The Island Capsule
Newsletter of the Prince Edward Island Pharmacy Board

June 2005

PRINCE EDWARD ISLAND PHARMACY BOARD

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MEMBERS

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Iain Smith (QEH)
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Connie MacKinnon, Layrep
Government Rep - Vacant

REGISTRATIONS

Pharmacists: 156
Permits: 41 + 7 hospitals + Provincial Phcy
Students: 28

This newsletter is distributed to all licensed pharmacists in PEI. Decisions regarding all matters such as regulations, drug related incidents, etc. are published in it. The PEI Pharmacy Board therefore assumes that all pharmacists are aware of these matters. It, and back issues, are also posted on the NAPRA website under "PE".

ENCLOSURES

1. Dal Preceptor Information
2. Dal Residency Program Info
3. Manual Additions
    a. Responsibilities of the Pharmacist-in-Charge, Pharmacist and Permit Holder
    b. Medication Errors Prevention and Reduction Guidelines
    c. Emergency Contraception Guidelines
4. PrISM – Emergency Contraception: An Introduction
5. Adverse Drug Reaction Newsletters
6. Health Canada Advisories - summary
7. Updated Physician/Dentist List & Pharmacist List
8. Survey on Loyalty Programs
9. Survey on Continuing Education and On-line CEs
10. New Regulation Changes and Additions

A DECADE OF ACHIEVEMENT – NAPRA CELEBRATES ITS 10 YEAR ANNIVERSARY

The National Association of Pharmacy Regulatory Authorities (NAPRA) is proud to announce that February 2005 marked its 1oth anniversary.

In 1995, Canada's provincial and territorial pharmacy regulatory bodies founded NAPRA to enable members to take a national approach in addressing common regulatory issues. Over the past decade, NAPRA has established itself as the formal recognized Canadian voice for pharmacy regulators, facilitating consistent input to Health Canada and other organizations on public protection issues related to pharmacy. The organization boasts a number of significant achievements including:

- The development of a national drug scheduling process and harmonized schedules regarding the conditions of sale for nonprescription drugs.
- The establishment of national competencies for entry-level pharmacists, which have been integrated into the licensing standards, as well as pharmacy educational programs' curricula and related accreditation standards.
- The implementation of the Mutual Recognition Agreement (MRA) that facilitates the movement of pharmacists across provincial borders.
- The development of 'Model Standards of Practice for Canadian Pharmacists' (April 2003), providing a framework and practical guidance for pharmacy practitioners to demonstrate compliance with professional standards of practice. NAPRA continues its commitment to superior pharmacy practice and the health of Canadians through the ongoing development of competencies reflected in the model Standards of Practice.
- The initiation of a collaborative relationship with international colleagues, such as the National Association of Boards of Pharmacy (NABP) in the United States.

NAPRA has built a strong foundation during its first decade of existence, under the leadership of founding Executive Director Barbara Wells. The organization remains committed to its values as the Board of Directors and new Executive Director, Ken Potvin, look forward to further strengthening the role of NAPRA as the national voice for Canadian pharmacy regulators both domestically and internationally.

HEALTH CANADA ADVISORIES

Health Canada Advisories and other Board GRID messages are being sent by e-mail directly to each individual pharmacist via the E-Link service and via Fax to pharmacies. Effective December 31, 2005 the Board will discontinue the Fax service of these messages. Pharmacists should ensure they have logged on to E-Link by then to receive this service. Pharmacy Managers are, and will continue to be with the E-Link service expected to inform pharmacists regarding all Health Canada Advisories and Board Grids.

MATERNITY LEAVES

Pharmacists are reminded that *Authorization Regulations 36(e)* states that licensure for less than four month is eligible for 50% of the licensing fee. Presently that would be $425÷2 = $212.50 + $25 CE ..net **$237.50.** The fee should be paid at regular registration time (i.e. March 31st) with clarification as to the months the pharmacists will not be practicing. The pharmacist must still maintain the 15 continuing education units for the next year's renewal.

AN ESTABLISHMENT LICENSE FOR PHARMACY NON-RETAIL SALES OF PHARMACEUTICALS

Provided by Canadian Association for Pharmacy Distribution Management

We have been informed via NAPRA of the following information. It was directed to the NAPRA office from James Bellis, Acting Manager of the Establishment Licensing Unit of the TPD of Health Canada.

A Drug Establishment Licence is required for all businesses in Canada engaged in any of the six activities related to the manufacturing and testing of all drugs in dosage form and bulk intermediates of Schedule C (radiopharmaceutical) and D (biological) drugs from the "Food and Drugs Act" and Schedule F to the Regulations The six activities are: fabrication, packaging/labeling, importation, distribution, wholesale, and testing.

