The Island Capsule
Newsletter of the Prince Edward Island Pharmacy Board

June 2008

PRINCE EDWARD ISLAND PHARMACY BOARD

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REGISTRATIONS

Pharmacists: 167
Permits: 41 + 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

ARE YOU USING YOUR NAPRA/PEIPB EMAIL?

Are you using the NAPRA/PEIPB e-mail system? If not, you are left out of receiving important information in a timely way.

The Board sends information to registrants using only electronic means. You could lose out on safety or other information important to your practice if you aren't part of the e-mail system.

If you haven't signed on, please do so soon. If you prefer not to have more than one mailbox to review each day, you can forward the Boards e-mail to another e-mail address.

Every P.E.I. Pharmacist has been given a username and password for the system. If you've forgotten yours, please contact the Board office.

www.healthregistrations.ca

Pharmacists are reminded that the renewal and file updating process is now done on-line. If you require assistance, contact the Board office. We are in the process of adding permits, and students to the process.

ONTARIO & QUEBEC TO REJOIN NAPRA

Over the past year, there has been considerable discussion between representatives from NAPRA, the National Association of Pharmacy Regulatory Authorities, and the Ontario College of Pharmacists (OCP) as well as the Ordre des pharmaciens du Quebec about both Colleges rejoining NAPRA. Presentations were made to the OCP Executive over the summer to discuss the proposed changes to the vision; funding and governance models that NAPRA hoped would entice Ontario and Quebec to rejoin. In November, President Gdyczynski and Registrar Williams, as well as Ms Lambert, Registrar, Ordre des pharmaciens du Quebec attended a visioning and strategic planning session of NAPRA where their governance model was reviewed. Size of the board, committee to board relationship, voting structure and funding issues were discussed. The result of this session was that NAPRA Council agreed to approve a consensus-based governance model, strongly supported by both Ontario and Quebec, similar to the one adopted by the Federation of Health Regulatory Colleges of Ontario. Council was satisfied that this model will focus on similarities rather than the differences, and will ensure that all NAPRA activities move forward on a consensus basis.

Council also supports the new funding structure which requires Alberta, British Columbia, Ontario and Quebec to pay annual fees of $75,000, a significant drop from the previous per capita levy of $26.57 when Ontario withdrew membership in 2001.

Council's unanimous support of this endeavor has ensured that Quebec rejoins NAPRA, confirmed in early January. NAPRA is now a truly national pharmacy regulatory organization.

NATIONAL PHARMACY TECHNICIANS COMPETENCIES DOCUMENT ADOPTED

In November 2006, NAPRA initiated a process to establish national competencies for pharmacy technicians at entry to practice. NAPRA recognized the need for a national competency document that will serve as a foundation for national educational, accreditation and examination standards.

Recognizing the considerable work already completed by other pharmacy stakeholder organizations, NAPRA facilitated a workshop that included pharmacy technicians from each province, and representatives from provincial regulatory organizations such as the Pharmacy Examining Board of Canada, the Canadian Society of Hospital Pharmacists, Canadian Pharmacy Technician Educators Association, Association of Faculties of Pharmacies of Canada, Canadian Association of Pharmacy Technicians and Canadian Council for Accreditation of Pharmacy Programs. The Board adopted the NAPRA *Professional Competencies for Canadian Pharmacy Technicians at Entry to Practice.*

The PEI Pharmacy Board is participating in Task Force with the NS Pharmaceutical Society studying for a process to formalize the training and licensing of pharmacy technicians. Norma Vass (Pharmacist) and Debbie Lavers (Pharmacy Technician) are representing P.E.I. on the committee.

BRUSH UP ON TEETH/HEART CONNECTION

Can oral hygiene regimen make or break a heart?

If you are looking for a topic to discuss with patients at an upcoming information session, how about the growing body or evidence that suggests a like between tooth decay and heart disease?

A recent study in the journal *Heart* has added more information to this theory. The journal study followed 12,000 people in the United Kingdom who entered university from the 1940s to 1960s, up to 2005.

The researchers examined the participants' school-entry medical and dental records, and then later traced them through National Health System records. The scientists were able to determine that those who experienced teeth loss due to cavities and gum disease early on in the study were at risk of developing heart disease later in life. Other academic studies have reached similar conclusions, although no study, including this most recent one, has based its findings on a comparative clinical investigation.

In the *Heart* study, researchers found that subjects missing nine or more teeth in young adulthood were one-third more likely to die of heart disease as older adults than contemporaries missing fewer than five teeth. Overall, those with the most severe tooth loss as students were 35 per cent more likely to have died than those missing fewer than five teeth.

