Newfoundland and Labrador Pharmacy Board

The Apothecary is the newsletter of the Newfoundland & Labrador Pharmacy Board.
It contains information on a wide variety of topics intended to enhance the practice of all pharmacists in the province of Newfoundland & Labrador.
Pharmacists are responsible for reviewing any and ALL INFORMATION contained within including documents which are made available on the NLPB website via links throughout the newsletter.
The Apothecary is now circulated electronically and is available in hard copy format only upon specific request.

The Apothecary

Spring 2010

100 Years of Pharmacy in Newfoundland and Labrador

"What's Old is New Again..."

This past January marked the **100th Anniversary** of a meeting held on Sunday, January 2, 1910 when ten St. John's druggists met (in the Reading Room of the Total Abstinence Club) to select a delegation to meet the Prime Minister to discuss a proposed Pharmacy Bill. (Remember that we were an independent country at that time.)

At the same meeting it was decided to have a further meeting the following Wednesday to form an association to be known as the Pharmaceutical Society of Newfoundland.

The first Pharmacy Act was passed by the Newfoundland Legislature on March 22, and on March 29 a meeting of the newly formed Pharmaceutical Society was held at which 29 founding members signed the original constitution of the Society. Then, on April 11, six members were elected by the Society for appointment by the government to the newly established Newfoundland Pharmacy Board.

It is interesting to note that in 1954 the Pharmacy Act was revised, in part to reflect the practice of pharmacy in the rest of Canada, and at that time the Pharmaceutical Society and the Pharmacy Board were merged into the Newfoundland Pharmaceutical Association (NPhA). Then in 2005 the Act was revised again, this time separating the NPhA into the Pharmacists' Association of Newfoundland and Labrador and the Newfoundland and Labrador Pharmacy Board. (As the old saying goes, what goes round comes round.)

It is interesting to note that the minutes of that first meeting on January 2, 1910 indicate that a motion was adopted "that the Druggists & Druggists' Assistants should form an association to be known as the Pharmaceutical Society of Newfoundland". This is an interesting parallel to the concept being pursued today in more and more provinces that Pharmacists and Pharmacy Technicians be seen as categories of the same profession.

Further "file cabinet archeology" in the archives of the Apothecary Hall Trust indicates that in 1910 the government saw the need for at least one pharmacy in St. John's to be open 24 hours a day (even if it meant a subsidy from government to keep it viable).

Also in 1910, the Royal Pharmaceutical Society in Great Britain proposed the mutual recognition of all pharmacists registered in the British Empire who met an agreed upon basic training and competency criteria.

(Incredibly to us today, our Society rejected the idea as "impracticable".) Again however, this is an interesting parallel to today's discussions around more open registration requirements from jurisdiction to jurisdiction, including international jurisdictions.

Photocopies of minutes of the earliest meetings of our Pharmaceutical Society (available for viewing on the James J. O'Mara Pharmacy Museum section of our website) give a fascinating glimpse into our profession 100 years ago and serve to illustrate both how far we've come and also how many issues haven't changed at all.

Dextromethorphan Abuse Still a Problem

As evidenced by a recent article on CanadianHealthcareNetwork.ca, dextromethorphan (DM) abuse is still a problem in this country. According to the report, the intentional overdoses by four teens in Victoria, BC in a two week span has led the College of Pharmacists of B.C. to recommend to pharmacies that they move cough remedies containing DM behind the counter. While the teens survived the overdose, they had to go through a 7-10 day detox process.

Youths use such cough remedies to get high by exceeding the recommended dose, which they refer to as "*Skittling*", "*Tussing*", or "*Robo-Tripping*". Abuse of such medicines has risen due to word-of-mouth via the Internet, and because youths think the products are safe as they're sold over-the-counter. Furthermore, cough remedies are easier to obtain than alcohol. DM overdose can cause such symptoms as breathing difficulties, nausea, dizziness and rapid heartbeat, as well as death.

In this province, all products containing DM are included in Schedule III of the Provincial Drug Schedules and the NLPB has intentionally not pursued any change to this status despite the fact that the National Drug Scheduling Advisory Committee did approve a change moving DM products containing less than 300mg DM base to Unscheduled status a number of years ago.

While we do not intend to change the scheduling status of DM-containing products to Schedule II at this time, we would advise pharmacists to be aware of the potential for abuse of these products. In particular, watch for purchases of large quantities of DM-containing products as well as any increase in the theft of these products from the pharmacy. If a problem is noted, it would be advisable to move these products, particularly single-entity high dose DM products, behind the pharmacy counter to reduce the opportunity for theft and to better monitor purchases.

