

The Island Capsule

Newsletter of the Prince Edward Island Pharmacy Board

July 2004

PRINCE EDWARD ISLAND PHARMACY BOARD

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MEMBERS

Wally Kowalchuk, Chair & NAPRA Delegate
(Zellers Phcy)
David McLeod, Vice-Chair(A&M Pharmasave)
Greg Burton, (Medicine Shoppe)
Linda Gordon-MacEachern (Shoppers Drug)
Kerry Murphy (Shoppers Drug)
Iain Smith (QEH)
Nancy Canham, LayRep
Connie MacKinnon, Layrep
Mar Thomson, Government Rep

REGISTRATIONS

Pharmacists: 143
Permits: 40 + 7 hospitals + Provincial Phcy
Students: 21

*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.*

ENCLOSURES

1. Manual Additions
 - a. Lock and Leave Physical Barrier Amended
 - b. Collection, Use & Disclosure of Registration Information
2. Adverse Drug Reaction Newsletters
3. Correspondence re Changes to the Canadian Diabetes Associations Meal Planning System
4. Dextromethorphan: A Drug of Abuse
5. Dalhousie Pharmacy Endowment Fund Update
6. Recommendations on Drug Use in the Elderly (Ontario College of Pharmacists)
7. Dalhousie University Hospital Pharmacy Residency Program Information
8. Strategies for Reducing Medication Errors in Pharmacies (Alberta College of Pharmacists)
9. Erroneous Daily Oral Methotrexate Dosing (Alberta College of Pharmacists)

VERIFIED INTERNET PHARMACY PRACTICE SITES (VIPPS)

NAPRA recently launched the Canadian VIPPS Program. The VIPPS program was developed in 1999 by the National Association of Boards of Pharmacy (NABP) in the United States, in response to public concern about the safety of pharmacy practice offered through the Internet. In 2003, NAPRA entered into a licensing agreement with NABP to administer the program in Canada, so that Canadian pharmacies could also be recognized.

Given the increased promotion of pharmacy services on the Internet, the Board encourages Island pharmacies that offer Internet access to

their professional services to obtain VIPPS certification. The Board has recommended the public look for this “seal of approval” before utilizing Internet pharmacy services. Further information on VIPPS certification and applications can be accessed through the NAPRA website: www.napra.org.

CURRENT STATUS REGARDING THE REGULATION AND SALE OF MELATONIN IN PHARMACIES

Melatonin was previously considered an unapproved drug and could not be sold in Canada. With the introduction of the *Natural Health Products Regulations* on January 1, 2004, melatonin is now listed as a natural health product (NHP) under these new regulations. However, it has not been assigned a Natural Product Number (NPN).

The NPN is an eight digit numerical code assigned to each natural health product that has been approved for market under the *Natural Health Products Regulations*. The NPN appears on the product label and provides assurance of the product’s safety, effectiveness and quality. Without a NPN, the safety and effectiveness of melatonin has not been established and has **not** been approved for sale in Canada. Since the *Natural Health Products Regulations* came into effect in January, there are many non-compliant NHPs on the Canadian Market. Melatonin has been identified as a priority “1” product by Health Canada. This means that as of July 1, 2004, manufacturers must have an application into Health Canada for NPNs – or action will be taken to remove the product from the market.

Until such time that melatonin is assigned a NPN and the manufacturers are in compliance with the *Natural Health Products Regulations*, **pharmacies cannot sell melatonin** products. Clearly the products now being sold in some health food stores would violate the *Natural Health Products Regulations*. However, Health Canada has not yet enforced the rules. Notwithstanding, The PEI Pharmacy Act and Standards would prevent pharmacies from selling melatonin containing products. Knowing this, the sale may disqualify the pharmacy’s liability and malpractice insurance coverage.

Health Canada is advising physicians wishing to prescribe melatonin to their patients to submit a request to Health Canada, using the Special Access Program request forms.

For further information about the federal regulations, please contact the Natural Health Products Directorate information line at 1-888-774-5555.

PHARMACY-TO PHARMACY INVENTORY TRANSFERS

Any pharmacy/pharmacist who provides drugs to another pharmacy should be aware that he or she must have a federal Establishment License. Although this is not a new regulation, it has not always been enforced by Health Canada.

Many small pharmacies traditionally group together to meet a manufacturer’s minimum order requirement and then divide the drugs amongst the various pharmacies. However, with the growth of International Prescription Services, Health Canada is reviewing stricter enforcement of Establishment Licensure.

According to Health Canada’s Drug Inspection Unit, “all persons who sell drugs to customers other than the final retail customer” must have an Establishment License. This applies to pharmacies involved in

- Fabricating
- Packaging/Labeling
- Testing
- Importing
- Distributing
- Wholesaling

Obtaining a license is not onerous, and the pharmacist-in-charge must demonstrate compliance with Good Manufacturing Practices. You can locate more information checking the links below, or by telephone from James Bellis, Acting Manager of the Establishment Licensing Unit at Tel: 613-954-6790, Fax: 613-957-4147.

Link to Establishment Licensing application form:

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/del_app_v4_nov2003_e.pdf

Link to Establishment Licensing guidance document:

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gui_doc_el_elf_tc_e.html

Link to Food and Drug Act:

<http://laws.justice.gc.ca/en/F-27/>

Link to other relevant information:

http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/establishment_licenses_e.html

NEW DRUG REDUCES OPIOID CRAVINGS

Health Canada is considering an application to make available a new drug that can be used instead of methadone to treat opioid addiction. Already available in France, Australia and the United States, buprenorphine is a sublingual tablet that is as effective as methadone, and safer.