The tooth decay-heart disease scenario is bacteria based. Scientists believe the same germs that cause cavities and gum disease may enter the bloodstream and either damage blood vessels or create an inflammation response in the body that lays the groundwork for future heart disease.

Lead researcher Dr. Yu-Kang Tu of the University of Leeds, told Reuters Health that unlike similar studies this one looked at oral health early in life rather than in old age.

Source: Reuters Health
www.heart.bmj.com

DIABETES DRUG COMBO

Blood sugar levels better controlled

A recent study published in *Diabetes Care*, the journal of the American Diabetes Association, found that two drugs are better than one when it comes to controlling blood sugar levels in Type 2 diabetes patients.

The two drugs in the study were sitagliptin and metformin. Just over 1,000 Type 2 diabetes patients received either one of the drugs, both of the drugs, or placebo. At baseline, the average A1C level was 8.8 per cent. All study patients who received drug treatment benefited over those in the placebo group, with those receiving both drugs registering the greatest improvement. After six months, 66 per cent, and 44 per cent of the same group had A1C levels of less than 6.5 per cent.

Source: Reuters Health
www.care.diabetesjournals.org

PRACTICE NOTES

New cancer website
Free oncology journal access

Healthcare professionals and patients seeking cancer-related treatment information have a new online source to consider. European publisher Reed Elsevier has launched a website with access to scientific journals that normally come with a subscription fee attached. The website (URL below) provides access to a number of academic publications, including *Lancet Oncology*, *The Breast*, *Cancer Letters* and *The American Journal of Medicine*, and links to other resources. Users must register with the site, but the company has waived subscription fees.

Go to: www.oncologystat.com

WHAT WENT WRONG?

The Institute for Safe Medication Practices Canada (ISMP Canada) published a safety alert earlier this year, following up on a comprehensive safety bulletin published in 2003, to help health care providers avoid errors in prescribing, dispensing and administering methadone.

Two case studies from the 2003 safety bulletin illustrate some of the potential problems.

Case Study #1

A patient was taking 13mg/day of methadone prepared by a community pharmacy using a methadone stock concentration of 1mg/mL. The patient was hospitalized, and a telephone order for 12 ml methadone po daily was received by a nurse from a physician, who assumed the hospital's stock solution was the same strength as the community pharmacy's.

A technician using 10 mg/mL stock solution of methadone prepared the order. A pharmacist checked it against the pharmacy copy of the original order and the patient's in-patient medication profile. The methadone stock bottle was verified, and the technician had left the syringe used to measure the volume pulled back to 12 mL.

The patient received 120 mg methadone, but fortunately, vomited much of the dose. The patient recovered without any further medical intervention.

Case Study #2

A patient receiving methadone for pain control from a community pharmacy reported that she felt unwell (pale, sweaty, clammy, shaky) two days after receiving her prescription for 8 mL of a 5 mg/mL stock solution (total dose 40mg)

When the prescription was checked, the prescribed dose for the patient was 14 mL (total dose 70mg). The significant under dose resulted in withdrawal symptoms, in addition to inadequate pain control.

Keeping patients safe

Methadone's dosing complexities and other contributing factors, such as dosing errors and errors associated with nomenclature, have resulted in multiple reports in Canada and the U.S. of medication errors resulting in serious patient harm.

ISMP Canada recommends that all health care providers involved in prescribing, dispensing and administering methadone have standardized policies and procedures for the management of the drug.

The following risk-reduction actions should be incorporated into practice if they are not already routine activities:

- All methadone orders must be written in mg, not mL
- Prescribers should write the methadone dosage in words.
- Dates and times for administration should be specified (avoiding the use of the word "daily").
- Concomitant use of methadone with other narcotics, benzodiazepines and sedatives should be avoided.
- Pharmacies should stock only one concentration of methadone.
- If more than one concentration is required to manage patients appropriately, use prominent warning labels.
- When compounding methadone from powder, use a standard manufacturing formula, maintain a manufacturing log and clearly label the finished product.

PRACTICE NOTES

Providing bone density testing results appropriately

Many pharmacists are now involved with offering bone density screening clinics in community pharmacies as a way to raise public awareness about the importance of preventative care.

Performing the technical functions of the bone density test is not a reserved action of any designated health profession. Because pharmacists are aware of their scope of practice limitations, the council of the Board agrees that pharmacists can provide this service.

However, it is incumbent on each individual pharmacist involved with bone density screening tests to ensure they have the required knowledge, skills and abilities to do so.

It is also very important that test results not be provided in the form of a diagnosis. Pharmacists can provide the numerical test results to the client, and clients with questionable results should be referred to their family physicians for follow-up and diagnosis by the physician.

