will be circulated to all physicians and pharmacists by late summer, with implementation scheduled for mid September.

Part of the background work that had to be put in place before this program could be implemented included:

- T** the addition of Schedule I of the Provincial Drug Schedules of a list of the drugs covered by the Tamper Resistant Prescription Pad Program;
- T** the addition of Section 44.1 to the *Pharmacy Regulation* which permits a pharmacist to fill a prescription for the listed drugs only if the prescription is written on the required tamper resistant prescription pad;
- T** updating of the Standards of Pharmacy Practice regarding the faxing of prescriptions to permit the faxing of prescriptions that have been written on the tamper resistant prescription pad, but required verification of such faxed prescriptions.

Copies of the amended Drug Schedules, amended Regulations and amended Standards of Pharmacy Practice Regarding Faxed Prescriptions are attached to this edition of *The Apothecary*, and **should be placed in your Pharmacy Manual for future reference.**

PHARMACY BOARD ENDORESES PANL MALPRACTICE INSURANCE

Under the revised *Pharmacy Act* all practising pharmacists are required to provide "proof that he or she has obtained professional liability insurance coverage in a form and amount satisfactory to the board". At its March 5th meeting, the Board reviewed the coverage provided by the group professional liability insurance provided to all practising members of The Pharmacists' Association of Newfoundland and Labrador, through PANL's membership in the

Canadian Pharmacists' Benefits Association. The Pharmacy Board has endorsed the professional liability insurance currently provided by PANL as meeting the requirements of the *Pharmacy Act*.

The Board has also received confirmation from CPBA that this policy also extends coverage to Pharmacy Students and Interns who are serving studentship or internship periods under the preceptorship of pharmacists who are covered by the PANL group professional liability policy.

PROVINCIAL METHADONE TREATMENT PROGRAM COMING SOON

Over the past number of months a committee formed by the Department of Health and Community Services has been laying the groundwork for a provincial policy on methadone maintenance and the establishment of a methadone treatment program in the province. This committee has included representation from the Department, the Newfoundland Medical Board, the Newfoundland and Labrador Pharmacy Board and the Addictions Services Division of Community Health.

Funding was included in the recent provincial budget for the establishment of a methadone clinic in St. John's, additional detox beds at the Humberwood Clinic in Western Newfoundland and the provision of a methadone program in other parts of the province. The program includes funding for pharmacy services associated with the methadone clinic in St. John's, which is hoped to be fully operational within the next six months.

One component of the provincial policy is the adoption by the Pharmacy Board of **Practice Guidelines for Pharmacists**

CONTINUING EDUCATION CREDITS

Since the separation of NPhA and PANL, the scheduling and circulation of notices concerning continuing education programs has been a service provided to the Membership by PANL. In addition, the study program is provided and marked by PANL. However, the responsibility for granting accreditation to CE programs, and assuring that members meet the minimum requirements of the mandatory Continuing Education Standards of Practices, remains the responsibility of the Newfoundland & Labrador Pharmacy Board. Members are reminded that you are responsible for ensuring your CE file is up to date at NLPB Offices. Records for all CE programs completed should be forwarded to Mrs. Joan O'Mara at NLPB Office by mail or fax (709-753-8615). If you have attended a "live" CE session you must sign the NLPB Attendance Sheet and the sponsor of the CE event must ensure that the ORIGINAL Attendance Sheet is returned to NLPB office for record purposes.

PHARMACY ACT **RECEIVED THIRD READING IN THE HOUSE OF ASSEMBLY ON NOVEMBER 30, 2004**

Third and final reading of the new "Pharmacy Act" took place in the House of Assembly on November 30, 2004. Upon closure of the House for the Christmas Season, the *Act* will come before the Lieutenant Government for royal assent, following which *the Act* - as amended - becomes law.

Once the Act is proclaimed, the Newfoundland Pharmaceutical Association will change its name to **The Newfoundland and Labrador Pharmacy Board**. The Newfoundland & Labrador Pharmacy Board will be responsible for all regulatory functions of the profession, including, but not limited to, public protection issues, disciplinary issues, and setting standards of practice for pharmacists and pharmacies as well as setting the standards for entry to practice, and standards for continuing competency.

In the coming weeks the necessary administrative processes will take place to officially change the name of our Association to coincide with the new *Act* and to update the various forms and applications, banking processes, Standards of Practice, etc., to reflect the new name of our organization.

Included with this edition of *The Apothecary*:

1. NPhA Practical Experience Requirements for Registration as a Pharmacist (as adopted by NPhA Council November 28, 2004)
2. NPhA Standard of Pharmacy Practice - Guidelines for the Supply of Exempted Codeine Products (as adopted by NPhA Council November 28, 2004)
3. NPhA Policy Regarding the Sale of Dimenhydrinate (as adopted by NPhA Council 28 November 2004)
4. Decision of NPhA Discipline Committee Hearing, November 27, 2004

FREQUENTLY ASKED QUESTIONS TO THE SECRETARY-REGISTRAR

The Secretary-Registrar frequently receives questions from pharmacists, and the general public, about various aspects of pharmacy regulation and pharmacy practice. Occasionally, the same question is asked by a number of pharmacists, indicating a question of general concern. The following questions/answers are reflective of some of the calls that routinely are handled by the Secretary-Registrar. If you require further information, or clarification, it can be obtained by contacting the Secretary-Registrar directly at our offices.

Q. I very frequently encounter prescriptions from a particular physician that seem to be excessive with respect to dosage or quantity prescribed. My calls to the physician about this seem to be ignored. Can I refuse to fill any prescriptions written by this physician?


A. Our advice is that no pharmacist is obligated to fill any prescription if you have professional concerns about the appropriateness of that prescription. Having said that, no pharmacist considers it their role to police the prescribing habits of physicians, that is properly the role of the Newfoundland Medical Board as the self-regulating body for physicians in this province.

A pharmacist who has concerns about a physician's prescribing, particularly repeated concerns, should bring those concerns to the Newfoundland Medical Board in the form of a complaint. If you are contemplating whether you should lodge a complaint in a particular situation, please feel free to consult with me at the NPhA office.

CONDOLENCES

Condolences are extended, on behalf of the pharmacy community to:

- Ed Galway on the loss of his wife, Mary, November 2004
- Thomas M. Kennedy on the loss of his wife, Lorraine, November 2004.
- Ralph Winsor, on the loss of his sister, Ann, February 2005
- Ellen Bouzan and family, on the loss of their husband/father, **John J. Bouzan** (former member of NPhA) on 25 February 2005.
- Liz Crosbie, on the loss of her father, James R. G. Torrville, on March 4, 2005.

Newfoundland and Labrador Pharmacy Board		
Apothecary Hall, 488 Water Street St. John's, NL A1E 1B3		
Telephone:	709-753-5877	
Toll Free:	1-877-453-5877	
Fax:	709-753-8615	
Website:	www.npha.nf.ca	
E-mail:	npha@npha.nf.ca	
Association Staff		
Don Rowe, Ph.C., Secretary Registrar		donrowe@npha.nf.ca
Veronica Harvey, Executive Assistant		vharvey@npha.nf.ca
Joan O'Mara, Administrative Assistant		jomara@npha.nf.ca
NPHA COUNCIL MEMBERS		
The following are the members of the Council of NPHA.		
Sandra Carey, Grand Falls/Windsor	President	
Karen Colbourne, Pasadena	Past President	
Jerry Young, Conception Bay South	President Elect	
Jason Druken, St. John's	Executive Member	
Michael Batt, Flower's Cove	Member	
Arlene Crane, St. John's	Member	
Susan Gillingham, Wesleyville	Member	
Tracey O'Neill, Goulds	Member	
Angie Payne, St. John's	Member	
Percy Greenslade, Manuels	Lay Member	
Donald Mifflin, Bonavista	Lay Member	
Eugene Toope, Grand Falls/Windsor	Lay Member	
Observers at Council are:		
Linda Hensman, Director - School of Pharmacy, Memorial University of Newfoundland		
Amanda Ropson, MUPS Representative		

(Start: 28 Feb 2005)

Lynn Hartery, 91-627

From: Pharmacist In Charge, Lawton's Drugs, Bay Bulls Rd., St. John's (End: 25 Feb 2005)

To: Staff Pharmacist, HSC/The General Hospital, St. John's (Start: 07 March 2005)

Leslie Aylward, 02-954

From: Staff Pharmacist, Lawton's Drugs, Bay Bulls Rd., St. John's (End: 25 Feb 2005)

To: Pharmacist In Charge, Lawton's Drugs, Bay Bulls Rd., St. John's (Start: 26 Feb 2005)

CHANGE IN BUSINESS LICENCE

Lawton's Drugs, KI-115

40 Bay Bulls Road, St. John's, NL

From: Pharmacist In Charge - Lynn Hartery (End 25 Feb 2005)

To: Pharmacist In Charge - Leslie Aylward (Start: 26 Feb 2005)

CHANGE OF LOCATION

Wal Mart Pharmacy, SJ-078

From: Avalon Mall, 48 Kenmount Road, St. John's, NL (End: 26 Jan 2005)

To: 75 Kelsey Drive, St. John's, NL (Start: 27 Jan 2005)

NEW BUSINESS LICENCES ISSUED

Wal Mart Pharmacy, LC-339

Opening Date: 27 January 2005

*Vanier Avenue, Labrador City, Labrador
Pharmacist In Charge: Christina Vairinhos-Butt (02-959)*

Wal Mart Pharmacy, MT-338

Opening Date: 27 January 2005

*McGettigan Drive, Marystown, NL
Pharmacist In Charge: Jennifer Pardy (01-917)*

CHANGES TO NLPB REGISTER

The following changes were made to the NLPB Register - as recorded from 01 January 2005 to 10 February 2005:

CHANGE OF EMPLOYMENT

Crystal Baker, 00-893

From: Staff Pharmacist, Lawton's, 10 Austin Street, St. John's (End: 04 Feb 2005)

To: Maternity Leave (Start: 05 Feb 2005)

Marjorie Gear, 03-979

From: Staff Pharmacist, Warr's Pharmacy, Happy Valley/Goose Bay, Labrador (End: 23 Feb 2005)

To: Staff Pharmacist, Health Labrador Corp., Happy Valley/Goose Bay, Labrador



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MESSAGE FROM THE BOARD CHAIRMAN

Dear Fellow Pharmacists,

With the passing of the revisions to the Pharmacy Act the Newfoundland Pharmaceutical Association became the Newfoundland and Labrador Pharmacy Board and the focus of the board has changed. The Board's mandate, as outlined in section 6 of the Act, is to:

- ▶ To establish and maintain standards of professional conduct, knowledge, education, qualification, skill and ethics among registered pharmacists;
- ▶ To assure to the general public, proficiency and competency in the practice of pharmacy,
- ▶ To regulate and govern registered pharmacists and the practice of pharmacy;
- ▶ To establish, maintain and develop standards for the operation of pharmacies;
- ▶ To administer this Act and perform duties and exercise powers that are imposed or conferred on the board, and
- ▶ To serve and protect the general interest in all matters relating to the sale of drugs and the practice of pharmacy.

It should be noted, however, that each of these objects of the Board are word for word, identical to what they were under the previous Act. These objects focus on the regulatory and public protection aspects of the practice of pharmacy and, to that extent, nothing has changed except our name and Board structure.

But, the previous Act also included two additional objects that were interpreted as dealing with the interests of pharmacists and the profession, and these are no longer included in the objects of the Board. Instead, the Board has a more narrowly defined mandate and our role is now more a "public protection" function rather than a pharmacist's function. Most of our board meetings thus far have dealt with the transition to our more focused mandate, to insuring that we are upholding the new Act, and putting processes and procedures in place to comply with the new Act.

We have many issues, today and in the future, that require pharmacists to be diligent and professional, and I feel assured that all pharmacists are meeting their obligations and professional responsibilities as the Board fulfills its mandate of public protection.

Jerry Young, Chair
Newfoundland & Labrador Pharmacy Board

JACK HOGAN RETIREMENT

The Newfoundland and Labrador Pharmacy Board would like to express our sincere thanks and appreciation to Mr. John Hogan on his retirement from the position of Assistant Registrar; Jack has given outstanding and dedicated service to the Board since he started in this position in February of 1996. He has traveled the province conducting regular site visits where he monitored the compliance of pharmacies with the applicable Acts, Regulations, Policies and Guidelines. On these visits he also acted as a liaison between the Board and pharmacists, informing them of policies and pertinent issues and receiving feedback for the Board. He also conducted investigations of complaints filed with the Secretary-Registrar.

Even before he assumed the office of Assistant Registrar Jack demonstrated exemplary service to the NPhA, including terms as member of numerous Committees, Council Member, Secretary-Registrar, and President. He has been the recipient of virtually every award the association offered, including the J. Frank Janes Meritorious Service Award, the E.C. MacDonald Memorial Medal, the Past President's Award, the Bowl of Hygeia, and Honorary Life Membership. He also has served on the Council of Delegates and the Board of CPhA.

John Hogan always displayed tact, discretion and sensitivity when fulfilling his duties in any aspect of his involvement in our association, at the same time bearing in mind that public safety and protection is the number one responsibility of the Board. We wish Mr. Hogan and his family all the best in his retirement and thank him for his outstanding example of professional leadership.

APPOINTMENT OF DEPUTY REGISTRAR

At its last meeting, the Board gave final approval of the appointment of Arlene Crane as Deputy Registrar. The newly created position of Deputy Registrar is a part-time contractual position and the duties of the position will include

- Carrying out the duties of the Secretary-Registrar in his/her absence;
- Development and implementation of procedures to ensure compliance with Standards of Service, Standards of Operation and Standards of Pharmacy Practice including pharmacy site visits and audits;
- Acting as the liaison between the Board and licensed pharmacists, informing them of Board policies and issues and receiving direct pharmacist feedback;
- Conducting of investigations arising from formal and informal complaints, attempting to resolve complaints before forwarding to the Complaints Authorization Committee, conducting further investigation and preparation before reporting to the Discipline Committee;
- Coordination of the Board's Continuing Education Requirements including liaison with the Pharmacists' Association of Newfoundland and Labrador and other CE providers as needed;
- Coordination of the development and implementation of the Board's Continuing Competency Assessment Program in conjunction with the development of a national model program under the auspices of the National Association of Pharmacy Regulatory Authorities;
- Coordination of Board's Practice Experience requirements

at entry to practice, including assessment of student training and provision of preceptor support services;

- Other duties as assigned by the Secretary-Registrar from time to time.

The creation of this position reflects the added emphasis that the Board will place on dealing with complaints in a timelier manner, an increased emphasis on standards based professional practice issues and the renewal of continuing education/continuing professional development requirements for pharmacists.

Arlene is well known to pharmacists in the province and has been actively involved with the former NPhA for quite a number of years. She is a past member of the Discipline Committee, a past Council member and is a past President of the NPhA. Arlene also served for 5 years as the NPhA representative on the Board of the National Association of Pharmacy Regulatory Authorities (NAPRA), including service on the Executive Committee of NAPRA. She is a winner of the J. Frank Janes Meritorious Service Award and the E.C. MacDonald Memorial Medal in recognition of her service to the profession and to the NPhA.

Arlene's exceptional service and experience will be a very valuable asset to the Board as she assumes the Position of Deputy Registrar and we welcome as a part of the Pharmacy Board staff. Arlene may be reached at the Board offices, or by e-mail at acrane@npha.nf.ca.

RE-APPOINTMENTS TO THE BOARD

The Minister of Health and Community Services has re-appointed **Donald Mifflin** of Bonavista and **Eugene Toope** of Grand Falls-Windsor to three year terms as General Public Members of the Board. Both Mr. Mifflin and Mr. Toope have served previously as lay-appointees to the NPhA Council/NLPB Board and have shown outstanding dedication to their duties as Board members. We congratulate them on their re-appointment and look forward to their continued active participation on the Board.

NEW APPOINTMENTS TO THE DISCIPLINE COMMITTEE

While past NPhA Councils have voluntarily appointed lay representation to the Discipline Committee, the recent changes to the *Pharmacy Act* (which are becoming standard for all self regulating professions in the province) include the provision for the appointment to the Discipline Committee of non-pharmacists by the Minister, to represent the public interest.

The Minister of Health and Community Services has recently appointed **Cathy Ann Cormier** of Corner Brook, **Nicholas F. Hurley** of Conception Bay South, and **Nellie Osmond** of Pasadena to three year terms as members of the Discipline Committee. We are happy to welcome these new members to the Discipline Committee, but would be happier still if we have no occurrences which will result in it being necessary to make use of their services in a discipline tribunal setting.

BOARD EXECUTIVE COMMITTEE ELECTED

At the first meeting of the Board the Executive Committee was elected. Members of the Executive Committee for the coming year are **Jerry Young**, elected as Board Chair, **Dr. Linda Hensman**, elected as Vice-Chair, **Jason Druken**, elected as Executive Member. **Sandra Carey**, the Immediate Past President, will participate in the Executive Committee, and at the Board meetings, in an ex-officio, non-voting, capacity.

BOARD COMMITTEE APPOINTMENTS

As a part of the transitional process from the NPhA to the NLPB, the Board has reviewed the Terms of Reference of each of the various Board Committees and also made appointments to those committees. In every case there were revisions made to the Terms of Reference that ranged from relatively minor standardization of documentation, to fairly significant clarification of the roles of the committee. The revised Terms of Reference of the committees can be found on our website www.npha.nf.ca or may be obtained from our office upon request. The normal term of appointments to committees has been standardized at three years.