From the Food and Drugs Regulations: **C.01A.01** – Wholesale – "means to sell any of the following drugs, other than at retail sale, where seller's name does not appear on the label of the drugs: (9) a drug listed in Schedule C, D, or G to the Act or in Schedule F to these Regulations; or (b) a narcotic as defined in section 2 of the *Narcotic Control Regulations.*

Practitioners and Pharmacists (from the Establishment Licence guidance document).

The activities of a practitioner, pharmacist or a person under the supervision of a practitioner are exempt from the licensing requirements of Division 1A only if all three of the following criteria are met: (i) the activity is pursuant to a prescription, (ii) the activity is limited to compounding or importing, (iii) the activity is related to a drug that is not commercially available in Canada.

The term "practitioner" as defined in Division 1 of the *Food and Drugs Regulations*, means "a person authorized by the laws of a province of Canada to treat patients with any drug listed or described in Schedule F to the Regulation".

Drug establishments are inspected by Health Products and Food Branch Inspectorate inspectors to assess whether the facility is operated in compliance with the requirements of Part C, Division 2 of the Food and Drugs Regulations pertaining to Good Manufacturing Practices (GMP). A Drug Establishment License will only be issued once the inspectors have assessed the firm as being in compliance with these requirements.

This requires a pharmacy manager to have an Establishment Licence to conduct any of the six activities outlined above, including pharmacy to pharmacy sales, bulk ordering for more than one pharmacy, or distribution to more than on pharmacy.

Not only does the need to have an Establishment Licence impact community pharmacies but it also has implications for Regional Health Authorities (RHA). To clarify, Health Canada personnel informed us of the following. A RHA that repackages drugs for distribution amongst facilities within the RHA and/or a hospital that purchases drugs for all the hospitals within the RHA and then distributes those drugs in the original manufacturer's container to other hospitals within the RHA would be considered a wholesaler and would require an Establishment Licence. This is also true when drugs are being distributed not only within the same RHA but also to other hospitals in adjacent communities in different RHAs. The RHA is obtaining, storing and distributing drugs and there is a charge for the transactions; therefore, it falls under the scope of this section of the "Food and Drugs Regulations".

Link to the Establishment Licence application form: www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/del_doc_el_elf_tc_e.html

Link to the Establishment Licensing guidance document www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gui_doc_el_elf_tc_e.html

METH WATCH PROGRAM

What is Methamphetamine?

Methamphetamine, also known as "meth," "speed," "crank," or "ice," is a powerful and highly addictive stimulant that affects the central nervous system. Meth is a synthetic drug produced or sold as pills, capsules, or powder that can be smoked, snorted, injected, or swallowed. As a neurotoxin, meth damages the nervous system. Its use can cause dependence and addiction, psychosis, stroke, dangerously high body temperature, and cardiac arrhythmia. Withdrawal often results in severe depression and paranoia.

Methamphetamine Production

Methamphetamine has been made in Canada and the United States, principally from bulk quantities of chemicals in so-called "super labs." Methamphetamine production, however, has changed significantly and law enforcement authorities have seen an increase in the number of small labs where meth cooks use "recipes," often found online, to create small amounts of the drug from legitimate household products. While these small homemade labs produce a tiny fraction of the methamphetamine a "super lab" may produce, they present a huge danger to the communities in which they operate because toxic, hazardous, and explosive chemicals are possible by-products of the production process.

Methamphetamine can be made from commonly available, legitimate household products

These small labs can be found in a methamphetamine "cook's" home, in an automobile, or alongside a road. The ingredients used to make methamphetamine are legitimate household materials, usually found at retail stores, such as:

- Over-the-counter cough, cold and allergy medicines containing pseudoephedrine or ephedrine
- Acetone
- Rubbing and isopropyl alcohol
- Iodine
- Starter fluid (ether)
- Gas additives (methanol)
- Drain cleaner (sulphuric acid)
- Lithium batteries
- Rock salt
- Matchbooks (red phosphorus)
- Lye
- Paint thinner
- Aluminum foil
- Glassware
- Coffee filters
- Propane tanks

Retailers are in a unique position to help law enforcement in the fight against methamphetamine, since the small-scale labs use a number of commonly found household products available at drugstores, supermarkets, and other retail outlets. The Meth Watch Program addresses this problem, and gives communities proven and powerful tools to help curb methamphetamine production.

Methamphetamine use is a growing problem across Canada and the United States. Law enforcement officials have raised concern about the illegal diversion of substances found in everyday items into underground methamphetamine production.

