

The Island Capsule

Newsletter of the Prince Edward Island Pharmacy Board

October 2007

PRINCE EDWARD ISLAND PHARMACY BOARD

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REGISTRATIONS

Pharmacists: 163
Permits: 40 + 7 hospitals + Provincial Phcy
Students: 25

This newsletter is distributed to all licensed pharmacies in PEI, emailed and posted on our website. 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

MISSING NARCOTICS

Takes steps to ensure accountability

A recent incident in a BC pharmacy demonstrates the importance of maintaining accurate narcotic records and having a system that minimizes diversion risk.

The situation

A pharmacist found an unmarked bottle of narcotic tablets on a dispensary shelf. Upon further investigation it became apparent that narcotics were missing. A call to the wholesaler confirmed the company had received pharmacist-signed narcotic invoices, but corresponding invoices which should have been in the pharmacy could not be located. It is likely the scheme was used to send the signed narcotic invoices to the wholesaler, destroy those that should have been kept in the pharmacy, and then divert the narcotics upon delivery.

Contributing factors

- It was a busy pharmacy with a large staff.

- There was a high level of trust among staff members.
- Narcotic drug supplies were unpacked by numerous people.

Steps you can take

In the past, site visits by federal narcotic inspectors (which no longer occur) might have caught the diversion scheme. Now, pharmacists in charge need to play an active role.

- Examine policies and procedures for ordering, receiving, and handling narcotics.
- Use a perpetual inventory system to track any drug supply changes.
- Hard count narcotic drug inventories every three to six months.
- If a narcotic drug inventory count is off, print local software system narcotic reports and match each entry against hardcopy prescription.

THE PUBLIC HEALTH AGENCY OF CANADA AND PHARMACISTS

The Public Health Agency of Canada (PHAC) is an agency that focuses on more effective efforts to prevent chronic diseases, like cancer and heart disease, prevent injuries and respond to public health emergencies and infectious disease outbreaks. The PHAC works closely with provinces and territories to keep Canadians healthy and help reduce pressures on the health care system.

Interestingly, a pharmacist who receives Health Canada Advisories via e-mail may not receive advisories from PHAC! What does that mean to you?

The use on nonoxynol-9 has been reported in the past newsletter. This information, however, has been available as early as April 2003. The PHAC provided an advisory, but because most pharmacists may not receive PHAC advisories, may not have been aware of the issue prior to the information provided through the Board.

To receive advisories and notices from PHAC, please go to www.phac-aspc.gc.ca/maillist_e.html (an underscore after maillist) and enter your email address.

HEALTH CANADA ADVISORIES

Health Canada posts safety alerts, advisories, warnings, recalls, health advisories and other notices from industry on the MedEffect section of its website. Pharmacists can join the MedEffect mailing list to receive email updates from Health Canada about these advisories, along with the most recent publication of the Canadian Adverse Reaction Newsletter by going to the MedEffect section of the Health Canada website and simply providing your email address and clicking “subscribe”. Health Canada advisories are also posted on the NAPRA website (www.napra.ca).

Pharmacists utilizing the PEIPB/NAPRA E-Link system are currently receiving these advisories via “Communications”. **It is the responsibility of all pharmacists and in particular pharmacists in charge to take reasonable steps to receive these critical safety notices and to take action to advise their patients (and pharmacists) where appropriate.**

CHANGE TO PASSPORT GUARANTOR DEFINITION

As of August 15, 2007, people renewing their passports who meet eligibility criteria will have to submit only the old passport, two new pictures and the names of two references. These references can be anyone the applicant knows and references don't need to sign anything.

Effective October 1, 2007, first-time applicants will still have to submit proof of citizenship and a form signed by a guarantor, but the guarantor can be any Canadian passport holder and need not be a member of any specific occupation. For more details on guarantors and Simplified Passport Renewal Program, see Passport Canada's website at <http://www.pptc.gc.ca/index.aspx?lang=e>

COUNTERFEIT DRUG AWARENESS

Domestic instances few; foreign examples abound

A patient who enjoys the warmth and relaxation of Southeast Asia every winter tells you about that region's unbelievable inexpensive erectile dysfunction drugs; another patient journeying to Africa for a wildlife safari asks about purchasing prescription drugs while away. Your response? Patient beware.