Appointees to the various committees are as follows:

Complaints Authorization Committee

Current Board Members
Don Mifflin, Chair
Jason Druken, Vice-Chair

Disciplinary Panel

Bernd Staeben, Chair
Colleen Abbott-Hibbs
Mike Batt
Janice Chalker
Barry Downey
Walter Fleming
Jeff Fost
Denise O'Brien
Ron Pomeroy
Wanda Spurrell
Steve Gillingham

Alternates:

Connie Burt
Cyril Daley
Bill Simmons
Brad Payne

Finance Committee

Linda Hensman, Chair
Sandra Carey
Roy Green
Margot Priddle
Eugene Toope

Legislative Committee

Jerry Young, Chair
Derrick Hierlihy, Vice Chair

Carson Collins
David Galway
Brian Healy

Legislative Committee (continued)

Keith Hogan
Seumas Gibbons
Susan Gillingham
Trent White

Joint Committee on Structured Practice Experience

Andrea Handrigan
Darlene Mansfield
Randy McFadyen

Registration and Licensing Committee (formerly the Education Committee/Board of Examiners)

Don Hillier, Chair
Darren Bursey
Jason Druken
Kimberly Duggan
Lynn Hartery
Dr. Debbie Kelly
Mike LeBlanc
Derek Long
Kraig Manuel
Gerald Peckham
Dr. Leslie Phillips
Jason Ryan
Barbara Scaplen
Heather Seeley
Barbara Thomas

Professional Practice Committee

Sandra Carey, Chair
 Keith Bailey
 Connie Burt
 Carson Collins
 John Downton
 Jason Druken
 Steve Gillingham
 Susan Gillingham
 Derrick Hierlihy
 Joanne Howlett
 Perry Humphries
 Norman Lace
 Tracey O'Neill
 Geraldine Osmond
 Margot Priddle
 Patrick Ryan
 Patricia Spurrell
 Christina Tulk
 Ken Walsh
 Terry Walsh

It should be noted that, while the membership of the Professional Practice Committee is large, it is intended that Sub-committees will be established to deal with specific issues and subjects. The former ad hoc Narcotic Utilization Committee will now be a Sub-committee of the Professional Practice Committee.

THANK YOU FOR PAST SERVICE TO THE NPHA AND NLPB

With the election of a new Board, the recent ministerial appointments to the Board and the Discipline Committee, and the appointment of members of the various Board Committees, a number of persons have completed service to our Board and Committees. The Board wishes to extend its sincere thank you to all those persons who have served our profession by agreeing to become members of the Board or Board committees. The involvement of pharmacists and public representatives in the on-going affairs of the Board is crucial to its success, and is genuinely appreciated.

Particular thanks are extended to **Percy Greenslade** for his service as a Ministerial public representative appointee to the Board; to **Patricia Grainger, Fred Hollingshurst, and Axel Sorensen** for their service as public interest members of the Discipline Committee; and to **Karen Colbourne, Arlene Crane, Mike Batt, Susan Gillingham, Tracey O'Neill, and Angie Payne** for their service as members of the Council/Board.

BOARD POSITION ON LOYALTY POINTS AWARDS

At the October 3rd meeting of the Board the policy on the awarding of loyalty points, or other similar inducements, on the purchase of prescriptions, which has been in place since September 1998, was discussed and reviewed. This review was made in view of the facts that the current policy has not been reviewed in the 7 years that it has been in place, that the Board has received questions from the public concerning the rationale for that policy and, the Board has been formally asked to review the policy by a pharmacy stakeholder.

While most of the other provinces currently permit the awarding of loyalty points or other inducements on the purchase of prescriptions, there have been suggestions that in a number of cases the basis on which such awards are given are not in the best interests of the public, or may denigrate the professional character of pharmacy. A review of the policy with respect to loyalty programs is also being, or has been recently conducted in some of the other provinces (notably Manitoba, Saskatchewan and Alberta).

The current policy arose from a resolution passed at the Annual General Meeting of the members in 1998, which interpreted an existing definition of professional misconduct in the Pharmaceutical Association Regulations. That resolution stated, "The use of promotional enticements related to the sale of prescription medication be considered professional misconduct under the meaning of Sections 37(1)(v) and 37(1)(z) of the Pharmaceutical Association Regulations; and that any pharmacist found engaging in such improper activity shall be subject to disciplinary action."

After discussion and consideration of this issue, the Board decided that there would be no change in the existing policy.

LOCK AND LEAVE STANDARDS COME INTO EFFECT JANUARY 1, 2006

Standards of Pharmacy Practice regarding Lock and Leave were approved by the Board in October of 2004 and came into effect on January 1st past with respect to new pharmacies or pharmacies that changed their location. Pharmacists-in-charge are reminded that these Standards of Practice will come into effect for all pharmacies on January 1, 2006. A copy of the Standard is included with this edition of the Apothecary.

The important points to remember about these Standards are:

- ▶ During any extended period when the pharmacist is not physically present in the pharmacy, the dispensary must be locked and not accessible to the public or non-pharmacist staff.

- ▶ It is NOT required under the Standards that front store products that can only be sold in a pharmacy (Schedule III drugs) be also locked up when the pharmacist is not in the pharmacy.
- ▶ Prescriptions that have been prepared, and are awaiting pick up by the patient, may be released to the patient or their agent while the pharmacist is not present. However, release of prescriptions when the pharmacist is not present must be done in accordance with the Standards of Pharmacy Practice for Delivery of Prescriptions and the pharmacist remains responsible for ensuring that the patient received the necessary counselling concerning those prescriptions.
- ▶ Pharmacies that intend to operate on a lock and leave basis at any time that they are open to the public must apply to the Board for permission to do, and must post on public display the hours when the pharmacist is scheduled to be present in the pharmacy. The form to apply for Lock and Leave approval will be included in the annual business licence renewal package that will be sent to all pharmacies in the near future.

CONTINUING PROFESSIONAL DEVELOPMENT

At the last meeting of the Pharmacy Board the Board of Examiners/Education Committee was renamed as the Registration and Licensing Committee to avoid confusion that might arise from the use of the name "Board" on a committee of the NLPB. One of the roles of this Committee is to make recommendations to the Pharmacy Board with respect to the requirements under the regulations for mandatory continuing pharmacy education.

At the last meeting of the committee a number of recommendations were made to the Board regarding Continuing Professional Development. It was recommended that the NLPB office discontinue the current process of recording CE records for individual pharmacists, effective January 1, 2006. At that time pharmacists will be required to maintain their own "Continuing Professional Development Learning Portfolio". An initial draft of the requirements for a learning portfolio package, which was modeled after programs already in place in other Atlantic provinces, was also presented to the Board for consideration.

The Board approved the recommendation of the committee that, effective January 1, 2006, the Board will no longer record the CEU records of pharmacists, but rather pharmacists will maintain their own records. The Board also approved in principle the draft requirements of the package presented by the committee, bearing in mind that the package requires further development and consultation with pharmacists.

This learning portfolio package is being further developed to integrate the comments and suggestions of Board and committee members and will be sent to all pharmacists for their feedback. Zone meetings will also be held in the New Year to clarify the process and answer questions. You will receive this package within the next month so please read it carefully and provide NLPB with your feedback and comments.

COMPLAINTS AND DISCIPLINE REPORT TO BOARD

At the last meeting of the Pharmacy Board a report was received from the Discipline Committee regarding two cases that have been completed recently by the Committee. In each of these cases the decision of the Committee included direction that each of these cases also be reported to all members in this edition of The Apothecary, since they involved significant medication errors. The panel also recommended that information about the prevention of medication errors, and the appropriate way to respond to errors should they occur, be circulated to all pharmacists in the province to make all pharmacists better informed about medication error issues. It is the hope that all members can learn from these unfortunate incidents and take all steps possible to avoid the occurrence of similar incidents in the future.

This edition of The Apothecary includes a package of educational information that deals with the factors that may lead to medication errors, and steps that can be taken to eliminate those errors as much as possible.

Pharmacists are urged to review this educational material in detail and implement those error reduction strategies suggested that are not already in place in their pharmacy.

The two complaint cases reported to the Board are as follows:

1. A complaint was received regarding a dispensing error related to a prescription for Diclectin. The original prescription had been entered incorrectly into the computer as Dicletel, and while the pharmacist realized the mistake and corrected the label, the transaction was not reversed and the error remained in the computer record of the prescription. The medication error occurred when the prescription was refilled based on the computer record of the prescription and the patient received Dicletel 100mg instead of Diclectin.

The decision of the screening panel of the Discipline Committee was that:

- a) The panel directed that a formal prescription checking protocol be initiated at the pharmacy that includes documentation on the original prescription; and that the pharmacist personally sign or initial each and every prescription filled or refilled as verification that the prescription was checked and dispensed accurately.
 - b) The computer system in this pharmacy at the time the prescription in question was originally filled appears to permit the generation of a corrected label without correcting the underlying incorrect transaction record. The panel advised that the pharmacy's computer system be updated so that such errors cannot occur in the future and that they notify the Secretary-Registrar when this upgrading had occurred.
 - c) If there is the slightest suggestion that there may be a dispensing error, it is incumbent upon the pharmacist to immediately investigate the situation to ensure that an error has not taken place. Such an immediate investigation would include referral to the original prescription to ensure that there is not an error in the computer entry of the prescription information.
 - d) The panel advised that the memory of the particulars of any incident can fade quickly and strongly recommends that a formal incident documentation process be implemented for internal purposes at the pharmacy.
 - e) Given the number of incidents reported across Canada involving the dispensing of Dicletel instead of Diclectin, the panel endorses the advise of Motherisk and the OCP that "Pharmacists are urged to take special care when dispensing prescriptions for either of these medications. It would be prudent to clarify the patient's diagnosis, either with the patient or the patient's physician, if there is any doubt as to the identity of the prescribed drug."
2. A complaint was received from the family of a gentleman who had been dispensed Novolin GE Toronto instead of Novolin GE 30/70 insulin on a refilled prescription. In the pharmacist's response to the letter of complaint there was an admission that the wrong insulin had been dispensed.

This letter of response, and the investigation, revealed that the prescription checking process in place at the pharmacy included a comparison of the DIN # on the prescription label to the DIN # on the drug package. These were checked by both the technician and the pharmacist involved with the refill but, due to the closeness of the last three numbers in the DIN's (the DIN # for Novolin GE Toronto 0204284 and the DIN # for Novolin GE 30/70 02025248) both persons had made the same mistake and the wrong insulin was dispensed. Subsequent to this incident having taken place a computer system upgrade has taken place where scanners are being used to compare and verify the UPC bar codes on the prescription label and the drug packaging. Other dispensing procedures have also been implemented in this pharmacy to reduce the likelihood of similar errors occurring in the future.

The decision of the screening panel was there were reasonable grounds to believe the respondent had engaged in conduct deserving of sanction. The panel directed that, by way of sanction, the Secretary-Registrar send a letter of counsel and caution concerning the adequacy of the pharmacist's actions with respect to this particular prescription refill. This letter will be placed in the pharmacist's file at the Pharmacy Board office and a copy be sent to the Pharmacist –in-Charge.

The panel also directed that a report of this incident be given, on a no-name basis, in the next edition of The Apothecary so that all pharmacists are made aware of the potential for such errors and the necessity of vigilance in adequately checking prescriptions before they are released to the patient. The panel further directed that the Secretary-Registrar meet with the family of the patient, since deceased, to make them aware of the basis on which the decision of the findings were made.

3. A letter of complaint was received alleging that the complainant had been treated unprofessionally at a pharmacy by a number of different pharmacists.

The decision of the screening panel was there were not reasonable grounds to believe the respondent had engaged in conduct deserving of sanction. The panel dismissed the allegation. The complainant has since filled a complaint with the Human Rights Commission.

ANOTHER COMPLAINT ISSUE RESOLVED

The NLPB office received a written complaint from a physician in central Newfoundland regarding the dispensing of Lovenox syringes. The physician alleged that, while his prescriptions for this drug are usually written for 14 syringes to be dispensed, on a number of occasions the pharmacy actually dispensed 2 boxes of 10 syringes.

The investigation of this allegation revealed that the incidents involve the issue that, while the manufacturer's monograph indicate that the usual duration of treatment is 7 to 14 days, the manufacturer only supplies the pre-filled syringes in boxes of 10 syringes and does not normally accept the return of unused part packages from pharmacies.

We are hoping this problem has been rectified through discussions with the manufacturer and their local representative; however, should anyone have a problem with part boxes of this product, please contact the Sanofi-Aventis representative.

CRYSTAL METH ADVISORY

The illegal street drug Crystal Meth has become a growing problem in Canada and local police have reported to our offices that this drug is now showing up in our province. Your pharmacy can play an important role in protecting the public.

The Nature of the Drug Crystal meth, or methamphetamine, is also known by the street names ice, crystal, chalk, and speed. The drug is illegal, potentially fatal and highly addictive. Crystal meth poses significant health risk to users, while both the use and production of this drug also impacts on public safety and the environment.

The drug can be made relatively cheaply with a key ingredient, pseudoephedrine, available in most cold medications sold over-the-counter in pharmacies, groceries and variety stores. Many of the additional ingredients required for producing crystal meth are readily available at pharmacies and retail stores.

According to Health Canada, methamphetamine can produce a powerful psychological dependence. Its use is associated with episodes of violent behaviour, paranoia, anxiety, confusion, and insomnia. Long-term use has also been associated with psychotic behaviour including paranoia, auditory hallucinations, mood disturbances, and delusions.

The paranoia may result in homicidal or suicidal thoughts. Psychotic symptoms may persist for months after the drug is discontinued. Methamphetamine can also cause a variety of medical complications including weight loss and cardiovascular problems. The risk of short-term or possible neurological damage is also a concern.

Methamphetamine is now reportedly being used by diverse groups of people and it appeals to people who wish to stay awake for extended periods of time and maintain their performance ability, for example, long-distance drivers and students.

Directions on how to make crystal meth are readily available on the Internet and this has led to a significant increase in "home labs" and individuals attempting to produce the drug. The chemicals used in production are highly flammable, combustible, toxic and present significant safety risks to both people and the environment.

Monitor to Prevent Diversion

While pseudoephedrine, and ephedrine (in limited package sizes), may be sold from the self-selection (i.e. front-store) of your pharmacy, your pharmacy should monitor the sales and determine if there are unusual sales or theft patterns with pseudoephedrine or ephedrine products so that you can take appropriate action to fulfill your responsibility in preventing diversion and ensure ongoing safe drug distribution.

It is the advice of the Pharmacy Board that if unusual sales of pseudoephedrine or ephedrine are seen in your pharmacy the product should be moved behind the counter so that you can exercise greater control over these sales.

Government Actions

Health Canada has amended The Controlled Drugs and Substances Act, increasing the penalties for possession, trafficking, and production of crystal meth. In 2003 Health Canada placed restrictions on wholesalers, manufacturers, and distributors in an effort to divert large quantities of pseudoephedrine from reaching the illicit market. Under these regulations of "precursor substances" package sizes that contain more than 20g of ephedra, 0.4g of ephedrine, or 3g of pseudoephedrine may not be sold at any one time unless an "End Use Declaration" is completed.

As a result, makers of crystal meth, including individual users, are now turning to the ingredients found in products with smaller quantities available from sources such as pharmacies. The Pharmacy Board is consulting with both the federal and provincial governments on this issue and will provide pharmacies with information as initiatives develop.

Following are certain practices that your pharmacy can adopt to help identify or curb this problem:

- Voluntarily join and support the Meth Watch Program at www.methwatch.ca. This program was originally designed in the U.S. (where crystal meth abuse is more rampant) to reduce methamphetamine production without disrupting the availability of legal products. Free information is available at www.methwatch.ca including educational resources for all pharmacy staff. Information on the Meth Watch Program was also published in the March/April 2005 issue.
- Visit Health Canada for information on crystal meth at its website www.drugwise.gc.ca.
- Get familiar with the precursor legislation by reviewing the article in the July/August 2003 issue of the Apothecary.

- Ensure all of your pharmacy's staff are aware of signs of abnormal purchases or purchase patterns for pseudoephedrine and other materials required for making crystal meth including rubbing alcohol, batteries, and acetone. Tips to identify these behaviours are available on the Meth Watch website.
- Consider whether you need to move products containing pseudoephedrine-only (single entity) behind-the-counter so that you can control sales of unusually high quantities whenever problems occur.
- Consider whether you need to move all pseudoephedrine products in your front store to a shelf closer to the dispensary counter so that these products remain highly visible for staff to observe.
- Consider increasing staff awareness and the use of anti-theft measures such as tags, as pseudoephedrine is also a target for potential shoplifting.
- Consider limiting the number of pseudoephedrine products that can be sold at one time, and post signage to this effect where cold medication is located to deter purchases for illicit use.
- Ensure your pharmacists and front store staff are aware of groups of people who enter the pharmacy together to buy a large quantity of pseudoephedrine products.
- Review your pharmacy's sales to identify unusual increases in pseudoephedrine purchases, or check sales against inventory to determine if your pharmacy is experiencing theft of these products.
- Advise local police if any unusual sales patterns of pseudoephedrine or other crystal meth ingredients occur at your pharmacy.

FREQUENTLY ASKED QUESTIONS TO THE SECRETARY-REGISTRAR

MELATONIN

Q: Vivitas Melatonin 3mg has been issued an NPN number 8000737 by Health Canada and is featured in our upcoming flyer. Is this product okay to sell in our province now? I thought there was some direction from the board not to sell Melatonin a while back. Please advise, as I don't want to contravene any provincial regulations.

A: Our advice to pharmacists was that they not sell natural products that had not received Health Canada approval. Melatonin was particularly singled out in our advice to pharmacists since Health Canada had made a point a few years back of specifically notifying pharmacists that melatonin was not approved for sale in Canada.

If Health Canada has now issued an NPN number to the Vivitas brand of melatonin this would indicate that this product has now been approved for sale in Canada. I would expect that the approval process also requires that this NPN number appear on the product packaging.