The Meth Watch Coalition partners support law enforcement efforts to stop the production and trafficking of methamphetamine. At the same time, the Coalition partners are dedicated to the rights of Canadians to obtain products needed in their daily lives.

That’s why they have introduced the “Meth Watch Program” to Canada to curtail the theft and suspicious sale of products containing pseudoephedrine and ephedrine, as well as other household items that can be used in the illegal manufacturing of methamphetamine. A Coalition of retail partners, law enforcement agencies, industry, pharmacy organizations and

government have come together to implement an effective national program to prevent diversion of legitimate products for illegal use.

Pharmacists are advised to visit the Meth Watch training program at www.methwatch.ca. Have your staff review the presentation on the website. Monitor the sales of pseudoephedrine and ephedrine. If you notice increased sales and/or larger volume purchases, you should contact the authorities and consider voluntarily moving the products onto a restricted area, such as the dispensary, where sales can be more closely monitored.

ENTRY to PRACTICE PHARM.D.

The "entry to practice Pharm.D." issue was raised during a national symposium hosted by the Leslie Dan Faculty of Pharmacy at the University of Toronto entitled "Pharmacy Education in the Future". There was discussion regarding the perceived need and desire for this change and what activity, if any, is occurring in the provinces. The University of Montreal has drafted curriculum that would admit their first all Pharm. D. class in the fall of 2006, with graduation scheduled for the summer of 2010. This change still requires the approval of the Quebec Government.

The Symposium did not produce a definite activity or defined goal to incorporate the entry to practice Pharm.D. into the Canadian Faculties of Pharmacy and will be ongoing.

PROFESSIONAL PRACTICE ISSUES

Copying Prescriptions in the Event of a Court Matter

In the event that the original prescriptions are required pursuant to a court matter, it is essential that the pharmacist retain/request a copy of the prescriptions removed from the premises as part of a subpoena.

Hydromorphone/Morphine Event

We wish to inform you of an ISMP (Institute for Safe Medication practices) report regarding the medication mix-up which occurred in Red Deer in June of 2004. In this case hydromorphone rather than morphine was administered to the patient. Unfortunately the patient died as a result of the mix-up. We offer this information as an opportunity to improve the safety of our own systems.

"On June 6, 2004 a fatal medication incident occurred at Red Deer Regional Hospital Centre in Alberta. A 69-year old patient received 10mg by intramuscular (IM) injection instead of *morphine* as intended. The patient experienced cardio-pulmonary arrest in the family car while being driven home by his daughter. His family transported him to the nearest hospital where he expired despite resuscitation efforts in the emergency department."
To view the ISMP report please access the ISMP-Canada website www.ismp-canada.org and select Bulletin Volume 4 Issue 6 June 2004.

Fentanyl Patch Alert

This incident reported by a family member of a Senior in an Ontario Nursing Home

"I want to share briefly an utmost unbelievable experience with the Fentanyl patches and its use in nursing homes, retirement homes, and home use. My father, and two other residents of a nursing home in another rural area, had the patches prescribed for chronic pain. After some time it was discovered that one of the unregulated workers at the home was using their patches for their own use. She has a drug dependency problem but stated to the court that she took them because she herself has arthritis.

She had access to the patches in several ways. They were discarded into the bedside garbage, or she took them off the resident's back, withdrew the medication with a syringe or made a small slit in the back of

the patch. She would replace the patch on their back, sometimes on backwards or replaced newly applied patches with old used ones.

One time she suffered respiratory arrest in my father's room and was resuscitated, taken to local hospital and transferred for a CT scan in a tertiary centre. Because the drug was not suspected then, no cause was noted for her arrest. Her own family MD stated it was due to hormonal changes so she returned to work, and continued her undetected activity for several more months.

These patches should be discarded in the sharps container or be incinerated. The risk of drug abuse is very high and accessible by vulnerable people if put in regular garbage. The package insert suggest flushing down the toilet, but that is not a safe disposal.

In my father's case the patch was changed every 48 hours, because his pain was so severe. At the time when the investigation was conducted, he was receiving 200mcg. Now his dose is 100mcg and his pain fairly well controlled. I am a registered nurse in a rural hospital and myself and other colleagues were unaware of the potential risk."

Blood Pressure Meter Accuracy
Saskatchewan College of Pharmacists
Taking accurate blood pressure is critical to managing hypertension. Since home monitoring is becoming very popular, correct use of the machines is also an important issue. A report by RUH hypertension experts found that local residents do make easily correctable mistakes when using home testing machines.