While Canada's prescription and OTC drug supply chains are relatively safe, the same can't be said for other countries, particularly in developing parts of the world. This reminder is included in *Counterfeit Pharmaceuticals*

in Canada, a publication by the Criminal Intelligence Service Canada posted on the CPBC website at www.cisc.gc.ca/pharmaceuticals/document/counterfeit_pharmaceuticals_e.pdf (underscores after counterfeit and pharmaceuticals).

According to the publication, the World Health Organization estimates 10 percent of global drug supply is bogus, with that number rising to 50 percent in some South East Asian and African countries. However, this problem can strike close to home. In 2005, two Ontario pharmacies were charged with knowingly selling counterfeit medications. Furthermore, Canadian enforcement officials increasingly come across fake prescription drugs. In 2003, 14.8 kilograms of fake Viagra® were seized by Port of Vancouver officials.

Counterfeit Pharmaceuticals in Canada describes:

- The types of drugs most often counterfeited.
- Organized crime and bogus drug making and distribution.
- Details on the two Ontario incidents.
- Societal effects of counterfeiting, at home and abroad.

ADR REPORTING INCREASES

Health Canada says most interactions go unrecorded

Is it good news or bad news? Health Canada is experiencing an increase in the number of reported adverse drug reactions. The federal agency received more than 10,500 new reports in 2006. While this is an increase of only about 100 more ADR cases than the previous year, it also coincided with a 43% jump

in the number of ADRs from other countries for drugs available in our nation, which came to Health Canada's attention.

While over two-thirds of the 2006 domestic ADR reports submitted by drug and health-care product companies were categorized as serious, some experts see the overall reporting as a positive sign that health-care providers, patients, and other stakeholders are recognizing the seriousness of medication side effects.

ADR is voluntary across the country, but Health Canada has been tracking a steady increase over the past few years. The agency doesn't believe that more people are suffering from ADRs, but rather, more people are aware of the importance of reporting these events. Regardless, a Health Canada spokesperson told CanWest News Service, "We are aware that in most situations, there is considerable underreporting of adverse reactions.

PRACTICE ISSUES

Domperidone and Breastfeeding

The Fraser Health Authority's breastfeeding practice council has released a one-page information sheet on domperidone in lactation and passed this information along as a link to this topic of interest to pharmacists.

www.fraserhealth.ca/HealthInfo/PublicHealth/MedicalHealthOfficerUpdates

PHARMACY ELSEWHERE

UNITED STATES

Purdue Pleads Guilty to Misbranding

The Purdue Frederick Company, Inc agreed to pay more than \$600 million to resolve criminal charges and civil liabilities in connection with several illegal schemes to promote, market, and sell Oxycontin®, which the company produces, the Food and Drug Administration (FDA) announced on May 10, 2007.

An investigation by the FDA Office of Criminal Investigations uncovered an extensive, long-term scheme by Purdue to maximize revenues from the sale of Oxycontin through various illegal means, such as training its sales force to make false representations to healthcare providers about the difficulty of extracting oxycodone, the active ingredient, from the Oxycontin tablet; and to claim that Oxycontin did not cause euphoria and was less addictive than immediate-release opiates.

In addition, Purdue falsely labeled Oxycontin as providing "fewer peaks and valleys than with immediate-release oxycodone," and by representing that "...delayed absorption as provided by Oxycontin Tablets is believed to reduce the abuse liability of the drug."

To resolve the criminal charges, Purdue pled guilty to a felony count of misbranding a drug with the intent to defraud and mislead. As part of the plea, Purdue will pay a \$600 million settlement.

The FDA MedWatch Safety summary and press release are available at www.fda.gov/medwatch/safety/2007/safety07.htm#OxyContin

New Travel Sickness Drug

The Food and Drug Administration has approved a new travel sickness drug – for dogs. Cerenia™ (maropitant citrate), the first drug of its kind to gain FDA approval, is a tablet prescribed for dogs to prevent and treat vomiting due to motion sickness, commonly caused by car rides. An injectable form was also approved for use in dogs to treat nausea caused by chemotherapy and a variety of illnesses.