I would also note, as you may already know, that NPN numbers are similar to DIN numbers in that the number applies to a specific manufacturer's product and that different brands of the product require individual approval by Health Canada, with different NPN numbers being assigned.

By the way, neither Health Canada, nor the manufacturer, has not notified pharmacy regulatory bodies of such approvals having been given. This makes it difficult to give clear and consistent advice to members on such issues.

I've also heard, from other pharmacies, that manufacturers of natural products have on occasion (and melatonin is such an occasion) have dealt with non-pharmacist front store buyers to place their products in pharmacies (based presumably on the proposition that natural products are legally not considered "drugs"). It would be very helpful if, internally, pharmacist buyers and non-pharmacist buyers could co-ordinate such issues internally, to avoid potential problems such as the one you recognized and sought advice on.

SEPARATE NARCOTIC FILES

Q: It is often difficult to locate original Schedule F prescriptions because they are filed on the narcotic file since the original document also included a narcotic. Is it still required to keep narcotic and controlled drug prescriptions on a separate file from the Schedule F prescriptions, or can we now file all prescriptions together according to the transaction number?

A: Section 40(1) of the Narcotic Control Regulations states that, "A pharmacist shall maintain a special narcotic prescription file in which shall be filed in sequence as to date and number all written orders for narcotics dispensed..." Section G.03.009 of the controlled drugs Part of the Food and Drug Regulations has parallel wording to this with respect to controlled drugs.

There has been no change to these regulations, so pharmacists are still required to keep prescriptions for narcotic and controlled drugs on a special file separate from other prescriptions.

Should it be a significant issue in your pharmacy to find Schedule F prescriptions that may be filed in the narcotic files, there would be no problem with placing a copy of the prescription on your regular files, as long as the original was kept on the narcotic and controlled drugs prescription file as required by the regulations. This, however, might create considerable extra work for you.

FAXED PRESCRIPTIONS

Q: We received a faxed prescription for a narcotic from a physician for one of our regular patients. The prescription was faxed on the required TRPP blank and our pharmacy was indicated as the pharmacy to which it was being faxed. We filled the prescription so that it would be ready when the patient arrived. That night the patient passed in a prescription to be filled by the pharmacist who had just come on duty at suppertime. In attempting to fill this prescription the pharmacist discovered that this was the original copy of the prescription that had been faxed to the pharmacy by the physician earlier that day. Isn't this a flaw in the system that could have resulted in the prescription being filled twice?

A: This incident probably arose from a common mis-understanding of the Standards of Practice regarding faxed prescriptions. Some physicians, and pharmacists as well, mistakenly think that the original copy of the prescription (especially if it's for a narcotic) must be received by the pharmacist before the prescription can be released to the patient. This is not required by the Standards of Practice, or the TRPP program.

What is required by the Standards of Practice and the TRPP program is that the physician either retain the original copy on file, or invalidate it so that it cannot be re-issued. It is also required that faxed prescriptions for drugs subject to the TRPP program be specifically verified with the prescriber's office or transmission site by the pharmacist.

If the prescription has been faxed in accordance with the Standards of Practice, it can be considered equivalent to a written prescription and the pharmacist does not require the original copy.

It has also been reported to our office that in some cases the prescriber has indicated the name of the pharmacy on a TRPP prescription, even though it is not being faxed, and then the patient has taken the prescription to a pharmacy other than the one indicated on the prescription. Except for the very few cases where a patient has agreed to be restricted to a single pharmacy, it is the patient's choice to take their prescriptions to whichever pharmacy they choose. However, if a prescription indicates that it is for another pharmacy, it would be very prudent for the pharmacist to confirm with the other pharmacy that the prescription has not already been faxed to that other pharmacy by the prescriber (similar to the incident above).

REPORTING OF CHANGES IN EMPLOYMENT

Q: I recently received a call from the Board office informing me that I was responsible for letting the office know that another pharmacist at our pharmacy had changed employment and moved to another pharmacy. I didn't know that I was supposed to give such notices. Isn't it the responsibility of the pharmacist in question to make sure you get notice of their changing jobs?

A: You were contacted by our office since you are the pharmacist-in-charge of the pharmacy in which you practice. The responsibilities of the pharmacist-in-charge are covered in the regulations as follows:

PART III - STANDARDS

Responsibilities of the pharmacist-in-charge

12. (1) All pharmacists who are designated and named on a business license as the pharmacist-in-charge of that pharmacy

- (a) are accountable to the council, through its designate the secretary-Registrar, for all professional activities occurring within that pharmacist and*
- b) shall be responsible for*
 - i. personally managing, controlling, or supervising a pharmacy,*
 - ii. prohibiting an owner or other person who is not a pharmacist from directing, influencing, controlling or participating in the management or operation of a pharmacy for which the pharmacist-in-charge is responsible under the Act and these regulations,*
 - iii. establishing policies and procedures for pharmacy personnel in accordance with pharmacy law and pharmacy practice,*
 - iv. advising the secretary-Registrar, upon request, of the identity of a person who contravenes established policies and procedures,*
 - v. notifying the secretary-Registrar in writing of the names of pharmacists employed by that pharmacy and when a pharmacist ceases employment with that pharmacy,*
 - vi. ensuring correct usage of the operating name of the pharmacy, which may differ from the corporation name, with regard to prescription labels, telephone directory listings, interior and exterior signs or media advertising,*
 - vii. ensuring compliance with all applicable licensing requirements under sections 6 and 7 of these regulations devoting the majority of his or her working time and attention to the operation of the pharmacy in respect of which the pharmacist-in-charge is responsible under the Act and these regulations,*

- viii. attending in the prescription department for a reasonable portion of the operating hours of the pharmacy, but this does not mean that the prescription department may not be open for business when the pharmacist-in-charge is not in attendance or on vacation, provided another licensed pharmacist is present,*
- ix. ensuring that information relating to the dispensing of monitored drugs is transmitted to the lawful monitoring body, and*
- x. generally ensuring that the pharmacy for which he or she is responsible complies with the Act and these regulations.*

12. (2) A contravention of paragraph (1)(b) shall be considered professional misconduct.

In addition to this requirement that the pharmacist-in-charge notify our office of any changes at their pharmacy, it is also the responsibility of the individual pharmacist to notify us of any change of practice site (that will be for more than 30 days). It is also important to note that if the pharmacist who is moving happens to be the current pharmacist-in-charge, this would also involve a change in business licence (since the business licence lists the pharmacist-in-charge) and notice of this must also be given to our offices.

Another issue that we frequently run into is that many members don't realize that if they leave practice for parental leave, or return to practice from parental leave, our office should receive a change of employment notice.

The required change of employment or change of business licence forms that we use can be downloaded from our website at <http://www.npha.nf.ca/forms.htm>, or are available upon request from our office.

If we don't receive a change of employment notice it could result in the pharmacist being unable to sign for narcotics or controlled drugs at the new site, or mail from our offices would continue to go to the old site and, last but not least (from the Board's point of view), our registers would not be accurate and up to date.

TRAMACET

Q. "Tramacet" a narcotic? We have a pamphlet from a representative that says it has "opiate" activity, but the package has "Pr" on the label. I gather from the package that it is schedule F and not a narcotic, but I couldn't find any information in my CPS or at the Health Canada website. Do you have any information about this product? Is this a drug that must be written on the Tamper Resistant Prescription Pad?

A: Tramacet has recently received a Notice of Compliance from Health Canada and is now being marketed by Janssen-Ortho. Tramacet contains: tramadol 37.5mg (an opiate agonist) and acetaminophen 325mg. The product monograph can be found at http://www.janssen-ortho.com/JOI/pdf_files/tramacet_E.pdf

The product monograph includes the information that, "Tramadol has a potential to cause psychic and physical dependence of the morphine-type (μ -opioid). The drug has been associated with craving, drug-seeking behaviour and tolerance development. Cases of abuse and dependence on tramadol have been reported. TRAMACET tablets should not be used in opioid-dependent patients. Tramadol can re-initiate physical dependence in patients who have been previously dependent or chronically using other opioids. In patients with a tendency to abuse drugs or a history of drug dependence, and in patients who are chronically using opioids, treatment with TRAMACET is not recommended."

Nevertheless, Health Canada has designated Tramacet as Schedule F status. The product monograph indicates that a "Risk Management" strategy to support the safe and effective use of Tramacet under Schedule F has been established, which would include the provision of progress reports from the ongoing drug abuse surveillance program and a reassessment of the success of the risk management strategy 2 years after product launch.

Tramacet is not one of the products covered by the TRPP program at this time since the program was intended to cover only narcotic and controlled drugs that might be subject to abuse. However, the advisory committee may be asked to consider this product for inclusion. In the meantime pharmacists should be aware of the opioid-like character of tramadol, counsel patients appropriately and be watchful for indications of possible inappropriate use or abuse.

EMERGENCY CONTRACEPTION TRAINING (ECP)

Pharmacists are reminded of the policy adopted by the Board with respect to mandatory training in ECP for pharmacist in this province. That policy states:

" All Pharmacists authorizing emergency contraceptive treatment must have completed educational training, either through a CCCEP approved program or through their university training."

Most community pharmacists in the province have already completed ECP training but the Board is urging those pharmacists who have not completed the training, but who will be dispensing ECP, to complete the required training program at the earliest possible opportunity.

The CPhA training program as well as sample forms to use in counselling are available on-line at CPhA website www.pharmacist.ca.

It is also important to become familiar with resources in your community where you can refer your patients for further care or counselling if needed (e.g. STD counselling, birth control, sexual assault). You should ensure a place in the pharmacy for assessment and counselling of patients, and where you can speak to patients in a private and confidential manner.

STATUS OF KETAMINE AMENDED UNDER THE CONTROLLED DRUGS AND SUBSTANCES ACT (CDSA)

Ketamine is a non-barbiturate anaesthetic approved for use in both humans and animals. It has become popular as a party or club drug due to its dissociative effects; it creates the illusion of an out of body experience. It has also been used as a date rape drug.

The Office of Controlled Substances has given notice that Health Canada has now moved ketamine from Schedule F of the Food and Drug Regulations and has now listed it in Schedule 1 to the CDSA and the schedule to the Narcotic Control Regulations. The effect of this change in the scheduling of ketamine is that all offences and penalties associated with Schedule 1 of CDSA are now applicable to ketamine. These offences include possession, trafficking, possession for the purpose of trafficking, importation, exportation, possession for the purpose of exportation, and production.

All practitioners, pharmacists and hospitals must comply with the Narcotic Control Regulations with respect to any products containing ketamine. Pharmacists must apply the security measures and record-keeping requirements of the Narcotic Control Regulations to ketamine. Please note that verbal prescriptions for ketamine are no longer permitted.

FLAVORX AND COMPOUNDING

Our office has received correspondence from the Non-prescription Drug Manufacturers Association of Canada (NDSAC) regarding Canadian pharmacists using a U.S. product called FlavoRx to change the taste of oral liquid medications.

Manufacturers have a concern that the addition of other, even non-medicinal ingredients could impact the integrity of their pharmaceutical products. The letter notes, "Pharmaceutical products are carefully formulated and manufactured to a very strict set of regulations necessary to ensure the product's purity, efficacy, safety and Good Manufacturing Practices compliance. While it is common for pharmacists to compound a variety of products, once the product has been altered manufacturers are not able to ensure appropriate product performance and integrity".

Pharmacists are cautioned on the following points:

1. Once a product is altered, the pharmacist bears responsibility for the product and should have specific stability data demonstrating that the addition of the flavours will not impact the product's expiry date, or they should assign a new date based on the data.
2. Unlike many prescription drug products that are generally used for a short period of time, self-care products may be used more intermittently and thus over a long period of time. The patient should be advised of a change in the expiry date from that on the package.
3. The pharmacist is responsible to ensure the altered product, be it prescription or non-prescription, continues to meet purity, efficacy and stability standards, as well as ensure there are no allergy issues.
4. There should be indication on the package/label that the product has been altered subsequent to production by the manufacturer.
5. Products to which additional flavours or other ingredients have been added must be properly identified as a compound on the prescription label. It is not acceptable to continue to identify the new compound using the DIN of the manufacturer's product.

CONGRATULATIONS

Congratulations are extended to the following members on behalf of the pharmacy community:

1. Keith Bailey on being awarded the Wal-Mart 2005 "Pharmacist Of The Year Award, Maritime Region"
2. Sandra Carey, recipient of Memorial University's "2005 Preceptor of the Year Award"
3. Karen and Sean Colbourne on the birth of their second daughter - Emily - on 28 September 2005
4. Bertram Warr, Sr. - 2005 Bowl of Hygeia Award
5. Connie Mercer, 2005 James C. Quick Award
6. William Simmons - 2005 Honorary Life Membership Award
7. Brenda Burse - 2005 Meritorious Service Award

TRPP UPDATE

The Tamper Resistant Prescription Pad (TRPP) program has been in effect now since July 1st and, while there were a number of initial difficulties associated with the implementation of the program, the calls being received at our offices and the problems being reported have by and large disappeared. The committee that advised the Department of Health and Community Services on the implementation of the program has met on a couple of occasions to review the program and the experiences encountered during its implementation and will continue to meet on a regular basis to consider any new issues that arise and to advise on the maintenance that is necessary from time to time on any such program.

The schedule of drugs covered by the program is one item that needs occasional review and updating. Already a number of amendments to this schedule have been discussed and recommendation to the minister to update to the schedule has been made. These requested updates include:

- a) correction of the typographical error that occurred in the original schedule that matched the product Phenobarbital to the generic name "pentobarbital". (It was intended that Phenobarbital be one of the drugs that must be written on the TRPP pad.)
- b) the addition of diphenoxylate (Lomotil) to the TRPP schedule of drugs (an unintentional omission from the original schedule).
- c) the addition of Adderall XR to the TRPP schedule of drugs, now that it has been re-introduced to the Canadian market.
- d) the addition of ketamine to the TRPP schedule of drugs now that it has been brought under the Controlled Drugs and Substances Act.

Not all drugs regulated under the Narcotic Regulations, or the Controlled Drugs and Substances regulations are subject to the TRPP program, only those specifically listed in the schedule of drugs. (For example, prescriptions for testosterone are not required to be written on the TRPP pad.)

At coming meetings the committee will also be considering the definition of "quantity of drug to be dispensed" and how that must be indicated on the prescription. Also be discussed will be the status of some of the just entering, or about to enter the market such as Stativex, tramadol, buprenorphine.

WEBSITE AND E-MAIL SYSTEM UNDERGOING UPDATING

The Board's website, www.npha.nf.ca, is currently being reviewed and updated to give it a fresh look, and also to ensure that all information is current, up to date and presented in as user-friendly a format as possible. The updating will include new website and e-mail addresses that will reflect our changed name.

It is also our intent to add a search function to the website to assist visitors in finding the information they are seeking. If you have suggestions for improvements or additions that can be made to our website to make it more useful to you, we would appreciate receiving them.

At the same time that we are updating of website, we are also looking at how we can communicate more efficiently with pharmacists, through the use of e-mail rather than hard copy. Progress on this initiative will depend on the extent to which all registered pharmacists have e-mail addresses that they utilize on a regular basis, and to which they have access from their practice site. Our experience has been that many pharmacists either do not have e-mail addresses that they use on a daily basis; have e-mail access at work that has security fire-walls that prevent attachments from being received; have e-mail access at home, but not at work; or have changed e-mail addresses but not notified us of that change. While the use of e-mail as the preferred method of communications has increased dramatically in the past few years, and it is essential that the Board be able to provide that mode of communication, it is still not possible to use e-mail and the Internet as the only means of communications at this point.

It is important, however, that we have a complete and up to date address book of pharmacist and pharmacy e-mail addresses. Our annual licence renewal forms this year will include a request for your current e-mail address. Please provide us with this important information, and notify us of any changes as they occur.

WHOLESALE AND ESTABLISHMENT LICENSES

The May/June 2004 edition of The Apothecary included advice from Health Canada, which had been circulated to all pharmacies, concerning the requirement for an Establishment Licence before a pharmacy could be involved in the wholesaling of drugs. This advisory from Health Canada arose from a number of inspections of Internet pharmacies that had been conducted by Health Canada inspectors, which revealed that a number of pharmacies have been involved with supplying drugs to other pharmacies, a practice that constitutes wholesaling under the federal legislation.

We have recently received letters from the Inspectorate Manager of the Atlantic Region of Health Canada that repeats this earlier advice, but also indicates that a similar Establishment License is required by pharmacies that sell "medical devices" on a wholesale basis. The letter notes, "Pharmacies are only exempt from establishment licensing if they sell solely to the ultimate consumer. An establishment licence is required for a pharmacy to sell to other pharmacies, healthcare facilities such as clinics and nursing homes, or healthcare professionals such as physicians, nurses and home care providers." While we think of "medical devices" as including items such as blood glucometers/test strips, lancets and syringes, it is important to note that, "Many other devices are generally available for sale within the pharmacy area such a condoms, pregnancy test kits, bandage and dressing type products, first aid kits/supplies, toothbrushes, medical examination gloves, blood pressure monitors, thermometers, saline for contact lens and home diagnostic kits."

Copies of the letters we have received from Health Canada are included with this edition of the Apothecary. It is important that you read these letters and if necessary refer to the Health Canada contacts indicated if you require further information.

PHYSICIANS' SUGGESTIONS FOR IMPROVED PATIENT CARE

A few months back we received a letter from a physician describing a practice issue and suggesting a way in which collaboration between pharmacists and physicians can be improved, and thus patient care also improved. This suggestion is a very useful one and worthy of being shared with all pharmacists.

The physician reported that it had come to his attention that two of the patients he had been treating were not getting all of the prescriptions that had been prescribed filled (in one case for over 3 years). When the physician called the pharmacist to try to determine why the prescriptions had not been filled, he found that the prescriptions had been logged into the pharmacy computer, but not filled, and there was no documentation as to why they had not been filled.