The pharmacist is an important source of information for helping patients make their purchase. Try a shelf talker – "*Looking for a blood pressure machine? Are you getting the correct cuff size?"* Here are some guidelines to help ensure accuracy:

1. Ensure the proper cuff size for your arm.
2. No tight clothing on the arm (no rolled up sleeves that are constrictive).
3. Rest quietly a few minutes beforehand. No talking and no one should talk to you.
4. No smoking or coffee prior to measuring.
5. Empty bladder before proceeding as a full bladder may cause your blood pressure to be high.
6. Keep the arm at heart level, resting it on the table.
7. Sit with you back supported, feet flat on the floor, legs uncrossed.
8. Take three readings and write them all down.
9. After purchasing a machine, have it initially checked at your doctor's office, then every six months to ensure its accuracy.

CFC-Containing MDIs
The last step in Environment Canada's efforts to eliminate CFC-containing MDIs became effective on January 1, 2005. As of that date, the production and importation of all MDIs containing CFCs are prohibited.

CFC-containing MDIs currently in your pharmacy or currently held by manufacturers and wholesalers may continue to be sold.

E-HEADCHE
College of Pharmacists of British Columbia Newsletter

When is an electronic signature or an electronic prescription acceptable? As technology creates new ways to generate and sign prescriptions, it's getting harder to decide what's OK and what isn't.

The key issue is whether you can ensure the authenticity of the prescription, including where it originated and who generated it. Here are some guidelines in what is acceptable:

Yes…. Computer-generated prescriptions presented by the patient with an original prescriber signature.

Yes…. Computer-generated prescriptions presented by the patient with an electronic signature and signed by the same prescriber.

Yes…. Faxed prescriptions signed by the prescriber (official form)

No…. Email prescriptions. If it appears on you screen it is not acceptable.

No…. Unsigned computer-generated prescriptions with only an electronic signature.

No…. Computer generated prescriptions

QUESTIONS AND ANSWERS

Q. I have a patient with cancer who wants to receive medical marijuana. What does the patient need to do?

A. The patient must apply to the Office of Cannabis Medical Access. Application forms are available online at www.hc-sc.gc.ca/hecs-secs/ocma.index.html, by telephone toll-free 866-337-7705, or by mail:
Office of Cannabis Medical Access
Drug Strategy and Controlled Substances Program
Healthy Environments and Consumer Safety Branch
Health Canada
Address Locator: 3503B
Ottawa, ON K1A 1B9

Q. We were working on a prescription for 100ml of Tussionex suspension. As the technician was attaching the label to the bottle, it tipped over and the contents spilled onto the counter and the floor. What should I do?

A. As required by the Regulations to the *Controlled Drugs and Substances Act*, you should report the loss (or theft) of controlled substances and substances directly to the federal Office of Controlled Substances within ten days of discovery. You can order loss and theft reporting forms from:
Compliance, Monitoring and Liaison Division
Office of Controlled Substances
Health Canada
Address Locator: 3502B
Ottawa, ON K1A 1B9

Tel: 613-954-1541
Fax: 613-957-0110

This is the same address to obtain permission for the destruction of outdated controls and narcotics.

MINISTER APPROVES NEW REGULATIONS

The Minister of Health has approved the following groups of legislation for the PEI Pharmacy Board:

Standards Regulations - effective retroactively to May 1, 2005
Authorization Regulations - effective retroactively to May 1, 2005
Drug Schedule Regulations - effective retroactively to May 1, 2005
Interchangeable Drug List Regulations - effective October 1, 2005.
I have attached copies of all the amendments for your information.

More information will follow, particularly with the Drug Schedules and the Standards Regulations as the Board works to develop an educational and implementation plan for pharmacists, pharmacies and the public. A full list of the drugs and how they are scheduled can be found at www.napra.ca. Please ensure the additional Pr products (e.g. Bactroban) are removed from front store sales, and that Schedule II products are

placed behind the dispensary. As well – the Standard of Practice must be complied with. There is still a supply at the Board office should someone need one, plus they are on the napra website.

METHADONE CARRIES

Pharmacists are reminded that "Carries" for methadone when used for opioid addiction can be given to patients *anytime for up to 4 days or a maximum of 400mg, whichever is the least.* .But if patients are taking more than 100mg per day – federal guidelines state that they cannot receive any carries except for weekends (to cover if the pharmacy is closed.

PHARMACY INSPECTOR

At the Board's annual meeting in June, David McLeod was elected Chair of the PEI Pharmacy Board for the 2005-2007 terms and Ken Ramsay was elected Vice-Chair. Because of this new position David has stepped down as pharmacy inspector. Should a pharmacist be interested in this position with the Board (there is an associated honorarium) please contact the Registrar.

Have a great summer everyone!