It may not be suitable for patients who need high doses of methadone to reduce their symptoms, but it will be a useful treatment option.

PIPEDA INFORMATION

Industry Canada has prepared an online questions and answers document on the *Personal Information and Electronic Documents Act* for the health care sector. It can be viewed at <http://strategis.ic.gc.ca/epic/internet/inecic-ceac.nsf/vwGeneratedInterE/gv00211e.html>

CANADIAN PHARMACISTS GET CONNECTED

Close to one-third of Canadian pharmacists can now take advantage of a webmail service provided by the National Association of Pharmacy Regulatory Authorities (NAPRA). Dubbed "E-Link", the nationwide service is designed specifically to suit the needs of pharmacists.

E-Link offers pharmacists free, secure email accessible any time, anywhere, from any Internet-connected computer. It provides an effective way to distribute urgent information such as industry and Health Canada warnings and advisories, changes in drug scheduling, and information regarding the regulation and practice of pharmacy.

"Pharmacists in Prince Edward Island have been one of the most enthusiastic groups to embrace E-Link", says (former) NAPRA Executive Director Barbara Wells. "With more than 50 users, PEI has one of the highest proportion of web-savvy pharmacists. Feedback from PEI pharmacists really helped us enhance the system".

Users told NAPRA they appreciate the ability to automatically forward their email to a personal email account and the user-friendly set-up that makes it easy to manage and customize email folders and addresses. E-Link also guarantees automatic password-protection and encryption of all messages.

At the NAPRA Annual General Meeting on March 28, 2004, Registrar Neila Auld and Board Chairman Wally Kowalchuk joined in discussions regarding aspects of E-Link with their counterparts from other provinces. Over the next few months NAPRA will promote awareness of E-Link across the country at various pharmacy meetings and events. "We really appreciate the Board's support in promoting this service", says Barbara.

"The success of E-Link depends on the support of Pharmacy regulatory bodies and pharmacists across Canada", says Barbara. "We believe E-Link can help control fee increases by reduced printing and mailing cost and saving staff time. Our goal is to have two-thirds of pharmacists from the Northwest Territories to Newfoundland – including those in PEI – registered with E0-Link by the end of 2005."

For more information on how you can sign on to E-Link, please contact the Board office at 902-658-2780 or email at peipharm@auracom.com.

PRESCRIPTIONS BY FAX

Pharmacists are reminded that physicians may fax prescriptions to pharmacies **provided the Health Canada/Board approved form/format is adhered to. This policy and form is available in Pharmacy Act Binders as well as at www.napra.org.** The order must be initiated "from" the physician and "to" the pharmacy (not the reverse).

METHAMPHETAMINE PRECURSORS

North American enforcement agencies are concerned about increased production and use of illegal methamphetamine. Due to the relative ease of methamphetamine production, they are urging greater control of the precursors, one of which is pseudoephedrine. Federal Precursor Control Regulations deal with bulk quantities and

wholesaler supply of targeted substances, but there is concern that illegal manufacturers may turn to consumer products containing pseudoephedrine.

The National Drug Scheduling Advisory Committee will review current placement of the drug in the Unscheduled category to determine if a higher level of control needs to be reinstated for pseudo-ephedrine products. In the meantime, pharmacists are asked to monitor large-quantity or frequent purchases of the products and to report any concerns to the national CrimeStoppers line at 800-222-TIPS.

DISPLAYING EPHEDRINE-CONTAINING PRODUCTS

Health Canada has reported that some ephedrine-containing products, such as 4 Ever Fit and Proenzi 99, are being incorrectly displayed in the weight loss section of retail outlets, including community pharmacies.

The department has asked us to remind you that products should not be displayed in a manner that promotes a non-indicated use. To do so could contravene the *Food and Drugs Act*, section 9(1).

If a product has a DIN, sales for a non-indicated purpose could put your pharmacy at risk if an injury to a consumer resulted from the inappropriate promotion of the product.

NAPRA NEWS

Here are some highlights of the services provided to the PEI Pharmacy Board and Island pharmacists by the National Association of Pharmacy Regulatory Authorities.

- *Compounding and Manufacturing Guidelines* – NAPRA has initiated work on the development of model national good compounding practices guidelines for pharmacists, and is working with the Canadian Veterinary Medical Association to develop guidelines for both pharmacists and veterinarians on the safe importation and compounding of drugs for animal use. In April 2004, NAPRA was represented on a

Health Canada focus group offering input into updating the department's June 2000 Manufacturing and Compounding Drug Products in Canada policy Framework.

- *Pharmacy Workforce Study* – NAPRA continues to play an active role in the pharmacy manpower study coordinated by the Canadian Pharmacists Association, the Canadian Society of Hospital Pharmacists, and the Canadian Association of Chain Drug Stores, through the support of Human Resources and Development Canada.
- *National e-Therapeutics Network* – Don Makowichuk, Alberta College of Pharmacists past president, is NAPRA's appointee to this CPhA project, designed to build drug management tools for physicians, pharmacists and nurses. The tools will provide evidence-based support for therapeutic decision making by delivering up-to-date drug and patient safety information to practitioners at point of care.
- *Cross-Border Sale of Prescription Drugs* – On April 27, 2004, NAPRA made a presentation to the US Human Health Services Task Force on Drug Importation. NAPRA's testimony and responses during the question period can be accessed on the US government's website at www.hhs.gov/importtaskforce/
- The NAPRA Annual Report is available at www.napra.ca/pdfs/about/03AnnualReport.pdf.