The physician suggested that if prescriptions are not filled as written, the pharmacist should record on the patient's record a note explaining if possible why the prescription had not been filled, including the date and time, and if it was the physician changing the prescription, or the patient who declined to have the prescription filled.

It is entirely appropriate that the dispensing pharmacist should document a reason for any difference between the prescription as written and the prescription as dispensed. The pharmacist should also discuss with the patient the appropriateness of their decision not to follow the physician's treatment plan, and to advise the patient that they should make the physician aware if they are not taking the drugs prescribed (since follow-up and review of the patient's condition assumes that the medication prescribed is being taken).

"Susie" the Semi-anonymous Pharmacist

A phone call received at our offices from a local specialist, concerned appropriate identification by the pharmacist when they contact a physician about a prescription. In the

situation he described, he was paged to receive a telephone call while on the ward of one of the St. John's hospitals.

When he answered the phone he was told, "This is the pharmacist speaking, I would like to talk to you about a prescription that you've written for Jane Doe."

The physician, being reluctant to discuss patient information without knowing exactly whom he was speaking to, asked, "Who exactly are you? Who am I speaking with?"

When the pharmacist replied, "This is Susie, at Pharmacy X.", the physician replied, "Susie who? At which Pharmacy X, there are 10 Pharmacy X's in Newfoundland?" To which the pharmacist replied, "My, that's an unusual request!"

Without belabouring the point, it is clear that there was a lack of appropriate identification by the pharmacist in this situation. It is always reasonable, not to mention polite, for someone contacting a person who does not know them to fully identify themselves and who they are. This is all the more important in a professional setting where personal information about a patient is about to be discussed. Who they are talking to and what relationship they have to the patient, or the issue being discussed, should be explicitly clear, to each of the participants in a conversation such as this one.

Consultation between pharmacists and physicians or other health care professionals is vital to the interests of the patient, but this must be done in a context of respect, trust and courtesy. We would encourage pharmacists, and indeed all pharmacy staff, to clearly and fully identify themselves and their position when conversing with other health care professionals or patients.

2006 RENEWALS

Member pharmacists are advised that your individual application for Renewals for 2006, and Business Licence Renewals will be forwarded to you in the coming weeks. Please remember that your completed application, together with the applicable fee, must be received at NLPB **ON OR BEFORE JANUARY 1, 2006**

CONTINUING EDUCATION CREDITS

Members are reminded that the granting of accreditation to CE programs and the assurance that members meet the minimum requirements of the mandatory CE Standards of Practice remains the responsibility of NLPB. Members are reminded that to ensure that your CE file is kept up to date **YOU** are responsible for sending records of CE programs completed directly to Joan O'Mara at the NLPB Office. Also members who attend live CE sessions must individually sign the NLPB CE Attendance Sheet and the sponsor of the CE event must ensure that the original of the Attendance Sheet is forwarded to Joan O'Mara at NLPB Offices for recording purposes.

CONDOLENCES

Condolences are expressed, on behalf of the pharmacy community, to

- * David Cook on the death of his mother - Mary Leamon Angel Cook- July 2005
- * Deborah Mercer, on the death of her husband - James Wheaton, August 2005

ATTACHMENTS TO THIS ISSUE OF THE APOTHECARY

1. Newfoundland & Labrador Pharmacy Board - Standards of Pharmacy Practice "Lock and Leave for Community Pharmacies" (Approval date: October 2005)
2. Correspondence from Health Canada, dated 18 July 2005, "Wholesaling & Establishment Licences"
3. Dispensing Accuracy - Some simple suggestions" (The Apothecary, Volume 20, Issue 2 extract)
4. Canadian Adverse Reaction Newsletter: Volume 15, Issue (July 2005) and Volume 15, Issue 4 (October 2005)
5. Memo to Pharmacies/Pharmacists - Prescribing Privileges for Optometrists, dated November 8/2005

Newfoundland & Labrador Pharmacy Board

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Linda Hensman, Vice Chair
Jason Druken, Executive Member
Linda Hensman, Executive Member
Joanne Howlett, Member
Brian Healy, Member
Roy Green, Member
Dave Jenkins, Member



The *Apothecary* is a newsletter of the Newfoundland & Labrador Pharmacy Board and may contain important Association regulatory information that all pharmacists in the province of Newfoundland & Labrador are expected to be aware of. All pharmacies in the province are required to keep at least two years' issues of *The Apothecary* on file as a part of the pharmacy's required reference materials.

REMINDER OF LICENCE RENEWAL AND CONTINUING EDUCATION DEADLINE

Pharmacists are reminded that the deadline for the return of applications for renewal of the annual pharmacist and pharmacy business licences is December 31st. Properly completed and signed renewal forms, and the required fees must be received at our offices by that deadline.

All Pharmacists-in-Charge are responsible for ensuring that their pharmacy's annual Business Licence is renewed by January 1, and that all pharmacists (including part-time and relief pharmacists) who practice in their pharmacy have renewed their annual licence to practice by January 1.

Renewal applications that are not at our offices when we open for business after the New Year's holiday on Wednesday, January 3rd will be subject to a reinstatement fee of \$50.00 for a pharmacist, or \$100.00 for a pharmacy.

Pharmacists are also reminded that they are not eligible for re-licensure until they have submitted documentation to our offices that they have obtained a minimum of 15 CEU credits in the past calendar year.

CONTINUING PROFESSIONAL DEVELOPMENT BOOKLET CIRCULATED FOR FEEDBACK AND COMMENTS

As was indicated in the last edition of the *Apothecary*, the Board has adopted the recommendations of the Registration and Licensing Committee and, beginning January 1, 2006, our office will no longer keep records of the continuing education credits obtained by each pharmacist licensed in the province. Instead we will be moving towards the system used in other provinces where pharmacists are expected to maintain their own "Learning Portfolio" in which they will document their continuing professional development.

The committee has been studying the continuing professional development programs used in other provinces and is working on finalizing a proposed program to be recommended for adoption by our Board. A draft of this document, which spells out the program and how it would operate, is attached to this *Apothecary* for your feedback and comments before a final version is submitted to the next Board meeting, scheduled for February 5th.

It is hoped that we can collaborate with the other Atlantic provinces in developing a common approach to continuing professional development. This proposal also represents a first step by our Board to ensure that our province does not fall behind in the movement towards a national consensus on how pharmacy regulatory bodies ensure the continuing competency of pharmacists.

Under the proposed program, which will also include a revision and updating of our Standards of Pharmacy Practice respecting Continuing Pharmacy Education, pharmacists' continuing professional development will be self-directed (as it is now) and also self-documented. Pharmacists will annually submit a log (called a "Professional Development Record") of their professional development activities for the year that includes a signed certification that they have completed the 15 CEU's required for re-licensure.

On a random basis, selected pharmacists will have their learning portfolios audited to verify the specific documentation of the activities listed on the Professional Development Record. Pharmacists who do not complete the required continuing professional development, or who fail to maintain an acceptable learning portfolio may be subject to disciplinary action for failure to maintain Standards of Practice, and may be subject to suspension of licence or ineligibility for re-licensure (as they are now).

Please take the time to read this important draft document and give us your feedback and questions. A series of zone meetings will be scheduled for the new year once the proposal is finalized and approved by the Board, so that pharmacists can discuss the specifics of the program, ask questions, and learn how to maintain a learning portfolio.

PEBC REPRESENTATION

For the past 7 years our province has been represented on the Board of the Pharmacy Examining Board of Canada by Scott Way. His service to this national body has included a term as President of PEBC in 2004. Scott's term of appointment comes to an end in February of 2006 and our Board will be nominating a replacement representative to the PEBC, to take office at that time.

Our Board invites pharmacists who have an interest in serving on the Board of PEBC to make our office aware of their interest in being appointed. Appointees to the Board of PEBC serve for a term of three years, which may be renewed once. The PEBC Act of Incorporation requires that appointees to their Board must have PEBC registration.

If you wish to know more about what is involved with becoming a PEBC Board member, you may contact Scott at 722-0149 for further information. Please let us know at your earliest convenience of your interest in serving on PEBC.

NEW WEBSITE AND E-MAIL ADDRESSES FOR NLPB

In recent weeks we have been working to update and re-vitalize our website and e-mail capabilities. One of the changes that is being implemented as this Newsletter is being prepared is a change in the address of our website and the e-mail contacts for our office and staff.

Our website can now be found at www.nlpb.ca and new e-mail addresses for Board staff are as follows:

Secretary-Registrar	Don Rowe	drowe@nlpb.ca
Deputy Registrar	Arlene Crane	acrane@nlpb.ca
Executive Assistant	Veronica Harvey	vharvey@nlpb.ca
Administrative Assistant	Joan O'Mara	jomara@nlpb.ca
General Enquiries		info@nlpb.ca
Website Administrator	Melanie Healey	website@nlpb.ca

Please make the appropriate changes in your computer address books and website bookmarks. In the meantime, the old website and e-mail addresses will remain functional for an appropriate transitional period.

The revised website now includes our registers of licensed pharmacists and licensed pharmacies in the province. Why not check out this register to ensure that information about you or your pharmacy is correct. We would also ask pharmacists to give us feedback on the revised website and any suggestions they can give to make it more useful and user-friendly.

SCHOOL OF PHARMACY REQUEST TO COMMUNITY PHARMACISTS

As part of the School of Pharmacy "Pharmacy Practice II" course, each first-year pharmacy student is required to spend at least four hours visiting a community pharmacy. While some students in this group have previous exposure to pharmacy practice, many have never been inside a dispensary before! The purpose of this assignment is to provide the students with an opportunity to observe a pharmacist's activities during a typical workday and to get a sense of his/her many roles and responsibilities. The students have been provided with a list of topics for discussion to serve as a guide for the visitation.

Therefore, during December and January, should you be approached by a pharmacy student asking permission to visit with you, we ask your cooperation in allowing him/her to do so at a mutually agreeable time. Thank you!

Wanda Spurrell, B.Sc. Pharm
Instructor, Professional Practice
Coordinator, Studentship Program - MUN

AMENDMENTS TO THE *PHARMACY ACT* PASSED IN THE HOUSE OF ASSEMBLY

On November 28th, Bill 59 was passed in the House of Assembly that made changes to Part IV of the Act, dealing with the procedures for dealing with disciplinary issues. These changes were made to harmonize the provisions of our Act with the standardized disciplinary procedures that government wishes to apply to all self-regulating professional bodies.

The changes made will:

- clarify who the complaints authorization committee and an adjudication tribunal may summons to give evidence,
- allow a certified copy of a record of a conviction to be considered as evidence in a hearing,
- extend the application of subsection 39 (4), (5) and (6) (which deal with the requirements to provide records during and investigation) to the Crown,
- allow copies of books and other documents to be considered as evidence in disciplinary proceedings,
- expand the measures available to an adjudication tribunal when a respondent pleads guilty,
- make the respondent responsible for the costs to the Board of ensuring compliance with an order of a disciplinary tribunal.

A copy of the Bill has been posted to our website, as has been an updated version of the *Pharmacy Act* that incorporates these changes. A hard copy of the Bill or the updated Act is available upon request from our offices.

TOBACCO CONTROL ACT CHANGES NOW APPLY TO PHARMACIES

In 2000 the House of Assembly approved changes to the *Tobacco Control Act*, which included the prohibition of the sale of tobacco in pharmacies. However, after lobbying by the NPhA, the government agreed that this particular section of the Act would not come into effect until a later date, to be determined by the cabinet. This delay in implementation was to allow the gradually increasing restrictions on the sale of tobacco in pharmacies provided for in our Standards of Pharmacy Practice to run their course.

Since our Standards of Pharmacy Practice regarding the sale of tobacco are now fully in place, government has now proclaimed the previously delayed section of the *Tobacco Control Act* to come into effect January 1, 2006.

This means that, as of January 1, 2006, the sale of tobacco by any pharmacy in this province will be prohibited both by our Standards of Pharmacy Practice, and by the *Tobacco Control Act*.

The newly proclaimed section of the *Tobacco Control Act* reads as follows:

Pharmacy

4.1 (1) *A person shall not sell, or offer for sale, tobacco in a pharmacy.*

(2) *For the purpose of subsection (1), "pharmacy" means a pharmacy as defined in paragraph 2(n) of the Pharmaceutical Association Act, 1994, and includes*

(a) *a kiosk that permits direct access to a pharmacist, whether in person or by telephone or another means, and from which prescription drugs or other medicines are sold or dispensed; and*

(b) *a retail store if*

(i) *a pharmacy is located within the store, or*

(ii) *customers of the pharmacy can pass into the store directly or by use of a corridor or area used exclusively to connect the pharmacy with the store, or*

(iii) *a kiosk described in paragraph (a) is located within the store.*

Q AND A'S ON LOCK AND LEAVE

- 1) **Q:** What is the necessity for "Lock and Leave"?
- A:** The *Pharmacy Act* and *Regulations* require that only a pharmacist can operate a pharmacy and that the pharmacy must be under the direct supervision of a licensed pharmacist whenever it is open for business. For many pharmacies there may be times when the front store is open but the dispensary, the professional services area of the pharmacy, is not "open for business". These Lock and Leave Standards are intended to give guidance to pharmacists as to when it is acceptable for the non-professional, "front store" part of the pharmacy to be open for business when a licensed pharmacist is not present. This is particularly relevant for regularly scheduled periods when a pharmacist is not present and available in the pharmacy.
- 2) **Q:** The Standards of Practice circulated refers to the "professional services area". What does that mean?
- A:** The Standards of Practice reads: " 'Professional Services Area' means the area of a licensed pharmacy, which includes the dispensary, active prescription records and all shelves, displays or fixtures bearing Schedule I or II drugs." Schedule I drugs are all drugs that require a prescription for sale, and Schedule II drugs are those that can be sold with out a prescription but must be kept in the dispensary. The "professional services area" essentially means the dispensary, but it would also include stock rooms or any area outside the dispensary where Schedule I and II drugs are stored, or where active prescription records are kept.
- 3) **Q:** Do I have to lock the storage area as well when the pharmacist is not present?
- A:** If the storage area contains Schedule I or II drugs or active prescription files then this area must also be locked when the pharmacist is not in the pharmacy.
- 4) **Q:** Our pharmacy is an "open concept" design. Do I have to put a gate around the entire dispensary area?
- A:** The Standards specify: *"The Lock and Leave physical enclosure which separates the Professional Services Area from the remainder of the premises must be:*
- (a) *A wall composed of transparent, semi-transparent or opaque materials, or any combination thereof, at least five feet high with adequate doors to permit complete security during periods of closure, and to permit full access by the public to the Professional Services Area when professional services are available; or*
 - (b) *A sliding or folding wall in accordance with the height and material specifications in (a) above, which will completely surround and secure the Professional Services Area during the period of closure, and*
 - (c) *A lockable entrance to the Lock and Leave enclosure, which prevents access by the public, or non-professional staff, when a pharmacist is not in attendance."*
- For an open concept "professional services area" there would appear to be no way of preventing access from the remainder of the premises without putting a gate around the entire dispensary area.
- 5) **Q:** Do I have to lock up my Schedule III drugs?
- A:** It is NOT required under the Standards that Schedule III drugs (front store products that can only be sold in a pharmacy) be locked up when the pharmacist is not present.
- 6) **Q:** How long is an "extended period when the pharmacist is not physically present in the pharmacy"? How long can I leave without having to lock the dispensary?
- A:** The Lock and Leave Standards state that: *" The times of operation of the Lock and Leave, and the times when professional services are available, shall be regular and consistent during the times when the remainder of the premises is open to the public."* This would indicate that if there are specific times every day or week when the pharmacist is not scheduled to be present, then the "professional services area" would have to be closed to the rest of the pharmacy premises. There is no exact amount of time

during which it would be acceptable for the professional services area to be open when the pharmacist is not present.

- 7) **Q:** Do I have to lock the dispensary when I go to supper?
- A:** If the pharmacist is unavailable, even if they are on the pharmacy premises, then the "professional services area" would have to be closed to the rest of the pharmacy.
- 8) **Q:** Can I leave a technician in the dispensary while the pharmacist is not there?
- A:** No. There are currently no regulations that permit the delegation of a pharmacist's duties to a non-pharmacist. Pharmacy technicians can only be present in a dispensary as an assistant to a pharmacist who is directly supervising them.
- 9) **Q:** Can technicians get refills ready for the pharmacist to check when the pharmacist is not present?
- A:** Since technicians are not permitted in the dispensary when the pharmacist is not present, they are not able to prepare refills, or new prescriptions either, when the pharmacist is not present to supervise them.
- 10) **Q:** Can Schedule II drugs be sold when the pharmacist is not present?
- A:** No. The regulations regarding drug schedules "require professional intervention from the pharmacist at the point of sale" of Schedule II drugs. Schedule II drugs (e.g. OTC codeine products, Baby Aspirin, Polysporin Eye/Ear drops) are available only from the pharmacist and cannot be sold when the pharmacist is not present in the pharmacy.
- 11) **Q:** Can prescriptions that are ready for pick-up be given to patients when the pharmacist is not present?
- A:** On this issue the Standards read: *"When a Lock and Leave installation is closed, prescriptions, which have been previously dispensed in accordance with the provisions of the Act and Regulations, may be stored for pick-up or delivery in a secured area outside the Lock and Leave. Such prescriptions must have attached appropriate information to the patient concerning the availability of the pharmacist for specific counselling regarding those prescriptions. The pick-up of prescriptions by patients, or the patient's agent, when a Lock and Leave installation is closed must be done in accordance with the Standards of Pharmacy Practice for Delivery of Prescriptions."*
- It is important to note that ideally the patient will receive the prescription directly from the pharmacist, because that is the point at which the important last check of the prescription is made, and the point at which the patient is counseled on the proper use of the medication. When the patient chooses a method of delivery other than directly from the pharmacist, it does not relieve the pharmacist of the duty to properly counsel the patient. If previously prepared prescriptions are delivered to the patient in the absence of the pharmacist, the pharmacist has a responsibility to ensure that the patient is properly counseled about those prescriptions.
- 12) **Q:** Can prescriptions be dropped off at the dispensary when the pharmacist is not there?
- A:** Yes, this is acceptable. However, appropriate procedures must be in place to ensure that the prescription is kept in a secure place and the patient's private information is protected. The person accepting the prescription should also ensure that contact information for the patient is obtained, so the pharmacist will be able to contact them if necessary.
- 13) **Q:** Do I have to fill out the Lock and Leave Application if a pharmacist is always present in the pharmacy?
- A:** If a pharmacist is always available when the pharmacy is open, there is no need to complete the Application for Approval of Lock and Leave form. An application form is available from the Board's offices, or from the website www.njpb.ca should you later decide to apply for Lock and Leave approval.
- 14) **Q:** I have to indicate the hours that a pharmacist will be present on the Application for Lock and Leave. Can I change those hours later?