Appointment of New Board Personnel

In recent weeks callers to our offices will have noticed a different voice answering the phone or a different name responding to e-mail messages. This change is due to the fact that our Executive Assistant, Veronica Harvey, has been placed on extended leave by her physician. Veronica has dedicated the past 7 years of her career to the Board as our Executive Assistant and we extend her our best wishes for improved health, as well as sincere thanks for the service she has given to the Board since January 2003.

Since Veronica will be on leave for an undetermined time, and to implement the office reorganization strategy adopted by the Board, the following personnel appointments are announced:

Aileen O'Keefe (aokeefe@nlpb.ca) has been appointed Registration and Licensing Administrator. Aileen began work with our office on a part time basis last November to assist with the annual registration and licensure renewal process. She has been filling in as Executive Assistant on a temporary basis since Veronica was required to go on sick leave in January.

Aileen's responsibilities include all the administrative processes related to the registration and licensing of pharmacies, pharmacists and pharmacy students, as well as the maintenance of Registers kept by the Board. She will also be responsible for maintenance and optimization of the Board's information database.

Meghan Handrigan (mhandrigan@nlpb.ca) has been appointed Office Administrator. Meghan began work with our Board on March 15th and once her training and familiarization period is completed she will be responsible for the day-to-day administrative functions of our office, including greeting callers and visitors needing services from our office as well as facilitating our communications to pharmacists and the public.

We welcome these two new employees as they look forward to responding to your needs, as well helping our office to operate as efficiently as possible.

Report from March Board Meeting

At the most recent meeting of the Board on March 6, 2010, the Board made the following decisions:

- A new **Policy on Accreditation of Professional Development Programs** was approved. In short, this policy establishes the formal process for applying to the Board for accreditation of live professional development programs. It also clarifies the responsibilities of the provider with regard to content and documentation of attendance at live events and adds a fee for processing an accreditation request. For more information on this policy, see the **Professional Development** page of the Board website.
- A **Project Plan for Proceeding with Pharmacy Technician Regulation** was endorsed. The Board staff and Professional Practice Sub-Committee on Pharmacy Assistants/Regulated Pharmacy Technicians now have the direction to proceed with the next steps in this process. Please watch future Board communications for more information on this initiative.
- It was decided to move the date of this year's **Annual General Meeting** to coincide with the Pharmacist's Conference in St. John's in September. For the last several years the meeting had been held in June with very few pharmacists attending. The hope is with this change, more pharmacists may choose to attend this meeting.
- Two **external appointments were made**:
  - Karen Mercer—appointed to the Pharmacy Examining Board of Canada (PEBC)
  - Dr. Linda Hensman—appointed to the National Association of Pharmacy Regulatory Authorities (NAPRA) Board of Directors
- A draft revision to the **Standards of Practice regarding the Provision of Pharmaceutical Care to Personal Care Homes** was circulated for information. This document is currently under review by the Professional Practice Sub-Committee on Long Term Care. Once completed, a final draft will be sent to the Board for approval. The next initiative on the sub-committee's agenda is to develop Standards of Practice regarding the provision of pharmaceutical care to residents of long term care facilities.
- The **NAPRA Position Statement—Sale of Non-Approved Marketed Health Products** was endorsed and approved for circulation to pharmacists (see page 4). Pharmacists are advised that this is not a new policy, but rather a reminder for pharmacists of the already existing Food and Drug Regulations regarding the sale of drugs in Canada (including natural health products and homeopathic products). We are releasing this position statement at this time due to the confusion caused by the increasing number of drug products showing up in pharmacies without the identification numbers required by Health Canada (DIN, NPN or DIN-HM). Subsequent to the release of this position statement by NAPRA, Health Canada is considering new regulations to appropriately deal with this situation, as well as how to best deal with the backlog of applications in the approval pipeline. However, pharmacists in this province are reminded of the existing federal regulations that prohibit the sale of unapproved drugs.

Subsequent to the meeting, two other documents were approved via email poll and can be found on the **Standards, Policies & Guidelines** page of the NLPB website:

- A new **Standard of Pharmacy Practice on Delegation of Duties in Community Pharmacy** was approved to replace the previous Standard of Practice - The Role of the Pharmacy Technician in Community Pharmacies. The intention of this change is to lead the way for the future regulation of Pharmacy Technicians and also to formally establish the delegation of tasks to pharmacy students and interns.
- A new **Policy on Committees of the Board**. The intent of this Policy is to set a basic level of expectation for all Board committees. Variations due to the specific needs and goals of any particular committee would then be outlined in the Terms of Reference for the committee.