AUSTRALIA

Pharmacists down under will soon be connected electronically with other health-care providers by an electronic prescription system. Similar to our proposed DIS program, the Australian version is the country's first foray into electronic patient records. All states and territories will be required to take part in the initiative, with a nationwide rollout planned within two to three years.

PHARMACY TECHNICIANS: UPDATE ON CURRENT STATUS AND COMING CHANGES NATIONALLY AND PROVINCIALY

There is a lot of activity nationally regarding pharmacy technicians. The recent "NAPRA (National Association of Pharmacy Regulatory Authorities) Notes" bulletins (also included with this newsletter) have kept pharmacists informed about national efforts to review the feasibility of administering a national

registration process for pharmacy technicians and the development of national competencies for Canadian pharmacy technicians at entry to practice. NAPRA has done an extensive literature review of existing competencies and guidelines. The Pharmacy Examining Board of Canada (PEBC) has been hired by the Ontario College of pharmacists (OCP) to develop an entry-to practice examination. Although the OCP has called this a "national examination", any development would have to be based upon nationally approved competencies before it could be considered "national". Throughout Canada, provincial pharmacy licensing authorities are reviewing the issues of definition, role and registration of pharmacy technicians.

The Canadian Council for the Accreditation of Pharmacy Programs (CCAP) is preparing for their role in the accreditation of pharmacy Technicians programs based upon the nationally approved competencies.

Clearly, the development of national competencies is critical and NAPRA has taken a lead role. At the end of February, NAPRA, through the work of the member provinces and the National Advisory Committee on Licensing (NACL), drafted entry to practice competencies for pharmacy technicians that will be forwarded to external stakeholders for review and feedback. At the April NAPRA Board meeting, these competencies will be presented for approval.

The status of pharmacy technicians in Manitoba remains the "status quo", as under the existing *Pharmaceutical Act*

and regulations. Presently, there is no definition or qualifications for “pharmacy technicians”. The intention of the Board is to include a definition of a pharmacy technician in the regulations and a description of the tasks and circumstances under which tasks can be delegated. Subject to the approval of the Minister, the decision regarding how regulations will define technicians and their role in pharmacy practice will be developed.

Clearly, it is important for P.E.I. to participate in the national activity regarding the definition and role of the pharmacy technician and the melding of this activity into the provincial regulations.

This is indeed exciting times. However, the important message is not to have the current practice evolve in advance of the regulations. The role of the pharmacy technicians in P.E.I. Pharmacies must reflect the present act and regulations.

PERINATAL EXPOSURE TO DRUGS

New guide complete resource for health professions

CAMH (The Centre for Addiction and Mental Health) and the Motherisk program (Hospital for Sick Children, Toronto) will soon offer a new publication of interest to pharmacists.

Perinatal Exposure to Psychotropic Medications and Other Substances: A handbook for Health Care Providers Covers safe use and risks associated medications and substances taken during pregnancy and breastfeeding. It is available at no cost.

Scheduled for publication in May 2007, the handbook can be ordered by contacting CAMH (see website listed). This comprehensive guide includes information on:

- Pregnancy myths and facts, and the use of psychotropic medications and substances.
- Key principles of caring for women with substance use or mental health issues.
- Screening for substance and medication use in pregnancy.
- Counseling and the therapeutic relationship.
- Effects of the following drugs:
 - Alcohol
 - Amphetamines
 - Antidepressants
 - Antiepileptic drugs (AED)
 - Antipsychotics
 - Benzodiazepines
 - Caffeine
 - Cannabis
 - Club drugs
 - Cocaine
 - Inhalants and solvents
 - Lithium
 - Other sedatives
 - Opioids (including methadone)
 - Tobacco (cigarettes)

www.camh.net/Publications/index.html

QUESTION & ANSWER

Do I have to call the doctor each time that I receive a fax when there is no fax header information on the fax or the header information is incomplete or incorrect?

Faxes with no fax header information create problems for pharmacists as these look like photocopies or scanned prescriptions. Documentation is required that it is in fact a fax. The other problem is determining

whether it was sent from the physician's office or faxed by a patient. Where this occurs regularly from a physician and verified by the pharmacists, physicians should be reminded of the problems that this type of prescription presents.

Faxing is a method of transmitting information, however the facsimile prescription transmitted is considered to be a legal prescription. The fax-header information is only a tool that can be useful to pharmacists in determining the authenticity of a fax transmission. Fax headers identifying the originating fax number can be manipulated or even be misleading in some cases.

