The Island Capsule
Newsletter of the Prince Edward Island Pharmacy Board

September 2005

PRINCE EDWARD ISLAND PHARMACY BOARD

P.O. Box 89
7-20424 Trans Canada Highway
South Shore Professional Bldg.
Crapaud, PEI C0A 1J0
902-658-2780 (fax 2198)
peipharm@pei.aibn.com

Registrar: Neila I. Auld, BScPharm
Office Hours: Monday thru Friday 9am-3pm

REGISTRATIONS

Pharmacists: 157
Permits: 41 + 7 hospitals + Provincial Phcy
Students: 28

This newsletter is distributed to all licensed pharmacies by mail in PEI. Pharmacists - in - Charge are expected to ensure their pharmacy staff receives a copy. Pharmacists will be receiving a copy via the NAPRA E-Link (email) service. 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. Flu Shot Info from The PEI Lung Association
2. Suplemental Standards of Practice for Schedule II and II Drugs

EMAIL AND FAX FAN-OUTS TO PHARMACIES

The Board will no longer be making large mail outs to pharmacists. The NAPRA email system – "E-Link" will be the primary source for information distribution. Information , Grids, newsletters will continue to be **faxed** to pharmacies. All pharmacists are encouraged to sign up to the NAPRA E-Link system – just email the Registrar for your user name and password. It is quite easy to forward the emails directly to your regular email…or use the NAPRA address as your own. Pharmacists-in-Charge will be required to ensure their pharmacy staff either have the email system activated, or receive a copy of the information distributed to the pharmacy.

Pharmacies- please ensure you have a functional fax for receiving Board information. There are several stores that it is extremely difficult to get a fax through to on a regular basis – and you risk missing important information.

Pharmacists are also reminded that under www.napra.ca (where you can link to E-link) there is a "PE" link that has all the Board's information and documents. The Act/Regs and all policies are guidelines are also there and updated regularly. The Board has a limited supply of copied Acts etc, and will no longer be providing them on hard copy.

CANADIAN ADVERSE REACTION NEWSLETTER

In the past the Registrar has included the Canadian Adverse Drug Reaction Newsletter in all mailings. Again, this will be distributed only to pharmacies. It is available through Health Canada on an automatic basis by signing up at www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/eubscribe_e.html. This will also see you receive other important Health Canada advisories and information important to practice in a timelier manner.

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.

KETAMINE UPDATE

Ketamine is now a "sales reportable narcotic". Ketamine has been used in extemporaneous products compounded by pharmacists. Health Canada has ruled that prescriptions for multi-ingredient extemporaneously prepared ketamine would be considered a "sales reportable narcotic" and requires a written order.

All ketamine coming into the pharmacy would need to be listed in the acquisition records of the pharmacy. All ketamine dispensed or used in the preparation of a compounded medication would need to be entered in the prescription sales record for narcotics. If it was used in the preparation of a compounded product, the amount used and the prescription number of the order, as well as all the additional required information, must be noted.

Prescriptions written by practitioners presently on file at the pharmacy with refills remaining can be considered as part-fills and/or confirmed with the prescriber as such. Health Canada has issued a statement that compliance with this new scheduling of ketamine as a narcotic was required by August 31, 2005.

SUMMER STUDENT

The Board received a grant from HRSDC this past summer. Troy Thomas, a Grade 11 student at Bluefield worked diligently on behalf of both the Board and the Association. He researched all Board files (as far back as we have) to compile a listing of pharmacists and certified clerks each year. He also designed a website for the PEI Pharmaceutical Association, and a "History of Pharmacy in Prince Edward Island". This was all given to the Association for further development and activation.

NAPRA's DIRECTORS and OFFICERS for 2005 – 2006

The following individuals have been appointed to the National Association of Pharmacy Regulatory Authorities (NAPRA) Board of **Directors** for the 2005 – 2006 term:

Janet Bradshaw – Saskatchewan College of Pharmacists
Sandra Carey – Newfoundland and Labrador Pharmacy Board
Jeannie Collins Beaudin – New Brunswick Pharmaceutical Society
Erica Gregory – College of Pharmacists of British Columbia
Jeannette Hall – Government of the Northwest Territories
Wally Kowalchuk – Prince Edward Island Pharmacy Board
Sandeep Sodhi – Nova Scotia College of Pharmacists
Burke Suidan – Alberta College of Pharmacists
Pat Trozzo – Manitoba Pharmaceutical Association
Regis Vaillancourt – Canadian Armed Forces
Janet Zral – Yukon Government

NAPRA Position Available [Sept. 2005]: Director of Pharmacy Practice Support

The primary role of this position is to direct and operationalize the management of NAPRA's activities within the scope of pharmacy professional practice. This includes, but is not limited to, professional competencies, licensing requirements, standards of practice, legislation, drug scheduling, safety advisories, and communication with practising professionals on regulatory matters. A position description is attached for further information.