NAPRA ANORP

National Association of Pharmacy Regulatory Authorities
Association nationale des organismes de réglementation de la pharmacie

POSITION STATEMENT

Sale of Non-Approved Marketed Health Products

January 2010

Position Statement

Pharmacists should not sell a marketed health product without a Drug Identification Number (DIN), Natural Product Number (NPN) or Drug Identification Number for Homeopathic Medicine (DIN-HM).

Background

All marketed health products for sale in Canada require a market authorization or product licence from Health Canada. This condition applies to drugs per the regulatory requirements outlined in the *Food and Drug Regulations*. This same condition applies to natural health products (NHPs) and homeopathic products per the regulatory requirements of the *Natural Health Products Regulations* (NHPR) promulgated by the federal government six years ago.

Under the federal drug approval process, drugs, natural health products and homeopathic products must complete a review process and obtain a market authorization or a product licence from Health Canada in order to be sold. The approval follows a review by Health Canada for the product's safety, efficacy and quality. Once approved for sale, a number is provided by Health Canada to identify the marketed health product. For instance, drugs are identified by a Drug Identification Number (DIN), natural health products by a Natural Product Number (NPN) and homeopathic products by a Drug Identification Number for Homeopathic Medicine (DIN-HM). These numbers are indicated on the package label by the manufacturers and serve as a means for the public and health care professionals, such as pharmacists, to know that the product completed Health Canada's review and is approved for sale. In place for many years, this approval process is the single most important element of the federal/provincial/territorial safety net system.

Pharmacists are obliged to hold the health and safety of the public or patient as their first and foremost consideration. As such, they must follow very specific standards of practice to fulfill this role. When presented with a product that does not bear a number issued by Health Canada, it leaves the pharmacist and their patient with no confirmation that the product was properly assessed for its safety, efficacy and quality nor granted approval for sale. In these situations, a pharmacist may consult Health Canada's website (Drug Product Database or the Licensed Natural Health Product Database) to obtain the list of approved products or inquire about a specific product's status. Verifying the information on the website is not always practical however it may be a useful tool for NHPs in view of the NHP licensing backlog experienced by Health Canada. The department set a revised internal target date of March 31, 2010 to address the remaining NHP product licence applications.

Even though an argument can be made that an NHP or homeopathic product without a product license is not necessarily unsafe, the reverse is also true. There is no guarantee that the required criteria for product safety were met. Pharmacists should not be placed in situations where they may be in a position to sell products that have not received approval for sale in Canada.

NAPRA and its members, the provincial and territorial pharmacy regulatory authorities, abide by the condition set out in federal regulations whereby marketed health products that have not been issued a market authorization or a product license by Health Canada for their sale, should not be sold by pharmacists. In formulating a specific position on this matter, NAPRA members wish to reinforce this fundamental regulatory requirement in the interest of public safety.

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Endorsed by the Newfoundland and Labrador Pharmacy Board March 6, 2010

Professional Development Audit 2010

The Professional Development Audit Process for 2010 is nearing completion. The Registration and Licensing Committee has noted that a fairly large number of pharmacists are still struggling to meet the documentation requirements of the **Professional Development Standards of Practice** and would like to remind pharmacists of the following points, in particular:

- The Professional Development (PD) Log and Learning Portfolio Record Sheet have both been updated several times over the years. Some pharmacists are still using the original forms (marked DRAFT) or earlier versions of the forms. **ALL PHARMACISTS SHOULD NOW BE USING THE MOST RECENT VERSIONS OF BOTH OF THESE FORMS.** These were circulated to ALL pharmacists earlier this year and are also available on the **Professional Development** page of the Board website.
- When documenting multiple similar CE's such as for programs like the Pharmacist's Letter *CE-in-the-Letter*, pharmacists must document **EACH ISSUE ON A SEPARATE LEARNING PORTFOLIO RECORD SHEET AND IN A SEPARATE LINE ENTRY ON THE PD LOG**.
- When documenting CE's earned while attending an event where multiple presentations were given (such as a conference), pharmacists must document **EACH PROGRAM INDIVIDUALLY ON A SEPARATE LEARNING PORTFOLIO RECORD SHEET AND IN A SEPARATE LINE ENTRY ON THE PD LOG**.
- **WHEN DOCUMENTING CE's EARNED FOR SERVICE AS A PRECEPTOR**, pharmacists are reminded that these CE's are considered "Self-Assigned". Pharmacists DO NOT have to complete a Learning Portfolio Record Sheet in this instance. As well, pharmacists must complete and retain the NLPB Form, Documentation of Credits for Service as a Preceptor, also available on the Professional **Professional Development** page of the Board website. Regardless of which university program the student is attending (MUN, Dalhousie, etc.), the NLPB formulas must be applied.
- When indicating the accreditation status of a program, pharmacists should document the CE's earned as **EITHER** "Accredited" (for programs with an accreditation file number) **OR** "Self-Assigned" **NOT BOTH**.
- Certificates of Completion or Participation **MUST BE RETAINED FOR ALL PROGRAMS INCLUDING ONLINE PROGRAMS AND VIDEO PRESENTATIONS BORROWED FROM PANL** (these are issued by PANL upon return of the video). These certificates MUST indicate success in the program and the number of CE's acquired.
- When selected for audit, pharmacists are asked to be respectful of the committee member's time (which they have volunteered without compensation) and **SUBMIT THEIR LEARNING PORTFOLIO IN AN ORGANIZED MANNER** – preferably in the order the events are documented on the PD Log. Learning Portfolio Record Sheets & supporting documentation for each item listed should be kept together wherever possible and extraneous material such as slides, handwritten notes, etc should not be included unless absolutely necessary. This is an ongoing problem as the committee members often have to spend considerable time organizing the portfolios before they can be reviewed.
- When selected for audit, pharmacists may only submit their Learning Portfolios by mail, courier, or hand. **FAXED COPIES OF LEARNING PORTFOLIOS WILL NOT BE ACCEPTED IN THE FUTURE**.

PHARMACISTS ARE REMINDED THAT NON-COMPLIANCE WITH THE STANDARDS RELATED TO THE PROFESSIONAL DEVELOPMENT LOG WILL LEAD TO YOUR PORTFOLIO BEING FLAGGED FOR AUDIT. IN ADDITION, ANY PHARMACIST WHO WAS NON-COMPLIANT IN THE PREVIOUS YEAR WILL LIKELY BE AUDITED AGAIN IN THE NEXT YEAR.

Professional Practice Issues

Documentation of Refill Prescriptions

Following up on our previous ***Professional Practice Issues*** article, "Check, Check and Check Again" (The Apothecary, Fall 2009), Pharmacists are reminded that section C.01.042. of the *Regulations to the Food and Drug Act* states:

(1) No person shall refill a prescription for a Schedule F Drug unless the practitioner so directs and no person shall refill such a prescription more times than the number of times prescribed by the practitioner.

(2) The person filling or refilling a prescription for a Schedule F Drug shall enter on the original of the prescription or in a <u>suitable record</u> of prescriptions kept under the name of each patient

(a) the date of filling;

(b) the date of each refill, if applicable;

(c) the quantity of drug dispensed at the original filling and each refill; and

(d) his [the pharmacist's] name.

The Secretary-Registrar would like to reiterate his previous advice to pharmacists regarding the Board's interpretation of a "suitable record":

The Board's interpretation includes the requirement that the **<u>record of the original filling, and of each refill, of a prescription be physically initialed or signed by the pharmacist at the time of filling or refilling</u>**.

A computer-generated copy of the refill is acceptable but it must still be signed or initialed by the pharmacist at the time of filling, as documentation of the final check of the prescription.

This documentation should then be filed in an organized manner and be available at the pharmacy for potential future inspection.

Prescription Counselling Requirements

A pharmacist's consultation with their patient, or their patient's representative, is one of the most important cognitive functions that a pharmacist performs. The *Pharmacy Regulations* are very clear with respect to Pharmacist's responsibility in this regard:

13.(16) On the original filling of each prescription, the patient shall be counselled by the pharmacist and that counselling shall include, but is not limited to

(a) the identity of the patient;

(b) the identity of drugs being dispensed;

(c) the dosage regimen and instructions required to achieve the intended therapeutic response;

(d) storage requirements; and

(e) major adverse side effects and cautions.