DRUG UPDATES

For full details please check:

www.napra.ca

- Side-effects of *Baby's Bliss Gripe Water* (apple flavor) – code 26952V
- Unauthorized health products by Wild Vineyard.
- Recall of Ultiva® (remifentanil hydrochloride) 1 mg vials.
- Precautions during cold and flu season.
- Suspension of MMR-II vaccine lots 1528U, 1529U, 1680U, sold by MerckFrosst Canada.
- Availability of Trasylol® (aprotinin).
- Use restrictions for Avandia® (rosiglitazone), Avandamet® (rosiglitazone and metformin), and Avandaryl™ (rosiglitazone and glimepiride).
- Precision Xtra™ blood glucose monitor from Abbott Diabetes Care

ARE PHARMACISTS ALREADY "PRESCRIBING"?

The answer should probably be "Yes", especially when we consider drug products designated as Schedule II in the NAPRA National Drug Schedules. While less strictly regulated than Schedule F, controlled or narcotic drugs, access to Schedule II drug products requires professional intervention by a pharmacist. While a written prescription is not required under the current legislation, a pharmacist providing an individual with access to Schedule II products has accepted responsibility for the safe and effective drug treatment of that individual.

Recently, the Manitoba Pharmaceutical Association (MPhA) received a complaint call from a patient who was denied access to a Schedule II injectable local anaesthetic product. After a brief conversation with the individual, it soon became apparent that the pharmacist had intervened and it had been the pharmacist's professional judgment that self-treatment with this drug product would have been unsafe for the individual. While this scenario illustrated responsible "prescribing" by the pharmacist, it also suggests that some individuals are under the misconception that the pharmacist cannot deny the public access to Schedule II products. The pharmacist, in this case, provided the appropriate care by refusing to provide the product and referred the patient to a medical practitioner.

It is possible that some pharmacists may have facilitated this public misconception. To comply with the regulations, the pharmacist can only sell a Schedule II drug, including exempted codeine products, after discussing with the purchaser (patient) the condition or symptoms being treated. A gesture to the pharmacy technician to supply a Schedule II product, does not comply with the regulations. At a time when the profession is involved in developing new legislation that may include increased prescriptive authority, it is important to review the regulations and the Standards of Practice for Schedule II and III Products to ensure practice meets the professional responsibilities with respect to providing safe and effective care for patients. *The Supplemental Standards of Practice for Schedule II and III Products (June 2005)* may be found on the NAPRA website (mapra.ca) by selecting Pharmacy Practice.

HOUSE GIVES ROYAL ASSENT TO PHARMACISTS PRESCRIBING

The Board continues to push for **"Continued Care Prescriptions"** and met with the Minister's department with a proposal for long term addressing of pharmacists prescribing. We were successful in having a Bill tabled in the legislature this spring that amends the Pharmacy Act to include pharmacists under the definition of "prescription": *a direction for the preparation and dispensing of a drug that is given by*
(i) a person authorized by the laws of any province or territory to practice as a physician, dentist or veterinarian
(ii) a person authorized to do so by the Minister under section 14.1 (eg: nurse practitioner), or
(iii) a pharmacist.

It also includes under the definition of the "practice of pharmacy" *"giving a prescription for a drug"*.
Under the "functions of the Board" is added "*prescribe conditions and restrictions on the authority of pharmacists to give prescriptions"*.

Compared to other jurisdictions, this wording is monumental for PEI. Now we can start work on the specific regulations. Our proposal is to initially have "continued care prescriptive authority" – that will, over time expand the role of the pharmacist in prescribing and ordering certain lab tests. If anyone would like to have a copy of the proposal – please contact the Board office and it can be emailed it to you.

SPECIALTY CERTIFICATION – ADVANCED PRACTICE IN PHARMACY

The Registrars met with CCCEP Executive Director in April to discuss their initiative in "**Post Entry to Practice Certification Programs in Pharmacy".** This is not intended to be "specialization" – it is not intended to add a designation to a pharmacist's license. Rather it will be a "certification" – or recognition of an "advanced practice". "Specialist" would need to be modeled after other health professions with broader education – eg: How a physician becomes a specialist in a particular field of medicine. Highlights of the CCCEP process include:

- Once certified, there would be a time limit and would need to be reviewed.
- If you have been practicing in that area, what you need to renew may be different than if you haven't been practicing the advanced field.
- The "certification" will not be done by CCCEP, but by the individual licensing bodies that will accept the recommendations of CCCEP.
- The programs cannot just be knowledge-based programs – they must be practice or substance-based.
- There is a need to develop standards for the programs and also to develop knowledge and practice standards for the programs.
- A pharmacist could be liable if they advertise a certification without ensuring the validity of the program they undertake. Standards will be needed around the promotion or advertising of the advanced training.
- There is a need to get on with a new rigorous framework for recognizing these programs. When a pharmacist invests in a program, they need to know the value of the course and the standards to work from.