If you are interested in joining our small but dynamic team in this full time permanent position located in Ottawa, please submit a cover

letter and resume via mail to the NAPRA office, or via email to kpotvin@napra.ca

DIRECTOR OF PHARMACY PRACTICE SUPPORT

Role

The primary role of the position of Director of Pharmacy Practice Support is to direct and operationalize the management of NAPRA's activities within the scope of pharmacy professional practice. This includes, but is not limited to, professional competencies, standards of practice, licensing requirements, legislation, drug scheduling, safety advisories, and communication with practising professionals on regulatory matters.

Reporting

This position reports to the Executive Director, NAPRA.

Key Responsibilities

- maintain the entry-to-practice competencies, with appropriate committee support
- maintain the Mutual Recognition Agreement
- maintain the National Model Licensing Framework
- screen and review all Health Canada and drug industry warnings and advisories to health professionals and ensure they are posted on the NAPRA website
- keep all relevant Federal legislation current on the NAPRA website
- maintain NAPRA's Model Standards of Practice for Canadian Pharmacists, practice guidelines, and statements, in conjunction with the National Advisory Committee on Pharmacy Practice and the Council of Pharmacy Registrars
- support the operations of the National Drug Scheduling Advisory Committee, as Secretary to the Committee
- assist in the maintenance and further development of a national resource centre of pharmacy practice guidelines and standards for the benefit of member PRAs
- assist in the development and administration of a national pharmacy jurisprudence assessment tool (pending)
- participate in collaborative work regarding specialty certification programs
- participate in consultations regarding technician competencies, certification and registration
- conduct a review of the VIPPS program in Canada and prepare a recommendation on its future
- liaise with departments within Health Canada to facilitate understanding and clear communication regarding issues concerning pharmacy practice
- liaise with pharmacy practice support staff in the member PRAs
- utilize and further develop the email communication system (E-Link), and the NAPRA website, to keep practising pharmacists informed about safety warnings and regulatory issues
- represent NAPRA on external committees or working groups, as delegated by the Executive Director
- manage projects assigned by the Executive Director
- function as the primary link to NAPRA Members and external stakeholders in regard to professional matters within the organization's Strategic Plan
- function as the staff resource to the National Advisory Committee on Pharmacy Practice
- function as the staff resource to the National Advisory Committee on Pharmacy Operations

Skills and Experience

As this position directly interfaces with pharmacy practitioners and regulatory bodies that oversee pharmacy practice, it requires an individual to be able to draw upon knowledge and experience gained over at least five years in pharmacy practice settings, particularly community practice. This position demands organizational, project management, and business writing skills. An ability to work well independently, along with a desire to become part of a small but dynamic team, is essential.

Qualifications

A minimum of a Bachelor degree in pharmacy, with a current license to practise in a province or territory in Canada, is required. Preferred qualifications would include advanced educational training and bilingualism (French).

SATIVEX® APPROVED WITH CONDITIONS

Sativex, a new drug on the market in July 2005, is a combination of plant-derived delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). It is administered via a pump spray under the tongue or on the inside of the cheek and is used for relief of neuropathic pain in adults with multiple sclerosis.

Cannabinoids such as Sativex and Cesamet® (nabilone) are listed in Schedule II of the Controlled Drugs and Substances Act. They are single entity narcotic drugs requiring a written prescription.

Pharmacists must record both the purchase and the sale of these products in the narcotic register.

For more information on Sativex, go to www.hc-sc.gc/dhp-mps/prodpharma/index_e.html

COMPOUNDED PREPARATIONS AND EXPIRY DATES

The Board has recently become aware that pharmacists may be unclear about how to establish an expiry or beyond-use date for compounded preparations.

We offer the following excerpts from *United States Pharmacopeia Dispensing Information (USP-DI) Vol. III Approved Drug Products and Legal Requirements*, 22nd ed. 2002.

The beyond-use date is the date after which a compounded preparation should not be used and is determined from the date the preparation is compounded.

Because compounded preparations are intended for administration immediately or following short-term storage, their beyond-use dates may be based on criteria that are different from those applied to assigning expiration dates to manufactured drug products. **When a manufactured product is used as the source of active ingredient for a non-sterile, compounded preparation, the product expiration date cannot be used to directly extrapolate a beyond-use date for the compounded preparation.**

In addition to using all available stability information, the pharmacist should also use his or her pharmaceutical education and experience. Pharmacists may refer to the manufacturer or applicable publications to obtain stability, compatibility and degradation information on ingredients. **All stability data must be carefully interpreted in relation to the actual compounded formulation.**

If there is no stability information that is applicable to a specific drug and preparation, the following maximum beyond-use dates are recommended for non-sterile compounded drug preparations that are packaged in tight, light-resistant containers and stored at controlled room temperature.