Beyond this requirement, we would also suggest that it would be appropriate for the pharmacist to also cover:

- **common drug and food interactions and therapeutic contraindications that may be encountered, including their avoidance, and the actions required if they occur,**
- **prescription refill information,**
- **information regarding:**
  - **how to monitor the response to therapy,**
  - **expected therapeutic outcomes,**
  - **action to be taken in the event of a missed dose, and**
  - **when to seek medical attention, and**
- **any other information unique to the specific drug or patient.**

Though the regulation only requires this counselling on the original filling of a prescription, **<u>we would strongly recommend that pharmacists also provide counselling to patients when they present for refills</u>** of their prescriptions to discuss issues such as side effects, compliance issues and any other challenges the patient may be facing with the medication.

Reminders

Election Timeline

This year's NLPB Board elections will focus on electing Board members for Zone 2 and Zone 3.

According to *NLPB Bylaw 17*,

- Zone 2 is considered to be the Conception Bay North/Trinity South peninsula, beginning at Avondale and extending west to Port Blandford, including Placentia and the Cape Shore to (but not including) Trepassey, the Burin peninsula, the Trinity North/Bonavista South Peninsula; and
- Zone 3 is considered to be that part of the island west of Port Blandford to the Hampden junction, and that part of the South Coast that does not include Burgeo and Ramea.

Pharmacists in these areas are reminded to watch for the Board's Call for Nominations around the middle of June.

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Nominations for Centennial Pharmacist Award

This year, as part of the 100th Anniversary Celebrations the Board will be awarding Centennial Pharmacist Award to 100 pharmacists who have made a significant contribution to the profession of pharmacy in this province over the past 100 years. Nominations may be submitted for pharmacists regardless of whether they are still living or are deceased. Please submit your nomination to Don Rowe at drowe@nlpb.ca including a brief paragraph describing the nominee's contribution to pharmacy.

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Scheduling Status of Adult Hepatitis Vaccines

Pharmacists are reminded that Hepatitis A and B vaccines for adults (Engerix-B, Twinrix, for example) are in Schedule I of the Provincial Drug Schedules and, as such, **require a Prescription for Sale**. For a quick summary of the Scheduling Status of the various vaccines and immune globulins, please see Appendix D of the NLPB document, ***A Guide to Understanding the Newfoundland and Labrador Provincial Drug Schedules***. The March 2010 edition was recently posted to the **Drug Schedules** page of the NLPB website.

Newfoundland and Labrador Pharmacy Board

Find us on Facebook
"NLPB-CHSP Joint Professional Development Day"

Joint Professional Development Day

HOLD THE DATE - Saturday, June 12, 2010 - HOLD THE DATE

9:30 AM—3:00 PM (with social to follow)

More Information Coming Soon!

Canadian Society of Hospital Pharmacists
Société canadienne des pharmaciens d'hôpitaux

Recent Updates to the NLPB Website

- **About the Board** page - NLP Board Meeting Minutes updated
- **"The Apothecary" & Other Communications** page - Notice of Changes to Drug Schedules added, MedEffect advisories
- **Professional Development** page - forms revised and updated, new *Policy on Accreditation of Professional Development Programs* added
- **Registration and Licensing** page - many forms revised and updated
- **Legislation** page - NLPB Pharmacy Binder updated to March 2010
- **Standards, Policies & Guidelines** page - new *Standards of Pharmacy Practice for Delegation of Duties in Community Pharmacies* added, new *Guidelines for the Destruction of Expired or Unusable Narcotics or Controlled Drugs* added, new *Policy on Committees of the Board* added
- **Professional Practice Resources** page - Canadian Adverse Reaction Newsletter—January 2010 added
- **Provincial Drug Schedules** page - NL Provincial Drug Schedules and Guidance documents updated to March 2010
- **Miscellaneous Forms** page - new form - Request to Destroy Drugs Covered by the Controlled Drugs and Substances Act added
- **Find a...** page - new staff members added, committee members updated, new external appointments added, pharmacist and pharmacy registers updated and list of registered optometrists added

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Newfoundland and Labrador Pharmacy Board

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BOARD MEMBERS

Elected Members

Zone 1 ..... Debbie Kelly
Zone 2 ..... David Jenkins
Zone 3 ..... John Rideout
Zone 4 ..... Christina Tulk
At Large ..... Keith Bailey, Brian Healy, Linda Hensman

Appointed Members

..... Don Mifflin
..... Eugene Toope

Observer

MUPS Representative ..... Emily-Ann Munden

EXECUTIVE COMMITTEE

Chair ..... Keith Bailey
Vice-Chair ..... Christina Tulk
Executive Member ..... Debbie Kelly
Past Chair ..... John Rideout