- A:** Yes. However, the Board's offices should be informed of any changes to the hours when the pharmacist is available in the dispensary by completing a revised application form.
- 15) Q:** Where can I get the required gates?
- A:** Firstly, gates are not necessarily required in every pharmacy. Many options may be open to you depending on the layout of your particular pharmacy. If gates are the option that is best for you and you're trying to find out where you can get them, you might start by checking the yellow pages of the telephone directory. Many glass dealers and locksmiths offer security gates in addition to other products and services. While the Board does not endorse any particular dealer, other pharmacists have informed us that such products may be available from Babb Security Systems, Thomas Economy Glass, Speedy Auto Glass, Lawrence Glass, Power Tire and Glass, and Penmar. You may wish to check on the availability of security gates or barriers from similar businesses in your local area.

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Jason Druken, Executive Member

Linda Hensman, Executive Member

Joanne Howlett, Member

Brian Healy, Member

Roy Green, Member

Dave Jenkins, Member

Donald Miffiin, Lay Member

Eugene Toope, Lay Member

Sandra Carey, Ex-Officio

ATTACHMENTS TO THIS ISSUE OF THE APOTHECARY

1. Continuing Professional Development Booklet
2. Updated list of Optometrists authorized to prescribe
3. Health Canada letter, dated November 29, 2005 re [amiloride](#) and [amilazide](#)
4. Canadian Coordinating Office for Health Technology Assessment (COMPUS) Article: *Community Building: Optimal Drug Prescribing and Use*



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UPCOMING ELECTION OF BOARD MEMBERS

Under the revised *Pharmacy Act* Board members are now elected on a rotating basis so that there will be continuity. Each year the term of office for some of the members will come up for renewal and elections will be held to fill those positions for a further three year term.

This year the term of office of Board members representing Zone 1 (Jason Druken) and Zone 4 (Joanne Howlett) are up for renewal and calls for nominations for election of Board representatives will soon be sent to pharmacists registered as practising in those respective geographic zones.

It is important that pharmacists take an interest in the Board and get involved in the election process.

CHANGES TO DRUG SCHEDULES APPROVED BY MINISTER

Board recommended changes to the provincial Drug Schedules were approved by the Minister of Health and Community Services on January 26, 2006. The changes approved include:

Desloratidine (Aerius)

desloratidine, in products marketed for adult use (12 years and older) have been moved to Unscheduled status. Note that products marketed for pediatric use (under 12 years of age) remain as Schedule III

Pramoxine

pramoxine, in products for topical application to the skin, and including lozenges, have been moved to Unscheduled status

Alpha 1 – Proteinase Inhibitor (human)

alpha 1 – Proteinase inhibitor (human), marketed in Canada as Prolastin®, has been added to Schedule I

Pseudoephedrine to come into effect April 10, 2006

pseudoephedrine (in single entity products) will be moved to Schedule II status, and pseudoephedrine (in combination products) will be moved to Schedule III status

[Note: Pharmacists are advised that in areas where there is evidence of abuse or particular concern about abuse, pseudoephedrine products should NOT be located in a self-selection area of the pharmacy]

Ephedrine to come into effect April 10, 2006

ephedrine (in single entity products) (in preparations containing no more than 8mg per unit dose, with a label recommending no more than 8mg/dose or 32mg/day and for use not more than 7 days, and indicated for nasal congestion) will be moved to Schedule II status, and

ephedrine (in combination products) (in preparations containing no more than 8mg per unit dose, with a label recommending no more than 8mg/dose or 32mg/day and for use not more than 7 days, and indicated for nasal congestion) will be moved to Schedule III status

[Note: Pharmacists are advised that in areas where there is evidence of abuse or particular concern about abuse, ephedrine products should NOT be located in a self-selection area of the pharmacy]

Tamper Resistant Prescription Drug Pad Program

the following drugs have been added to the section of Schedule I titled "Tamper Resistant Prescription Drug Pad Program".

- . Amphetamine mixed salts
- . Ketamine HCL
- . Delta-9-tetrahydrocannabinol
- . Cannabidiol
- . Phenobarbital

CONTINUING PROFESSIONAL DEVELOPMENT

The Pharmacy Board gave final approval to the draft Continuing Professional Development Document at its February 4th meeting. This draft document was circulated to all pharmacists for comment in the Christmas edition of the Apothecary. The final version of this Continuing Professional Development document is available on the NLPB web site at <http://www.nlpb.ca/pd.html>.

We encourage all pharmacists to read this Continuing Professional Development document so they understand that they are now responsible for maintaining a Learning Portfolio that documents their continuing education and professional development activities. If you did not receive a copy of this document, or do not have access to the Internet, the NLPB office will be glad to forward a copy upon request.

Pharmacists are also encouraged to start their Learning Portfolio now and begin maintaining their professional development documentation.

NEW WEBSITE AND E-MAIL ADDRESSES FOR NLPB

As part of the updating of the Internet capabilities of our office, the staff of NLPB now have new email addresses. Please update your address book to include the following revised addresses:

Donald Rowe, Secretary-Registrar	drowe@nlpb.ca
Arlene Crane, Deputy Registrar	acrane@nlpb.ca
Veronica Harvey, Executive Assistant	vharvey@nlpb.ca
Joan O'Mara, Administrative Assistant	jomara@nlpb.ca
Information or General Office Contact	info@nlpb.ca
Website Feedback	website@nlpb.ca
Website address	www.nlpb.ca

For the past number of weeks the Board's website has been under revision and updating. This updating includes the addition of a search engine to the site to assist in finding specific topics of interest. The website now also includes a register of licensed pharmacies in the province and a register of licensed pharmacists and their location of practice.

Please visit the NLPB website often at www.nlpb.ca. We would welcome feedback about the site, particularly if you see anything that is not up to date or is missing.

Other recent updates to the website include:

[Professional Development Page](#) updated January 31, 2006 *new information added for pharmacists and presenters!*

[Pharmacy Act](#) updated January 28, 2006

[NLPB Binder](#) updated January 28, 2006

[List of Provincial Pharmacists](#) updated January 28, 2006

[Bill 59 & Updated Act](#) - now approved updated January 14, 2006

[Notice re: Scheduling Change of Pseudoephedrine and Ephedrine](#) added January 9, 2006

[Summary of Proposed Drug Scheduling Changes](#) added January 9, 2006

SEND US YOUR ADDRESS

The annual licence renewal notices sent out at year-end asked pharmacists to provide us with their current e-mail address. More and more, using e-mail is a more efficient, less costly and timelier way to send information to our pharmacists. When we conducted a test e-mailing recently quite a number of email addresses were returned as invalid. NLPB would appreciate being notified of your current e-mail address so that our files can be updated. Please also include us in the list of those you notify should your e-mail address change.

CONDOLENCES

Condolences are expressed on behalf of the pharmacy community to:

- Robert McGrath on the passing of his brother, Derm McGrath (December 2005)
- Pam Smith on the loss of her mother, Elizabeth Gardner (December 2005)

The Board also records, with regret, the deaths of the following pharmacists:

- Thomas Bindon - Honourary Member (18 January 2006)
- Roland Reid - Community Pharmacist (9 December 2005)

PRACTITIONER IDENTIFICATION NUMBERS FOR HEALTH PROFESSIONALS OTHER THAN PHYSICIANS

From time to time pharmacists may need to confirm the registration status, or registration number, of prescribers other than physicians. While pharmacists should contact the appropriate regulatory body for these prescribers for definitive confirmation of status, the NLPDP secure (X-Wave) website has a listing of prescriber registration numbers that includes information on not only physicians, but also dentists, Nurse Practitioners, and Optometrists licensed to prescribe certain drugs. The link for NP registration numbers on the NLPDP secure (X-Wave) website is <http://nlpdp.xwave.com/Physician/physearch.asp>. Veterinarians are not included in the NLPDP listing since they do not prescribe for NLPDP clients. However, a listing of veterinarians licensed in this province is attached to this edition of the Apothecary.

EARLY FILLING OF PRESCRIPTIONS

A pharmacist has recently brought to our attention an incident that happened regarding one of his patients. This patient, who has a history of compliance problems, often seeks early refills or renewals of narcotic prescriptions, to the extent that the physician and the pharmacist have been working together to monitor this patient.

More specifically, the physician now issues prescriptions to this patient that are not to be filled until a specific date. In the incident related to us by the pharmacist, the patient wanted such a prescription filled prior to the date indicated by the physician and became upset when the pharmacist refused this request. Subsequently the patient took the prescription to another pharmacy, where the prescription was apparently filled without the pharmacist having questioned the date indicated on the prescription, or having contacted the physician for clarification.

It is a requirement that the date be indicated on all prescriptions and pharmacists should always check that the date on the prescription is appropriate. Pharmacists should question any date that does not appear to be "normal", particularly if the prescription appears to be post-dated.

NEEDLE EXCHANGE PROGRAM

The AIDS Committee of Newfoundland and Labrador made a presentation at the last meeting of the Board to familiarize Board members with the Needle Exchange Program operated in the St. John's area by the ACNL. This program, based on a harm reduction philosophy, is aimed at reducing the risk of the spread of HIV/AIDS, hepatitis C (HCV) among injection drug users.

Following the presentation, the Board expressed willingness to circulate information about the ACNL and the needle exchange program to pharmacists in the province, and to provide contact information for those pharmacists who might want further information or be interested in becoming involved in this type of program. A copy of the ACNL pamphlet that outlines the needle exchange program and contains contact information is included as an attachment to this edition of the Apothecary.

NEWFOUNDLAND AND LABRADOR REPRESENTATION ON PEBC

The February 2006 meeting of the Pharmacy Examining Board of Canada marked the completion of the term of office of Scott Way as the representative for Newfoundland and Labrador. Scott has served on the Board of PEBC since the spring of 1999 and his term of office on PEBC has included service on a number of their committees, including the Executive committee. Scott served as the President of PEBC for 2004-2005. The Pharmacy Board extends its sincere thanks to Scott for the representation he has given over the past 7 years, and to congratulate him on the exceptional contribution he has made to PEBC in that time.

Our Board has named Tracey O'Neill as the new Newfoundland and Labrador representative on PEBC. Tracey will begin her three-year appointment at the end of the February 2006 PEBC Board meeting.

Attachments to this issue of The Apothecary:

1. Listing of TPA Certified Optometrists (as of January 27, 2006)
2. Listing of Veterinarians Licensed to Practice in Newfoundland and Labrador in 2005
3. NAPRA Supplemental Standards of Practice for Schedule II and III Drugs (June 2005)
4. Brochure "Reaching Injection Drug Users" - A project of the Aids Committee of Newfoundland and Labrador
5. Correspondence from Minister of Health, dated January 26, 2006 reference revisions to the Provincial Drug Schedules

ABBREVIATIONS CONTRIBUTE TO MEDICATION ERRORS

A recent medication error in this province has been brought to the attention of NLPB. The error in question resulted from the following line (photocopied from the prescription):

Isotamine 300 mg (R) QD

The abbreviation "QD" in this line was mistakenly read as "QID". The prescription was dispensed with instructions that the medication was to be taken four times a day instead of once a day. As a result, the patient suffered adverse effects requiring admission to hospital.

We would remind pharmacists to take particular care when reading abbreviations that are handwritten, to confirm the recommended dosage ranges of drugs they may not be familiar with before dispensing, and to question any aspect of a prescription that may be unclear.

The article in the box to the right was taken from the December 2005 edition of Pharmacy Post and illustrates that the similar error that occurred in our province was not an isolated incident.

The message that should be learned is that every unclear prescription should be questioned.

CONGRATULATIONS

Congratulations are extended, on behalf of the pharmacy community, to:

- Beth Ann Winters & Terry Broomfield on the birth of their son "Riley", November 12, 2005
- Andrea and Sean Handrigan, on the birth of their daughter "Julia Elizabeth, November 14, 2005

Watch abbreviations, Calgary doctors told

Common short forms banished by Capital Health Region BY KRISTAN WOLFE

In an effort to reduce the number of medication errors in Alberta's Capital Health Region, physicians in the area have been ordered to stop using certain abbreviations when writing prescriptions.

For many doctors, using short forms on a prescription has become habit. But while abbreviations may save the doctor time, they can cause confusion and, subsequently, a medication error later on. Wanting to improve patient safety in accordance with the Institute of Safe Medication Practice's (ISMP) position on the matter, Capital Health banned a total of seven common abbreviations.

Capital Health has told doctors to write out "unit" instead of "IU" for "international unit" and instead of "U" or "u" for unit; "daily" instead of "QD" or "qd"; "every other day" instead of "QOD" or "qod"; and to use the complete spelling of generic drug names.

In addition, physicians have been instructed to always use a zero before a decimal when the dose is less than a whole unit (e.g. 0.5 mg) and never to use terminal zeros for doses expressed in whole numbers (e.g. 1 mcg).

"What it means for pharmacists is that in receiving prescrip-

tions that are written this way, we hope that we have greater clarity and therefore improved communication between the physicians and the pharmacist and, mutually, through that communication process, opportunity to minimize error that comes from these communication downfalls," says Greg Eberhart, registrar for the Alberta College of Pharmacists.

Eberhart adds that the college has brought these abbreviations to the attention of those developing the electronic health record.

"If these errors can occur through manual communication, then certainly, as we turn into an electronic environment, there's every reason to believe that they can be replicated," he says. "So when we develop our electronic systems, we want to look to similar standards and incorporate them before implementation occurs."

On its website (www.ismp.org), ISMP has a more detailed list of abbreviations, symbols and dose designations that "should never be used when communicating medical information" because they've been reported to ISMP through the USP-ISMP Medication Errors Reporting Program "as being frequently misinterpreted and involved in harmful medication errors."

PRIMARY HEALTH CARE AND PHARMACISTS

A number of pharmacists in the St. John's area may have received calls from Dr. Stephanie Young of MUN's School of Pharmacy seeking information about patient prescriptions. These requests for information are in connection with a significant project that is being undertaken as part of the Primary Health Care Initiatives of the province. Consent has been obtained from the patients involved in this project to allow the sharing of personal prescription information with Dr. Young, and such sharing of patient information, with their consent, is permitted under the Standards of Pharmacy Practice adopted by the Board with respect to privacy and confidentiality of patient's personal information.

Dr. Young has provided the following information regarding this initiative:

Primary Health Care (PHC) is an approach to health and wellness that extends beyond the traditional system. It includes all services that play a part in health care. PHC serves a dual role in the healthcare system: 1) it provides first contact services (e.g., physician, pharmacist), and 2) coordinates services to ensure continuity and ease of movement across the system. Part of the reform with PHC on a national and provincial level is a shift to "teams" of providers and developing partnerships for better patient care.

The isolation in which health professionals often function is a barrier to improved patient care. Pharmacists have traditionally been viewed as the dispensers of medications; and while most patients are aware of the knowledge of the pharmacist, the extent of the skills, education, and services often go unrecognized. An additional barrier for pharmacists is the "tension in the pharmacy culture – the push and pull of the commercial and clinical" (Strand et al, 2004). As a profession, we have to examine how we currently care for patients, and how we can participate in patient care to optimize positive outcomes. The practice of pharmacy is evolving to incorporate pharmaceutical care practice. The premise of pharmaceutical care is a patient-centered practice which ensures effective and safe medication use that patients will comply with. Pharmacists, pharmaceutical care practice and PHC are a natural fit.

In an effort to provide research at the local level on the involvement of pharmacist in an expanded role within PHC, the School of Pharmacy has established an exciting pilot initiative. A two year project was begun in November, 2005 with the Primary Health Care Pharmacist position. The focus of the project is to develop an expanded pharmacist role within a Family Medicine PHC site, and to complete research to evaluate the initiative. Involvement in the St. John's region PHC Team as well as liaising with the pharmacists in the Twillingate PHC team is also ongoing. Within this model the physicians at the Newfoundland Drive Family Practice clinic or PHC team members may refer patients to the pharmacist. The clinic chart and laboratory information are reviewed by the pharmacist, and an appointment is made with the patient to complete a pharmaceutical care assessment. This assessment, usually occurring in the patient's home, involves reviewing demographic information, social history, immunization history, current medical conditions, medication history, allergies, adverse drug reactions, attitudes towards medications, experiences with medications, and a systems review.

For each medication, specific information is collected including how and when it is taken, how long it has been taken, effectiveness, toxicity, and the patient's willingness to comply with therapy. The community pharmacist providing care to the patient is an integral part of the team, and provides key information. From the assessment, drug therapy issues are identified. A care plan is developed to define the goals of therapy and to resolve or prevent the drug related issues. The assessment and care plan information are communicated to the referring physician via letter and if needed, a face-to-face meeting. Follow up evaluations are carried out to assess patient outcomes and evaluate progress. The community pharmacist is included in the plan for therapy changes, monitoring and follow up.