Pharmacists should not depend on the fax-header information as the determining factor that a prescription is authentic for the same reason that they should not rely on the header on a physician's prescription pad. Pharmacists should be using their expertise and judgment to determine the authenticity of the prescription as they would with any prescription.

It is not necessary to verify every faxed prescription, however, where doubts arise about the authenticity of the prescription, an unknown or unusual fax number may reinforce a pharmacist's doubts and it may be appropriate to verify the number against available information on the physician or their practice sites, e.g. walk-in clinics, nursing home, hospital, etc. Where any doubt or question about the prescription still exists, the physician should be contacted.

When I receive a faxed prescription, am I required to know what has happened with the original prescription?

This is a question many pharmacists ask as the original written prescription and the faxed prescription are both considered valid prescriptions. The responsibility for the original prescription lies with the prescriber. In situations where a prescription has been

faxed and the patient brings in the written prescription, pharmacists should remind physicians of the potential risks of this practice (especially with narcotics) or educate physicians to suggest the prescription "faxed to ABC Pharmacy, patient has original" or other methods.

A patient from Alberta moved into my community pharmacy's neighborhood, and he would like me to dispense a prescription prescribed by an Albertan pharmacist. Can I do this?

No – PEI pharmacists cannot fill prescriptions initiated in Alberta because in PEI they are not currently recognized as prescribers.

What is the status of DHEA, dihydroepiandrosterone, in Canada?

Health Canada has recently declared DHEA a controlled prescription drug. This means it no longer requires special access. Since a DHEA product is not currently available in Canada, the drug must be prepared in compounding pharmacies. As with all controlled drug products, a prescription for DHEA cannot be transferred. Refills may be authorized on original written or verbal prescriptions and must indicate the number of refills and corresponding intervals.

Flomax® (tamsulosin) 0.4 mg in no longer available in Canada. I have a number of patients who still have active refills left on their original prescription. Can I automatically substitute Flomax CR® (tamsulosin) 0.4 mg?

The manufacturer says Flomax CR® is not automatically interchangeable with Flomax® regular release because their pharmacokinetics aren't the same; even though they are both dosed once daily, the AUC and the T max are different. Physicians should be made aware that Flomax® regular release is no longer available. Use your professional judgment to dispense Flomax CR® when a previous

Flomax® prescription allowed for refills. The key is to communicate with the physician and the patient. Fax or call the physician with information about what is being dispensed so he or she can approve the switch and monitor the patient. This process is equivalent to getting a new authorization for Flomax CR®.

I have just received a prescription for Champix™ (varenicline tartrate), the new selective nicotinic receptor agonist to help people quit smoking. The starter kit contains white 0.5 mg tablets and a blue 1.0 mg tablets. The starter pack does not have its own DIN. How should I process the prescription on PharmaNet?

Health Canada did not provide a unique DIN for the product, so the starter pack will have to be processed as two separate prescriptions, one for the 0.5 mg tablets and one for the 1.0 mg tablets.

Pharmacists should use their professional judgment when labeling the starter kit.

The labeling for the 0.5 mg Champix™ tablets could be: “On day 1-3 take one white tablet daily; day 4-7 take one white tablet twice daily.”

The labeling for 1.0 mg Champix™ tablets could be: “on day 8 onward take one blue tablet twice daily.”

DIS IMPLEMENTATION

Pharmacists are reminded they must be prepared to comply with the Pharmacy Informatics Act and Regulations via the DIS project this coming January. If you did not participate in the Live CE held in Charlottetown or Summerside you must complete the on-line CE (valued at 1.5 CEU). See www.gov.pe.ca/go/pharm. You must also complete the 20 questions following the CE.

PATIENT-INITIATED PART FILLS

When presented with a prescription for a narcotic and the patient only wants a part of the order, you can treat the prescription as a part-fill even though there are no physician-indicate intervals. Be sure to document the request on the prescription.

NEW ADMINISTRATIVE ASSISTANT

The Board would like to welcome Rachel Lowther to the Board office as an administrative assistant. Her addition to staffing will see the Board office accessible for full weekdays, and she generally will be working Mon – Fri 1-5pm.