For non-aqueous liquids and solid formulations,

- **where a manufactured drug product is the source of the active ingredient**-the beyond use date is not later than 25 per cent of the time remaining in the product's expiration date or six months, whichever is earlier;

- **where a USP or NF chemical substance (which is not a manufactured drug product) is the source of the active ingredient**-the beyond-use date is no later than six months;

- **for water-containing formulations (prepared from ingredients in solid form)**-the beyond-use date is not later than 14 days when stored at cold temperatures; and,

- **for all other formulations**-the beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.

These beyond-use date limits may be exceeded when there is valid supporting and scientific stability information that is directly applicable to the specific preparation, i.e. the same drug concentration range, PH, excipients, vehicle, water content, etc.

WHEN THE FAX ISN'T FACTUAL

[Extracted from "ISMP Canada Safety Bulletin", Volume 4, Issue 12, December 2004)

If you're using fax machines or scanners to communicate prescriptions or medical orders, it's critically important to create a system of regular equipment maintenance and platen (roller in a fax machine or glass surface of a scanner) cleaning to avoid medication errors. An order, originally mistaken as **250 mg of FLAGYL** (metronidazole), was correctly interpreted as 500 mg once the original order was viewed. Since fax machines are connected to telephone lines, significant line "noise" can obliterate important information, such as portions of a drug name or even the dose. Transmissions via fax machines or proprietary image scanners can show streaks or fade-outs when dirt, dust, stuck paper, correction fluid, and even hole punches interfere with the scanned image. One frequent problem

occurs when unit coordinators affix small stickers to orders, such as a "sign here" arrow for prescribers, then forget to remove them when they scan or fax. The stickers can get caught in the machine, causing a black line across every order sent until it is cleared, or obscure information on scanned documents. A related problem: prescribers sometimes write on the very edge of the order form, making it impossible for fax machines and scanners to "read" the entire order. Thus, an order for "Lomotil QID PRN" may appear as "Lomotil QID" if the "PRN" is in the extreme right margin. In addition to ensuring regular maintenance, those who transmit orders need to be aware of the above stated conditions that could impede communication, and when recognized, correct them immediately.

PRACTICE Q & A

1. **Drug Schedules: What is the status of …?**

   Pharmacists and pharmacy technicians can determine drug schedules by accessing the NAPRA website and generating a drug schedule list. You should have the www.napra.org website bookmarked on your pharmacy's computer or keep an up-to-date print copy for quick and easy reference. Following is an example of the most common products whose status is requested:

Epi-Pen……..Schedule II

Mupirocin (topical)…….....Schedule I

Nitrolingual Spray…..……...Schedule II

Otrivin® 0.05% ophthalmic..Schedule II

Quinine……..Schedule I

Vitamin B12 injection……...Schedule II

Progesterone (topical)……Schedule I

Enclosed with this mailing is a copy of the "Supplemental Standards of Practice for Schedule II and III Drugs". These standards are to supplement the Model Standards of Practice for Canadian Pharmacists that were previously distributed. Both documents are available on the NAPRA website under "Pharmacy Practice". The Board office still has some copies of the National Model document – but this supplemental one must be downloaded if pharmacists wish a copy of their own.

3. **Expiry/Wastage/Drug Loss/Theft of Narcotic or Controlled Drugs: What do I do?**

You should contact the Health Canada office listed below for the appropriate forms and reports. All narcotics reporting issues should be reported to the Ottawa office. Controlled substances must be destroyed by a pharmacist and witnessed by another pharmacist, practitioner, or a registered pharmacy student.

Compliance, Monitoring and Liaison Division
Office of Controlled Substances
Drug Strategy and Controlled Substances Programme
Health Canada
Address Locator: 3502B
Ottawa, ON K1A 1B9
Tel: 613-954-1541
Fax: 613-957-0110

Reporting Expired/Unused/Wasted Narcotic and Controlled Drugs: send an itemized list to the above address for approval to destroy.
Reporting Narcotic Loss/Theft/Forgeries: submit a report to the above address within 10 days of discovery.

4. **Methadone: Can I verify a methadone prescriber with the Board?**

The Board no longer maintains a current list of methadone prescribers. Pharmacists can verify prescribers' terms of exemption (including expiry) by contacting Health Canada or the College of Physicians and Surgeons.
To confirm a methadone prescriber, or obtain information on MD revocations or suspensions, contact:
Health Canada Drug Control Unit:
For methadone and MD notifications: Ms. Kim Barber, 613-946-5139
PEI College of Physicians and Surgeons
Melissa MacDonald, 902-566-3861