The goal of this initiative is not to focus on the role of a single provider, but to promote and evaluate the changing role of the pharmacist, and to examine potential for economic feasibility of these expanded roles.

Please feel free to call or e-mail for further information:

Stephanie Young, Primary Health Care Pharmacist, MUN School of Pharmacy, 777-8833 or syoung@pharm.mun.ca .

Suggested references:

- (i) Strand LM et al. The impact of pharmaceutical care practice on the practitioner and the patient in the ambulatory practice setting: twenty-five years of experience. *Curr Pharm Des.* 2004;10(31):3987-4001. (Please contact Stephanie Young if interested in a copy).
- (ii) CPhA's publication "Pharmacists and Primary Health Care"
http://www.pharmacists.ca/content/about_cpha/whats_happening/cpha_in_action/pdf/primaryhealth2a.pdf

FREQUENTLY ASKED QUESTIONS

We receive numerous questions at the Board offices in the run of a week, on a wide variety of regulatory issues. The following is a sampling of some of the questions we have received, and the answers that were given.

1) Monitoring the sale of products containing pseudoephedrine

Q: I was wondering how, as pharmacists, we can participate in the meth watch program and still honor a patient's/customer's right to privacy when visiting the pharmacy.

There is an individual who frequently visits our pharmacy for a cough and cold syrup. He does not always come to the pharmacy to get checked in, and does not purchase in bulk. I have overheard some of the front store staff voice their concern about the frequency of his purchases. Your advice and direction would be appreciated.

A: One approach would be for the pharmacist to speak to the customer, indicating that they noticed he has been using the cough and cold product for a while and inquiring about his symptoms. This consultation with the patient would be done with a view to advising whether the symptoms may indicate a more serious condition that would be more appropriately treated by consulting a doctor rather than self-treating, or whether there is a more appropriate non-drug approach that could be used on a self-treatment basis.

It goes without saying that such consultation with the patient should be done in a way that respects the patient's right to privacy and confidentiality. It is for this reason that private counselling areas in a pharmacy are desired. It is also for this reason that pharmacists sometimes find themselves in a dilemma regarding how to properly deal with patients who are unwilling to share personal information about their medications or medical condition.

Your question doesn't indicate whether the patient appears to be using an excessive quantity of the product, or whether it is simply being used chronically. Is this person actually taking the product himself or just purchasing it for another family member or other person? Is the patient also on other prescription drugs that might be affected by this OTC product? Is there a patient profile at the pharmacy for this patient, and if so should OTC's that are being used regularly also be added to that profile to give a more accurate and complete drug profile?

These are a number of questions that might need to be clarified before a proper assessment of this situation can be made. If this is simply a case of a chronic condition, the symptoms of which can appropriately be self-treated, there may be nothing more that needs to be done than to counsel the patient on appropriate use of this product, the side effects to look out for, and the signs or symptoms which might indicate that they should check with their doctor about their chronic condition. You might then keep an eye out for this patient and follow up from time to time on how they are doing.

Such an approach would hopefully indicate to the patient that that you don't see yourself as the "cough syrup police", but rather, your concern is to assist him in assuring that his approach of self-treatment is appropriate for his particular condition; that if self-treatment is appropriate it is done most effectively, and that if self-treatment is not appropriate this patient is referred to his physician.

On the other hand, if there were an indication that this product is being used in excess of the appropriate dosing, or in other ways abused, it would not be inappropriate for a pharmacist to ensure that the patient was made aware of the appropriate use of that product and the risks associated with inappropriate use. If this counselling did not resolve the issue, it would then be appropriate if the pharmacist were to restrict sale of this product to this patient, or even move the product behind the counter and require direct pharmacist involvement in the sale of the product, to ensure that purchases were appropriate.

A pharmacist is not obligated to stock, or sell, any product the patient wishes to purchase, particularly if there are reasonable grounds to believe that the product may be used inappropriately or misused. Appropriate pharmacist intervention is often crucial to appropriate OTC, as well as prescription drug use.

2) E-mail Warning about Phenylpropanolamine (PPA)

Q. A patient of our pharmacy called me to get more information about an e-mail that she had just received from a friend about cough and cold preparations being removed from the market for safety reasons. I was not aware of any products being removed from the market recently and asked if she could send me a copy of the e-mail.

It turns out that the e-mail concerns phenylpropanolamine (PPA). I thought that this drug had been removed from the market a few years ago. Can you refresh my memory and direct me to some background information that might assist this patient?

A: The e-mail that a patient brought to you, and others similar to it have been in circulation since June of 2001, when phenylpropanolamine (PPA) was removed from the market. This warning surfaces from time to time, even though the drug is no longer available as an OTC.

Before responding to your question I myself had to try to remember how long ago it was that the recall took place and was surprised that this e-mail warning is still in circulation. A Google inquiry on the Internet turned up an entry at <http://urbanlegends.about.com/library/blppa.htm> that may be helpful to you. This site gives the following update:

"2005 Update: Most if not all of the products listed above which formerly contained phenylpropanolamine hydrochloride have been reformulated to eliminate the ingredient. Consumer questions about phenylpropanolamine and its potential health hazards may be directed to the U.S. Food and Drug Administration at 1-888-INFO-FDA.

Some manufacturers of over-the-counter medicines containing phenylpropanolamine have offered refunds to consumers who purchased the products before they were voluntarily recalled in late 2000. To inquire about the availability of such refunds, dial the 800-number for consumer questions listed on the product packaging.

Comments by Carla Homan: This email has it mostly right. In November 2000, the FDA issued a public health advisory about phenylpropanolamine hydrochloride (PPA), the drug mentioned in the email. This drug is found in many over the counter (OTC) medicines, specifically in cold and flu remedies, as well as appetite suppressants. The drug will likely be banned, but because this process takes time, the FDA issued the health advisory in the meantime and manufacturers are voluntarily recalling and/or reformulating medicines containing PPA.

The main problem with this drug is that it elevates your risk of having a hemorrhagic stroke, especially with (but not limited to) first time use among women. Because the uses of PPA are not serious enough to warrant taking even that small chance, the FDA recommends that you stop taking any medications containing the drug.

Rather than looking at a limited list such as the one contained in the above email, you'd be better off checking the package of any cold, flu or appetite suppressant medication for the drug, which will appear in the list of active ingredients and may be listed as phenylpropanolamine, phenylpropanolamine hydrochloride, or phenylpropanolamine bitartrate. Many manufacturers offer several formulations of their cold and flu remedies, some of which do not contain PPA. Pseudoephedrine is an effective alternative to PPA for use in cold and flu preparations, but unfortunately, there is no approved alternative OTC drug for use in appetite suppressants. Therefore, if you are using any OTC medications to suppress your appetite for weight loss or other reasons, you should stop using the medicine and talk to your doctor about getting a prescription drug instead. Additionally, some prescription decongestants and cold and flu preparations contain PPA, so if you are using any prescription medicines for these purposes, talk to the prescribing doctor to see if you should continue using the medicine.

One word of caution: Though the email states your risk is for "increased hemorrhagic stroke (bleeding in brain) among women ages 18-49 in the three days after starting use of medication," don't think you are safe if you've used the drug for longer than three days. The three-day window was merely one of the guidelines used in the study that prompted the health advisory; for the study, they defined PPA exposure as having used PPA within three days prior to the stroke. Risk of stroke may be present after three days of use. For detailed information, see the final report of the Hemorrhagic Stroke Project, Web-published by the FDA.

As always, your best resources for reliable information on medicines and medical conditions are your own physician and pharmacist. "

Subsequent to the initial advisory about this drug in November of 2000, in June of 2001 Health Canada cancelled the DINs of all phenylpropanolamine containing products in Canada and requested all manufacturers to remove those products from the retail market. It is important to note that the formulation of the products listed in the e-mail forwarded to you by your patient, if they are still on the market, have been changed to remove PPA from them. The new PPA-free formulation should no longer represent the potential risk that may have existed under the old formulation.

3) Nurse Practitioner Prescriptions

I have some questions regarding the Nurse Practitioner Regulations and the extent to which I am responsible for determining if a prescription is valid. More specifically:

- Q When a nurse practitioner prescribes a renewal of a drug that was previously prescribed by a physician, and indicates the name of the original prescriber, can she prescribe all classes of drugs (Schedule F, Narcotics, Controlled Drugs, Targeted Substances)? It doesn't specifically say they can't in the Nurse Practitioner Regulations. Correct me if I'm wrong, but I can't see any mention of Nurse Practitioners in the federal legislation, but our provincial Nurse Practitioner Regulations provide for prescribing by Nurse Practitioners. Can you please clarify this and point me to the place in the regulations where I should be looking.
- A Part of the confusion about the prescribing authority for N.P.'s stems from the fact that there are different definitions of "practitioner" in the federal Food and Drugs Act (with respect to Schedule F drugs) and the Controlled Drugs and Substances Act (with respect to narcotics, controlled drugs and benzodiazepines).

The Food and Drugs Act defines a prescription as “an order given by a practitioner...” where a “practitioner” means “a person authorized by the laws of a province to treat patients with any drug listed or described in Schedule F to the regulations” (This essentially allows the province to decide who may prescribe Schedule F drugs.) On the other hand, the Controlled Drugs and Substances Act has the same definition of a “prescription”, but limits the definition of a “practitioner” to mean “ a person who is registered and entitled under the laws of a province to practice the profession of medicine, dentistry or veterinary medicine ...”(This essentially means that under federal regulations only a physician, dentist or veterinarian may prescribe narcotics, controlled drugs or benzodiazepines.)

- Q With respect to the requirement for a “collaborative working relationship”, how do I know who has a collaborative working relationship with whom? Am I to assume that the fact that a prescription, originally written by a physician, was renewed by a Nurse Practitioner means that those two professionals have such a relationship? Can this relationship be with multiple doctors in the province?
- A The Nurse Practitioner Regulations require that the N.P. establish a “collaborative working relationship” with a primary care physician for the purposes of consultation. There is no apparent reason why an N.P. could not have such a collaborative relationship with more than one physician.

Unless s/he has information to the contrary, it would be reasonable for a pharmacist to assume that the appropriate collaborative relationship between the N.P. and a physician has been established, and pharmacists are not expected to seek documented evidence of such a relationship. If a pharmacist has reasonable grounds to believe that an N.P. has not established the required collaborative relationship with a physician, or is otherwise acting contrary to the regulations, they should report those concerns to the Association of Registered Nurses of Newfoundland and Labrador (the regulatory body for nurses in this province).

- Q Renewals of previously prescribed drugs: Can the nurse practitioner continue to write these refills over and over again, without being written by the physician in between?
- A N.P.s may issue renewal prescriptions for patients on their case load who are being managed consultatively with a physician (and the reality is that this may not be the same physician who issued the original prescription). However, a patient with a chronic condition must be reassessed by a physician on an annual basis, or sooner if the patient's condition destabilizes or requires changes in the treatment.

When a physician reassesses a patient, it will be the physician who orders the new, or revised, prescription. No prescription, regardless of who prescribes it, can be filled for longer than a year.

- Q Is there a maximum days supply for refills? For example, a prescription I am looking at currently is written “correctly” for oxazepam 15mg hs for 3 months as per Doctor X's orders.
- A: There are currently no restrictions, either federally or provincially, on the number of days supply that may be ordered or dispensed at one time (with the exception of methadone for the treatment of opioid dependency). However, third party payers may have limits on the maximum quantity that they will pay for at one time, or a pharmacist's knowledge of the circumstances or history of a particular patient may give them professional reasons to recommend limitations on the quantity of a particular drug that should reasonably be dispensed in a given circumstance. In some cases pharmacists have refused to dispense at one time the full quantity prescribed, **using** professional judgement based on their knowledge of the particular circumstances of the case in question.

It should be noted, however, that the example you used is a benzodiazepine, which (since it is now regulated under the Controlled Drugs and Substances Act) cannot be prescribed by an Nurse Practitioner and thus this particular prescription cannot be dispensed by a pharmacist, regardless of the days supply indicated.

- Q: I am aware that it is the pharmacist's responsibility to know whether every prescription they fill is valid or not, but exactly how far are we liable, to know whether or not a particular patient is on an NP's case-load, etc?
- A: As was indicated in the response above concerning the requirement for a collaborative relationship between the N.P. and a physician, it is reasonable for a pharmacist to assume that a N.P. is acting in accordance with their regulations and scope of practice, unless that pharmacist has reasonable evidence to the contrary. Should a pharmacist become aware that an N.P. (or physician, or another pharmacist) is practising in a manner that is not consistent with legislation or regulations they might first wish to discuss that with the person in question and later, if no resolution had been found, report those concerns to the appropriate regulatory body of the person in question.



The *Apothecary* is a newsletter of the Newfoundland & Labrador Pharmacy Board and may contain important regulatory information that all pharmacists in the province of Newfoundland & Labrador are expected to be aware of. All pharmacies in the province are required to keep at least two years' issues of *The Apothecary* on file as a part of the pharmacy's required reference materials.

ELECTIONS COMPLETED

Under the revised *Pharmacy Act* Board members are now elected on a rotating basis so that there will be continuity. Each year the term of office for some of the members will come up for renewal and elections will be held to fill those positions for a further three-year term.

This year elections were held for Board members representing Zones 1 and 4, the results of which were formally announced at the Annual General Meeting of the Board on June 16th. Joanne Howlett was re-elected in Zone 4 and Margot Priddle was elected by acclamation in Zone 1.

Dr. Linda Hensman has begun her term as Chair of the Board and, at the special meeting of the Board held immediately after the Board's AGM, Donald Mifflin was elected Vice-Chair and Joanne Howlett was elected Executive Member.

JOAN O'MARA Honoured Upon Retirement

A retirement luncheon was held by the Board on Saturday, June 16 to honour Joan O'Mara upon her recent retirement as Administrative Assistant at the Board offices.

Joan's service to the NPhA, now NLPB, goes back more than 20 years, when she began assisting her husband, the late Jim O'Mara on a voluntary basis. Her position later became part-time, and then full-time.

She continues to manage the operations of the James J. O'Mara Pharmacy Museum for the Apothecary Hall Trust, and will assist at the Board offices on a casual basis.

We are indebted to Joan for her dedicated service over so many years.

CONTINUING PROFESSIONAL DEVELOPMENT CHANGES

Pharmacists are reminded of the changes made January 1, 2006 to the requirements for Continuing Professional Development for Pharmacists (formerly known as "Continuing Pharmacy Education").

Some of the changes were:

- Pharmacists now must keep their own record of their Continuing Education/Professional Development activities in a Learning Portfolio
- Pharmacists must document each learning activity on a "Learning Portfolio Record Sheet"
- Each completed Learning Portfolio Record Sheet must be logged on their annual "Professional Development Record"
- The Professional Development Record must be included with their annual NLPB renewal for licensure application
- The Registration & Licensing Committee will audit twenty percent of the Learning Portfolios annually
- At least 7.5 CEU's per year must be from accredited sources
- Non-Accredited sources must follow the self-assignment guidelines

A copy of the revised Standards of Pharmacy Practice regarding Continuing Education adopted by the Board at its June 16th meeting is included with this edition of the *Apothecary*.

The Continuing Professional Development package, including the recently approved audit process and the required forms are available on the NLPB website www.nlpb.ca, under the "Professional Development" button, or from the NLPB office. If you have any questions please contact Arlene Crane at the NLPB office.

The Registration and Licensing Committee encourages pharmacists to begin compiling their annual Learning Portfolio if they have not done so already.

ACCREDITATION OF CE/CPD PROGRAMS

Pharmacists should be aware that requests for accreditation of CE/CPD programs are decided upon by the Board's Registration and Licensing Committee, based on the CE/CPD program guidelines and Standards of Practice. While the PANL/CSHP Joint Education Committee coordinates and facilitates the holding of education sessions they are not responsible for accreditation decisions. Questions about accreditation decisions should be directed to the NLPB offices.

TAMPER RESISTANT PRESCRIPTION DRUG PAD PROGRAM

Highlights of changes to Program Policy, Guidance Brochure and Schedule of Drugs

- Inclusion of Newfoundland and Labrador College of Veterinarians and update of other organization names. (p.2)
- Clarification that benzodiazepines are not included in the schedule of drugs and are not required to be written on the tamper resistant prescription pad. (p.2)
- Maximum quantity per order set at 10 pads, due to security issues (p.3)
- Information as to how to report the suspected theft of prescription pads, with contact numbers for the police (p.3)
- Information as to how to report suspected fraud (p.3)
- Bolded statement regarding faxed prescriptions, clarifying that the original is not to be given to the patient (p.4)
- Clarification of prescribing by quantity versus duration, and proper completion of a prescription (p.4) **(It was agreed that prescribing the duration is acceptable, but it should be written in both alpha and numeric form. For purposes of prescribing it was also agreed that "one month" means 30 days and "three months" means 90 days.)**
- Prescribing format and proper completion of a prescription – updated example that includes a part-fill situation (p.5)
- Instructions for completion section has been updated to clarify when the section on 'name of pharmacy to dispense' is required to be completed (p.6)
- Updated Schedule of Drugs (p.7) **The following drugs have been added to the section of Schedule I of the provincial drug schedules titled "Tamper Resistant Prescription Drug Pad Program":**
 - Mixed salts amphetamine
 - Phenobarbital
 - Ketamine
 - Cannabidiol
 - Dronabinol (delta-9-tetrahydrocannabinol)
- Updated Fax order form, indicating maximum allowable quantity per order (p.11)

An updated Program brochure can be downloaded from the Government web site at www.gov.nl.ca/health/nlpdp/drugpadprogram, or a print copy can be ordered by calling 709-729-1557.

BY-LAW CHANGES

Major revisions to the by-laws were approved at the April meeting of the NLPB Board. The revised by-laws are posted on the NLPB website www.nlpb.ca. The NLPB Binder has also been updated on the website.

As a part of these revisions a number of board policies (such as the Code of Ethics, Board Expense Policy etc.) are now incorporated as appendices.

We would point out that by-law changes now provide for a fee of \$25.00 to be charged for preparation of a Letter of Standing by our office.

INSPECTORS' NOTES

The Inspectors would like to make pharmacies aware that part of the inspection process will include:

- a review of pharmacies' monthly narcotic audits,
- whether prescriptions and refills are being signed by the pharmacist,
- are pharmacies complying with Standards of Practice for Lock and Leave,
- checking for outdated stock
- a review of the pharmacy self-audit form (available from our website).
- checking for compliance with federal requirements that purchases of narcotic and controlled drugs be entered in a register upon receipt.

ANNUAL REPORT AVAILABLE

The 2006 Annual Report of the Newfoundland and Labrador Pharmacy Board was approved at the June 16th AGM of the Board and is available on our website at www.nlpb.ca. A hard copy of the report is also available upon request from our offices. Call 753-5877 or 1-877-453-5877.

RECENT UPDATES TO THE NLPB WEBSITE INCLUDE

- NLPB Board Members and Executive Committee Members *added June 1, 2006*
- NLPB By-Laws *updated June 1, 2006*
- NLPB Binder *updated June 1, 2006*
- NLPB Program of Examinations *updated June 1, 2006*
- Forms *updated June 1, 2006*
- Policy - Professional Liability Insurance *added June 1, 2006*
- Policy - Privacy of Pharmacists' Personal Information *added June 1, 2006*
- Notice of Professional Liability Insurance *added May 21, 2006*
- Provincial Pharmacists Registry *updated April 2006*
- Provincial Pharmacies Registry *updated April 2006*
- Summary of Narcotic, Controlled Drugs and Benzodiazepine Regulations *updated April 30, 2006*
- Practice Experience Program Requirements *updated April 20, 2006*
- Supervised Studentship/Final Internship Preceptor Acceptance Form *updated April 20, 2006*

TRAMACET ABUSE REPORTED

A recent case has been brought to the attention of our office regarding the apparent abuse of Tramacet by a female patient in the St. John's area. In the 18 day period from June 13 to July 1st 2006 this patient has received prescriptions for 420 tablets of Tramacet from 5 different physicians and 4 different pharmacies.

Although Tramacet is a combination of tramadol, a centrally acting synthetic opioid analgesic, and acetaminophen, it is regulated by Health Canada as a Schedule F Drug under the Food and Drugs Regulations (rather than under the Controlled Drugs and Substances Regulations).

Pharmacists are reminded that Tramacet is not recommended for minor pain that may be treated adequately through lesser means where benefit does not outweigh the possible opioid-related side effects; and that Tramacet is approved for the short term (five days or less) management of acute pain. The recommended dose is 1 or 2 tablets orally every 4 to 6 hours as needed for pain relief, up to a maximum of 8 tablets per day.

The product monograph for Tramacet includes the following information: *"Tramacet is contraindicated in any situation where opioids are contraindicated. Tramacet should not be used in opioid dependant patients. Tramadol can re-initiate physical dependence in patients who have been previously dependent or chronically using other opioids. In patients with a tendency to abuse drugs or a history of drug dependence, and in patients who are chronically using opioids, treatment with Tramacet is not recommended."*

Pharmacists are advised to be watchful for possible inappropriate use or abuse of Tramacet.

AVAILABILITY OF PORK INSULIN

In July 2005, Eli Lilly Canada, the sole manufacturer of pork insulin with Canadian market authorization, announced its decision to cease production of their insulins Iletin II Regular and Iletin II NPH. These insulins have not been available on the Canadian market since April 1, 2006.

Since then Health Canada has authorized for sale in Canada two new pork insulins, Hypurin Regular and Hypurin NPH, manufactured by Wockhardt in the UK. These products have been available for sale to Canadians since April 1, 2006. There are no other pork or animal-sourced insulins currently authorized for sale in Canada. More information on these products may be found on the Health Canada Drug Product Database at <http://www.hc-sc.gc.ca/drug2/company/c12151.html>. If you need further information on these products contact Lindsay Blaney at (613) 946-0372 or by e-mail at lindsay_blaney@hc-sc.gc.ca.

PROFESSIONAL LIABILITY INSURANCE

Based on the recommendations of a committee established to review the criteria that should be applied when determining the acceptability of pharmacist professional liability insurance as required by section 21(2)(b.1) of the *Pharmacy Act*, the Board sets the following criteria:

- 1) **Amount of Coverage:** An amount of \$1,000,000 per claim made is the minimum acceptable coverage. It may be preferred in some types of pharmacy practice that a higher level of coverage be available on an optional basis, however, \$1,000,000 is adequate as a core minimum level.

It is further required that, for a policy to be acceptable, there be no aggregate limit to coverage.

- 2) **Type of Insurance:** "Claims made" type of insurance coverage is required.

This requirement reflects the fact that "occurrence" type of insurance is not commonly available in Canada, which may restrict availability of competing providers. "Claims made" insurance may also reduce the likelihood of prolonged litigation over which insurer is liable should a claim be made a significant time after the occurrence of the action for which the pharmacist may be liable.

- 3) **Extended Reporting Period:** For a policy to be acceptable, there must be "trail coverage", or an extended reporting period provision that continues coverage after the pharmacist ceases to practice and the policy is still in place.

Such an extension of coverage ensures that liability insurance protection is available to the patient when the claim has not yet been submitted, but the pharmacist is no longer in practice and no longer a subscriber to the policy.

- 4) **Personal Insurance:** The understanding of the Board is that employers' group insurance policies typically cover the pharmacist only with respect to practice of pharmacy as an employee of that employer. This raises questions of coverage being in place should a pharmacist engage in practice of pharmacy outside of that employer's setting.

To be acceptable, coverage under professional liability insurance must be personal insurance, which names the pharmacist personally as an insured and covers the pharmacist for all aspects of the practice of pharmacy and in all locations in which that practice occurs.

- 5) **Certification of Coverage:** An annual certification of professional liability insurance, provided by the insurance carrier, is required that confirms personal coverage by a policy that meets the criteria set by the Board.
- 6) **Recognition of Policies:** Recognition of policies considered acceptable to the Board is not exclusive to the policy offered by PANL. Any other professional liability insurance policy that meets the criteria adopted by the Board would receive the approval of the Board.

The Board recognizes that section 21(2)(b.1) of the *Pharmacy Act* refers to pharmacist professional liability insurance. However, the Board has been made aware of at least one instance where a pharmacy in this province was the subject of a professional liability insurance claim, only to discover that the insurance policy in place for that pharmacy did not cover professional liability. The Board strongly recommends to Pharmacists-in-Charge that similar professional liability insurance coverage be in place for their pharmacy, should a claim be made that also names the pharmacy as well as the pharmacist.

These criteria for acceptability can be viewed at:

[www.nlpb.ca/Documents/News/Communications/060518 Notice Renewal PL Insurance.pdf](http://www.nlpb.ca/Documents/News/Communications/060518%20Notice%20Renewal%20PL%20Insurance.pdf)

INSTITUTE for SAFE MEDICATION PRACTICES (ISMP) PROGRAMS AVAILABLE

The Medication Safety Self Assessment (MSSA) program developed by the Institute for Safe Medication Practices can provide help to community and hospital pharmacists to identify risks in their dispensary processes and procedures and suggest improvements that can be made as part of ongoing quality assurance and improvement initiatives.

ISMP also has available a "Medication Reconciliation getting started kit". ISMP Canada is organizing a faculty to facilitate sharing and learning across Canada in the Community of Practice for Medication Reconciliation, Safer Healthcare Now!

The ISMP documents can be found on the ISMP website at <http://www.ismp-canada.org/caps.htm> and <http://www.ismp-canada.org/medrecon.htm>. If you wish to sign up for the campaign or participate in the Community of Practice for Medication Reconciliation please go to the campaign website at www.saferhealthcarenow.ca.

HEALTH CANADA *MedEffect* SITE

Last August Health Canada launched *MedEffect*, a website that will provide centralized access to relevant and reliable health product safety information in an easy-to-find location on the Health Canada website. The new website also makes it as simple as possible for consumers and health professionals to complete and file reports of adverse reactions to drugs and other products. The site is a reliable information source for health product safety information for all Canadians and for health care professional.

The website address of *MedEffect* is www.healthcanada.gc.ca/medeffect. It also can be found on the homepage of Health Canada's newly, redesigned departmental website. A single click on the *MedEffect* icon helps visitors quickly locate the latest information on warnings, recalls and advisories, register for e-mail notices, obtain the Canadian Adverse Reaction Newsletter, and search the Canadian Adverse Reaction database. Links to advisories from Health Canada's *MedEffect* site are posted on the NLPB homepage at www.nlpb.ca.

CONGRATULATIONS ON ACHIEVEMENTS

Congratulations are in order to a number of pharmacists for their recent achievements. These include:

Sandra Carey, who has been elected as Vice-President of the National Association of Pharmacy Regulatory Authorities (NAPRA),

Jason Druken, who has just completed six years service on the NLPB Board, including terms as Executive Member,

Lorie Duggan, Jeremy Parsons, Justin Peddle and Jody Pomeroy, who were the MUN School of Pharmacy team members, and First Place winners in this year's annual CAPSI National Compounding Competition,

Basil Gallant and the staff of The Drug Store, Murphy's Lane, Corner Brook who were the Pharmacy of the Year Award winners for Loblaws Atlantic,

Margot Priddle, who has been elected Chair of the National Drug Scheduling Advisory Committee (NDSAC).

ADJUDICATION TRIBUNAL OF THE DISCIPLINE COMMITTEE

The following are decisions of the Adjudication Tribunal of the Discipline Committee from their hearings on May 26, 2006.

Complaint # 1: A complaint resulting from an allegation made that a pharmacy was operating with no pharmacist present, in contravention of the *Standards of Pharmacy Practice* respecting *Lock and Leave for Community Pharmacies*.

Having considered and accepted an Agreed Statement of Facts, Admission, and Joint Submission made by the Secretary-Registrar and the respondent pharmacist, the Committee found the pharmacist in question to be in violation of Sections 14.1(1) of the *Pharmacy Regulations* that states:

14.1(1) All pharmacists shall adhere to standards of practice approved by the council.

and subsection 37.(1)(w) of the *Pharmacy Regulations* which states:

37.(1) The term unprofessional conduct or professional misconduct for the purpose of consideration of a complaint and the institution of disciplinary proceeding includes but is not limited to .

(w) Failing to maintain the standards of practice of the profession, including written standards.

Having made this finding, the panel ordered as follows:

- a) That the pharmacist be reprimanded,
- b) That the owner of the Pharmacy receive a copy of the Order of the Disciplinary Panel,
- c) That the Order of the Disciplinary Panel be published in the Apothecary, on an un-named basis,
- d) That the pharmacist pay the costs of the investigation and Hearing of the Complaint (an amount of \$2226.38) within six months of the Order of the Disciplinary Panel, or as further directed by Board of the NLPB.

Complaint # 2: The Discipline Panel was presented with an Agreed Statement of Facts, an Admission Statement and a Joint Submission that had been agreed to by Gerard F. Thomey and the Secretary-Registrar. Mr. Thomey admitted to having renewed prescriptions for himself, including prescriptions for narcotics and benzodiazepines, without the prescribing physician's authorization, and having falsified inventory records to conceal this. This case had been previously referred to an adjudication tribunal, to be held when Mr. Thomey was medically fit to return to practice. The tribunal accepted the agreed statement of fact and joint submission on penalty.

The penalties included provisions that the time he had been out of practice is considered to be a suspension, that he cannot act as the pharmacist-in-charge or sole pharmacist at a pharmacy, must notify the Secretary-Registrar of all pharmacies in which he practises, must notify all pharmacists-in-charge where he practises of the restrictions on his licence, will be subject to spot checks and inspections, must cooperate with the Clinical Coordinator of the Professionals Assistance Program and ensure compliance with necessary counselling and follow up, that the findings of the tribunal be published in the Apothecary on a named basis, and that he pay the costs of the investigation and hearing (an amount of approximately \$1700).

COMMUNITY PHARMACEUTICAL CARE PROJECT (CPCP)

The Community Pharmaceutical Care Project (CPCP) is currently underway at Memorial University. This project will develop and implement a means to provide individualized patient care from the community pharmacy setting to people with diabetes.

In early May, invitation packages were mailed to all practicing pharmacists in Newfoundland and Labrador. Information packages were also mailed to all regional pharmacy managers who expressed great interest in the project. To date, we have received replies from 33 pharmacists who are willing to participate. We have started follow-up phone calls with the hopes of inviting more pharmacists into the project. The Newfoundland and Labrador Medical Association posted information regarding the project on their web site, and have sent a notice to all NLMA members briefly describing the study.

The training session for participating pharmacists is tentatively booked for October 14th and 15th, 2006 in St. John's. Reasonable travel expenses incurred by pharmacists living outside the metro area to attend the training session will be covered by the project. Over the next couple of weeks, we will be circulating

information about the project to various media outlets so some of your patients may be contacting you for further information.

Please note: if you think you may be interested in participating in the CPCP project but have not yet returned your RSVP card, it's not too late! Simply fax or email your information and expression of interest to one of the research team members and we will follow up with you to complete your enrolment. Several pharmacists have indicated that they have not returned their cards because they haven't had an opportunity to confirm employer support. If this describes your situation, please let us know of your tentative interest and we will follow up with you. It is important that you let us know if you are considering participating as soon as possible so that the study preparations can continue in a timely manner.

If you have any questions, please feel free to contact the project coordinator Montgomery Keough at montyk@mun.ca, phone 709-777-6905, fax 709-777-7382 or any member of the CPCP research team:

Team Member	Contact Info
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Roy West, PhD	709-777-7274 roywest@mun.ca
Jerry Young, PhC	709-834-2111 jeyoung@nf.sympatico.ca

QUESTIONS & ANSWERS

1) **Q:** I was wondering how long records for blister packs need to be kept.

A: Our standards may not speak to this directly, but I would say that any documentation or records related to prescriptions should be kept for at least 2 years (the same as the prescriptions themselves are required to be kept by the federal regulations).

I'd also note that the two-year retention rule for prescriptions means two years from the date of the **last refill**, not the date that the prescription was written or first filled. Some prescriptions may have refills for up to a year, in which case the records should be kept for at least 3 years from the date it was first filled.

While it is not a pharmacy regulation or requirement, it has also been suggested that Canada Revenue may require that certain records be kept for a minimum of 7 years for taxation audit purposes. You may wish to get the advice of your accountant on whether this might include actual prescription files and records that are the underpinning documents of some of the financial transactions of your pharmacy.

2) **Q:** When the approval was given recently by the provincial cabinet to proceed with the development and implementation of a Pharmacy Network one of my patients wanted to know whether he would be able to keep his personal medication information private, or whether it would be accessible to whoever could access the network. What answer should I give him?

A: The Newfoundland and Labrador Centre for Health Information, the agency responsible for building the Pharmacy Network, recognizes that security and privacy of personal information are important aspects of the network and considerable work has already been devoted to those issues.

The network, when it becomes established, will indeed have provision for a patient to “mask” their personal information so that it can be visible only to those persons that they authorize. Information provided by NLCHI is as follows:

“Masking is one component of the security and privacy architecture within the Pharmacy Network. Other elements include:

- *Consent*
- *Authentication and Authorization*
- *Communication Security*
- *Auditing and Logging*
- *Tiered Network Security*
- *System Security*
- *Secure Application Development*

Masking allows patients to have the right to request that data elements within their health record be masked so that they are not visible to users of the system unless the patient provides that right to view the masked data. However, masked data will still be used for centralized drug utilization review (DUR) checks and appropriate messages will be returned from the drug information system (DIS) to the health care provider.

The Pharmacy Network solution includes support for masking and un-masking elements within a patient’s record. If a health care provider determines that he/she needs masked data to make a proper decision, he/she can ask the patient for access in order to get a full view. In specific cases (for example, an unconscious patient in an emergency room) masking could be overridden, however, all such instances would be logged along with the reason for the override.

In the case of patients with drug seeking behaviour, the patient will have the right to mask medications (such as Oxycontin) however; the DIS will alert the pharmacist and physician that there is an interaction with previously filled (masked) medications. The specific message is called a “duplicate therapy” alert. If a health care provider determines that he/she needs masked data to make a proper decision, he/she can ask the patient for access in order to get a full view. If the patient refuses to give the health care provider access to their masked information, then he/she has the right to refuse care.

In order to support masking, patients may associate a keyword with their record. In order to access the masked data in a patient’s record, a provider must either obtain the keyword from the patient or have the patient enter it directly at the keyboard and submit the keyword as part of the request.”

COUNTERFEIT DRUGS APPEARING IN CANADA

Until recently, the issue of counterfeit drugs in the Canadian drug supply chain was a non-issue, and one that pharmacists did not feel a need to be concerned about. However, in the past year there have been two incidents of counterfeit drugs appearing in the system in Ontario and Health Canada inspectors report that there is evidence that this is becoming a growing issue of concern.

This past spring the British Columbia College of Pharmacists warned its members that a representative of a foreign pharmacy had been approaching Victoria area pharmacies with an offer that was too good to be true – the opportunity to purchase brand name prescription drugs at a 20 per cent discount over regular wholesale drug prices. The company that the representative was associated with did not hold a Health Canada Drug Establishment Licence (DEL). A DEL is required for any company wishing to sell prescription medications to a Canadian pharmacy. As well, drug wholesalers can only sell products that have been approved by Health Canada.

Pharmacists must only purchase Schedule I, II, or III drugs from a wholesaler or manufacturer licensed to operate in Canada, or in the case of an emergency supply, from another pharmacist. Additionally, it is illegal for pharmacists to sell, offer for sale, advertise, or facilitate the sale of unapproved drugs to other countries or to destinations within Canada. Pharmacists have been advised by Health Canada, and advised in the Fall 2005 edition of the *Apothecary*, that any company selling these drugs (including pharmacies) must have a valid Drug Establishment Licence.

Pharmacists in this province are reminded that it is professional misconduct under sub-section 37(1)(dd) of our *Pharmacy Regulations* to purchase a drug “other than from another pharmacist, a recognized drug wholesaler, or the manufacturer of the drug”.



The Apothecary

The *Apothecary* is a newsletter of the Newfoundland & Labrador Pharmacy Board and may contain important regulatory information that all pharmacists in the province of Newfoundland & Labrador are expected to be aware of. All pharmacies in the province are required to keep at least two years' issues of *The Apothecary* on file as a part of the pharmacy's required reference materials.

YEAR END MESSAGE FROM CHAIR OF BOARD

As 2006 draws to an end, we pause for a minute to reflect on the accomplishments of the Board over the past year. Having completed the process of transition from the former Newfoundland Pharmaceutical Association to the present Newfoundland and Labrador Pharmacy Board, it has been time to review our mission and strategic plan and to now focus on the challenges the Board faces to "set, govern and advance the standards and scope of pharmacy practice for the service and protection of the people of Newfoundland and Labrador."

Considerable work has been started by the Board and its committees to enhance the practice of pharmacy in our province and to promote optimal pharmaceutical care to its citizens. Further on in this edition of the *Apothecary* you can read about some of those activities.

Thank you to all of those pharmacists who have contributed to the work of our committees over the past year. I also invite any others who are interested in making a difference in their profession to join us in meeting those goals in the coming year.

Thank you also to my fellow members of the Board who have contributed their time and talents to these efforts and to Don, Arlene and Veronica who have worked so hard over the past year. Special thanks and sincere appreciation are extended to Joan O'Mara, who retired this past summer after innumerable years of service to the NPhA and the Board (many years of which were on a voluntary basis). We look forward to Joan's continuing leading role in the operation and activities of the James J. O'Mara Pharmacy Museum and involvement as a trustee of the Apothecary Hall Trust.

Best wishes for a Merry Christmas and a Happy and Prosperous New Year.

Linda R. Hensman

Linda R. Hensman, Pharm. D., MBA
Board Chair

PROFESSIONAL DEVELOPMENT RECORDS

The NLPB office appreciates the response from pharmacists in returning their renewal forms and Professional Development Records (PDR) by November 30, 2006. Your cooperation will allow us to process the 2007 renewals in a more efficient manner and will reduce the traditional mad rush that we've experienced over Christmas and New Year holiday period.

This is also a reminder that those who have not returned their renewal form and PDR by December 31st 2006 will not be licensed for 2007.

The PDR audit process has begun and most records were completed as required. In the audit process pharmacists will be selected according to the following criteria:

Selection of members for audit

The Registration and Licensing Committee each year will determine a percentage, or a specific number, of pharmacists to be selected annually for audit. (For example, 20% of members may be audited each year in order for most pharmacists to be audited in a 5-year time frame.)

The audit period will usually be the previous CE year, although the committee may alter the time period under review. Three ways that a member can be selected for audit are:

- 1. Members will be randomly selected from the Register for audit. Note that this may lead to a pharmacist being audited in consecutive years, or a pharmacist not being audited for a number of years.*
- 2. A pharmacist, who has been non-compliant in the previous audit year, will be audited in the current audit year.*

3. In addition to this random selection, the following situations identified by office staff or the Registration and Licensing Committee as a result of screening the Professional Development Record submitted annually may also be audited where the activities in question are required to meet the minimum standards of 15 CEU's.
- Any Professional Development Record deficient in required hours, or otherwise incomplete will be audited
 - Any Professional Development Record received late, i.e. after December 31
 - Any Professional Development Record containing activities not within the approved content areas
 - Any Professional Development Record that contains other questionable activities

Screening of the submitted Professional Development Record

The Registration and Licensing Committee, or designated reviewers, will examine the Professional Development Record submitted by the pharmacist selected for audit. This examination will evaluate

- i. the completeness of the form
- ii. the number of hours documented
- iii. the kinds and source of the recorded activities
- iv. the pharmacist's comments or notations

Pharmacists selected for audit will receive a letter in early January requesting that their full Learning Portfolio be sent to the NLPB office for review. After review, the pharmacist will receive a letter from the Registration and Licensing Committee informing them of the results of the audit.

In the New Year the Committee will be revising the PDR, based upon the experiences of this past year and the comments and suggestions received from pharmacists. An electronic version will be sent to all pharmacists who have e-mails. This will make it easier to fill out the forms electronically and save copies of them in your computer. If you have any questions or comments regarding the audit process, or the forms used for PD documentation, please forward them to Arlene Crane at acrane@nlpb.ca.

PROPOSED CHANGES TO STANDARDS OF PHARMACY PRACTICE FOR FEEDBACK:

At the last meeting of the Board changes and/or additions to the Standards of Pharmacy Practice were approved in principle, and are now being made available to pharmacists in the province for comment and feedback. The proposals approved in principle are:

Methadone Guidelines:

Recommendations from a sub-committee of the Professional Practice Committee that the *Practice Guidelines for Pharmacists for the Newfoundland and Labrador Methadone Maintenance Program* be strengthened to become **Standards of Practice** were endorsed in principle by the Board, subject to comment and feedback from pharmacists.

It is important to note that section 14 of the *Pharmacy Regulations* requires that "All pharmacists shall adhere to standards of practice approved by the Board." Formally adopted Standards of Practice are mandatory (as opposed to recommended guidelines). Pharmacists, particularly those who dispense methadone in their practice, are asked to review the proposed Standards of Practice and bring any concerns or comments to the Professional Practice Committee (via the Board office).

The proposed Standard of Practice may be found at <http://www.nlpb.ca/spg.html>, with deletions shown as crossed through and additions shown underlined and highlighted in yellow.

Standards of Practice respecting Delivery of Prescriptions:

A sub-committee of the Professional Practice Committee has been reviewing issues arising from the prohibition of depots in section 24(1)(e) of the *Pharmacy Act* and has recommended to the Board that these issues might more readily be addressed through a substantial amendment of the *Standards of Pharmacy Practice (Delivery of Prescriptions by Community Pharmacies)*. The recommended changes to this Standard of Practice have been endorsed in principle by the Board subject to comment and feedback from pharmacists.

It is important to note that, if adopted, the proposed changes to the Standard of Practice would permit a prescription to be delivered to a person who is designated by the patient as their agent but not to a site designated by the patient. It is also important to note that this revised Standard of Practice will apply to ALL situations where prescriptions are given to a person other than the patient (i.e. they would also apply to a situation where a person, other than the actual patient, picks up a prescription at the pharmacy dispensary on their behalf).

The proposed revised Standard of Practice can be found at <http://www.nlpb.ca/spg.html>.

Required and Suggested Reference Materials

A review of the current *Standard of Pharmacy Practice (Schedule of Required and Suggested Reference Materials for Community Pharmacies)* was conducted by a sub-committee of the Professional Practice Committee and the recommendations of the sub-committee have been endorsed in principle by the Board, subject to comment and feedback from pharmacists.

It should be noted that the proposed revisions to the Standard of Practice would apply to hospital pharmacies as well as community pharmacies. The proposed revisions can be found at <http://www.nlpb.ca/spg.html>.

Electronic versions of these documents can be found elsewhere on our website, or hard copies may be obtained upon request from the Board's office.

BILL 50, PHARMACEUTICAL SERVICES ACT

Bill 50, An Act Respecting Pharmaceutical Services, was introduced into our Legislature on Monday, November 27th and finished Third and Final Reading on Tuesday afternoon, November 28th. The Bill received Royal Assent at the end of the fall sitting, on December 12th and is now in effect.

The Bill, which may be viewed at <http://www.hoa.gov.nl.ca/hoa/bills/Bill0650.htm>, primarily provides legislated authority for the **Newfoundland and Labrador Prescription Drug Program**. Also, the legislation respecting generic substitution under the **Interchangeable Drug Products Formulary** and the legislation respecting the **Tamper Resistant Prescription Drug Pad Program (TRPP)** have been moved from the *Pharmacy Act* to the new *Pharmaceutical Services Act* since these two programs are administered by the Pharmaceutical Services Division of the Department of Health and Community Services.

It is important to note that section 6 of this new act makes specific reference to the duties of pharmacists who participate in the NLPDP programs. This section reads:

Duties under Act

6. (1) Pharmacies, pharmacists, dispensing physicians, prescribers and beneficiaries participating in the programs established under this Act shall comply with this Act and the regulations made under it, including any policies and terms and conditions set by the minister in the administration of this Act and the regulations.

(2) Pharmacists, dispensing physicians and prescribers participating in the programs under this Act shall at all times abide by all applicable federal and provincial legislation relating to their professional practice, as well as the by-laws and codes of practice set by their relevant governing bodies.

PROFESSIONAL PRACTICE COMMITTEE ACTIVITIES

The Professional Practice committee has identified quite a number of practice issues that need to be addressed or reviewed by the Board, and are now working with the Board to prioritize these issues. All of our current Standards of Practice will be reviewed and in addition sub-committees will be assigned the task of dealing with specific issues.

So far, issues that are being addressed include:

- revision to Required Reference Material list
- revision to Standard of Practice regarding Delivery
- revisions to Methadone Guidelines
- standards on the use of pharmacy technicians
- pharmacist authority for continuation of care and prescribing

Updates on the activities of the Committee, and requests for comment and feedback will be sent to pharmacists as the work of the sub-committees progresses.

HEALTH CANADA ADVISORIES

Health Canada Advisories, both to pharmacists and to patients, are regularly posted to our website www.nlpb.ca. Pharmacists are encouraged to check this website frequently for new advisories.

The advisories for the past month (at the time of writing) are:

For Pharmacists November 21, 2006 – New Safety Information about EVRA

For the Public
 December 7, 2006 – Health Canada advises consumers of the lack of child-resistant cap on certain Robaxacet Caplets bottles
 November 29, 2006 – New information regarding Tamiflu
 November 21, 2006 – New Safety information about EVRA

For older advisories, please check the appropriate archive on our website.

BOARD STRATEGIC PLAN

The Board conducted a strategic planning session on September 29th which was facilitated by Dr. Roy West. At this session the mission, goals and objectives of the Board were reviewed and approved. The Strategic Plan is a blueprint of what the Board expects to accomplish, however, it should be noted that the priorities may change as issues evolve.

Mission Statement

The Mission Statement of the NPhA was reviewed in light of the changes to the *Pharmacy Act* in recent years and the separation of advocacy and regulatory functions that has taken place. Upon review it was decided that the Mission Statement needed only minor changes and the following revised version was adopted as the Mission Statement of the Newfoundland and Labrador Pharmacy Board.

“The mission of the Newfoundland and Labrador Pharmacy Board is to set, govern and advance the standards and scope of pharmacy practice for the service and protection of the people of Newfoundland and Labrador.”

Goal Areas

The general “goal areas” for the Board, which include both practice of pharmacy and operational areas, were identified as follows:

1. Advancing the Scope of Practice
2. Registration and Licensing
3. Competency and Professional Development
4. Legislation, Regulations and Standards of Practice
5. Patient Safety
6. Complaint Processing and Discipline
7. Governance, Administration and Operations
8. Partnerships and Collaboration

Specific Goals and Objectives

Five specific Goals were identified, with a number of Objectives under each Goal, as follows:

GOAL # 1 OPTIMIZE THE PRACTICE OF PHARMACY TO ENHANCE PATIENT CARE

- Objective 1.1 Define the role of Pharmacy Technicians
- Review and Update Standards of Practice for Pharmacy Technicians
 - Develop and Implement regulations relating to Pharmacy Technicians
- Objective 1.2 Pursue collaborative prescribing authority
- Define
 - Develop Guidelines
 - Investigate
 - Gain consensus and adoption
- Objective 1.3 Raise awareness of Pharmacists and the Public on Patient Safety Issues
- Medication reconciliation
 - Self-audits
 - ISMP programs
 - Education
- Objective 1.4 Develop Standards of Practice for Pharmacy Network

GOAL# 2 ***GUIDE AND DIRECT CONTINUOUS PROFESSIONAL DEVELOPMENT OF PHARMACISTS AND OTHERS INVOLVED IN THE PRACTICE OF PHARMACY***

- Objective 2.1 Establish priorities for Professional Practice Committee
- Objective 2.2 Communicate and consult with pharmacists regarding changes impacting the profession
- Objective 2.3 Review and develop regulations relating to Pharmacy Students
- Objective 2.4 Engage in national initiatives related to pharmacy technicians
- Objective 2.5 Promote pharmacists involvement in Board and NLPB Committees

GOAL #3 ***ENSURE ON-GOING EVALUATION FOR THE IMPROVEMENT OF POLICY AND PRACTICES***

- Objective 3.1 Complete transition of self-reporting for Professional Development and review learning portfolio process
- Objective 3.2 Review and assess Board requirements for Practice Experience for licensing
- Objective 3.3 Review and Update Inspection Process and Practices
- Objective 3.4 Endorse and promote research activities to enhance practice and policy
- Objective 3.5 Review and Assess CE Requirements
- Objective 3.6 Review and assess Registration Exam (to ensure QA and reflect practice)
- Objective 3.7 Develop and Implement a Self-Evaluation Process for the Board

GOAL #4 ***PROMOTE AND ADVANCE THE PROFESSION THROUGH COLLABORATING AND BUILDING PARTNERSHIPS WITH VESTED PARTIES***

- Objective 4.1 Liaise and interact with government and regional health authorities to ensure the involvement of the Board in all relevant health issues
- Objective 4.2 Participate with other provincial regulatory authorities, advocacy groups, educational institutions and student organizations.
- E.g. NAPRA, CPhA, PANL, CSHP, CCCEP
 - Other Health Professional Boards (e.g. ARNNL, College of Physicians and Surgeons)
 - Other Community Organizations (e.g. RNC/RCMP, Schools, etc.)
 - School of Pharmacy, Technician Training Programs
 - MUPS, CAPSI
- Objective 4.3 Ensure a process of adequate and timely communication to the public regarding public health issues

GOAL 5 ***REGULATE AND GOVERN THE PROFESSION IN A MANNER WHICH ASSURES THE PUBLIC OF PROFICIENCY AND COMPETENCY IN PHARMACY PRACTICE***

- Objective 1
Part A Evaluate and Establish Priorities, and monitor success
- Objective 1
Part B Revise constanting documents as required to reflect changes in pharmacy practice
- Act and Regulations
 - Standards of Practice
 - By-Laws
- Objective 2 Develop and implement a process to make the public(s) aware of the impact of regulatory changes
- Objective 3 Determine Board governance in accordance with the Act for implementation by the NLPB

REMINDER ABOUT MONITORING OF SALES OF EPHEDRINE AND PSEUDOEPHEDRINE

Reports about the presence of crystal-meth abuse in this province continue to arise. In addition, unapproved use of ephedrine for weight loss or energy boost purposes continue to be promoted in certain areas. In recent weeks the Board sent notice to a sports nutrition outlet in St. John's that they were in contravention of our provincial regulations by selling ephedrine.

The importance of the monitoring of the sale and use of ephedrine and pseudoephedrine is recognized by the provincial regulations that restrict the sale of these products to pharmacies, and in the case of single entity products, the requirement for direct pharmacist involvement in the sale of these products.

When changes were made to the drug scheduling regulations last April, the Minister of Health and Community services, having withstood considerable resistance from non-pharmacy outlets regarding these restrictions, specifically asked our Board to advise pharmacists of their responsibilities regarding these and other drugs listed on Schedule III. He indicated, *"The Department of Health and Community Services needs to be assured that pharmacists will exercise diligence with respect to their responsibilities in supervising and monitoring the sale of single entity and combination products containing ephedrine and pseudoephedrine."*

Please contact our offices if you need additional information about way to deter the improper use or diversion of these precursor drugs.

ELECTION FOR ZONE 2 & 3

The terms of office for the Board members representing Zone 2 (David Jenkins) and Zone 3 (Roy Green) will conclude in 2007 and the election process for representatives from both of these Zones for the next 3 years will begin after the New Year.

Pharmacists in each of those zones are asked to consider offering themselves as candidates for election. Please watch for the Call for Nominations which will be circulated in January.

APPOINTMENT TO NATIONAL COMMITTEE

Juan Edwards has been appointed by our Board as its representative on NAPRA's National Advisory Committee on Licensing (NACL). The mandate of the committee is to make recommendations to NAPRA Council on matters relating to the initial licensing of pharmacists in Canada and the Terms of Reference of the committee includes:

1. Monitor the [Professional Competencies for Canadian Pharmacists at Entry-to-Practice](#) and make recommendations on revisions required to ensure that the competencies reflect the evolving practice of pharmacy and the needs of the Canadian public.
2. Make recommendations for revising the [Model Licensing Program](#) components (i.e. proficiency requirements, jurisprudence program, licensing examination, and structured practical training requirements) reflect the national competencies, to ensure that they continue to meet the needs of NAPRA members in protecting the public.
3. Identify areas in provincial licensing processes where development and/or standardization would be beneficial to NAPRA members
4. Address other matters regarding licensing as may be referred by Council from time-to-time.

We thank Juan for his commitment to participation on this important national committee.

ATTACHMENTS TO THIS ISSUE OF THE APOTHECARY

- Standards of Pharmacy Practice, Continuing Pharmacy Education (Continuing Professional Development) Approved by NLPB Board – 16 June 2006 (available on the website at www.nlpb.ca/spg.html)
- NAPRA Notes, December 2006, Volume 1, Number 4