When a program is accredited – the pharmacist would receive a "certificate of completion" being certified. For vendor type of programs (eg: Roche INR) CCCEP could possibly assess the program based on set standards.
Each licensing body has a CCCEP representative that should be keeping their respective Registrars informed of the process – as there are regulatory issues that need to be monitored and addressed as this

all unfolds. Nationally, the NAPRA ED will maintain a close link with the CCCEP ED.

Pharmacists are reminded again:

Section 29 defines professional misconduct as:

(k) "purporting to have a qualification or special expertise which he does not in fact possess and which has not been recognized by the Board"
(o) "advertising that is, in the judgment of the Board with reference to such written guidelines as may be developed, improper or misleading"

Such advertising guidelines go further to say with regards to advertising language:

(2)(c) *"use of the term "Specialist" or any similar designation suggesting a recognized special status or accreditation as a pharmacist or pharmacy on any letterhead or business card or in any marketing activity, unless the person to whom the advertising related possesses a specialization granted pursuant to a program approved by the PEI Pharmacy Board".*

The Board has routinely advised pharmacists of this issue, including a newsletter in December 2007, through emails and most recently in the Annual Report to the PEI Pharmacists Association. Until such time as the CCCEP accreditation process is complete, pharmacists may not claim a specialty or advanced practice in any area of pharmacy practice.

Again, I do have a copy of the initial draft document from CCCEP should anyone like a copy.

PRACTICE ELSEWHERE

Ohio Pharmacist Indicted for Manslaughter after Lethal Error

Ohio pharmacist Eric Cropp was responsible for reviewing the work of the technician whose medication error claimed the life of a 2-year-old girl in February 2006. As a result, an Ohio grand jury indicted him on August 9, 2007, for involuntary manslaughter and reckless homicide. Both charges carry penalties of up to five years in prison. The technician, Katie Dudash, was not indicted.

The medication error occurred at Rainbow Babies and Children's Hospital in Cleveland, OH, where Emily Jerry was undergoing chemotherapy. The intravenous medication that Emily received should have been mixed in a standard bag of 0.9% saline. Instead, Dudash reportedly mixed the drug with a 23.41% concentration of sodium chloride.

Cropp, the supervising pharmacist, was responsible for reviewing her work; nonetheless, the mistake was overlooked, and the lethal dose was administered. The patient died three days later.

Dudash was fired after the incident. The Ohio Board of Pharmacy revoked Cropp's license in April 2007 for this mistake and 14 other errors he committed since Emily's death while working at three retail pharmacies. As the Board has no jurisdiction over technicians, Dudash did not face any disciplinary action.

(See "Child's Death Prompts State and Federal Governments to Propose Regulations for Pharmacy Technicians" in May 2007 issue of the NABP Newsletter, accessible at www.nabp.net)

COMPETITION BUREAU SELF-REGULATED PROFESSIONS STUDY

The Competition Bureau released its study of Self-regulated Professions on December 11, 2007. The report focused on accountants, lawyers, optometrists, pharmacists and real estate agents. Some of the issues identified were related to Pharmacy Human Resources (labour, mobility and International Pharmacy

Graduates) and advertising. The Executive Summary is a disappointing read from the pharmacy practice perspective. Not too surprisingly, the report leans towards an increase in competition within the self-regulating professions, and removal of advertising restrictions will better serve the public interest. However, the section devoted to Pharmacy is a little more applicable to the self-regulation of a health care profession. The report can be view at: www.competitionbureau.gc.ca/epic/site/cb-bc.nsf/en/02523e.html

ELECTRONIC PRESCRIPTIONS (e-Rx)

Contrary to the previous advice given to Canada's provincial and territorial pharmacy and medical regulatory authorities by Health Canada we are now in receipt of a *Policy Statement on E-prescribing* stating "there are currently no regulatory impediments to moving ahead with electronically generated and transmitted prescriptions and that these are permissible to the extent they achieve the same objectives concludes by advising Health Canada has initiated discussions with regulatory authorities in order to determine how it can be of assistance in facilitating cooperation between the provincial and territorial stakeholders regarding e-Rx implementation.

The Provincial regulators (PRA's) are responsible to Health Canada to ensure the appropriate standards are in place regarding authenticity, security, privacy-protection and authorities are looking to Canada Health Infoway for the technical standards and there are development projects underway in both Alberta and Newfoundland and Labrador.

To date there is no system of e-Rx approved for implementation in Prince Edward Island or any other Canadian province. **Prescriptions faxed to pharmacies from a physician's office software system, without being actually signed or providing a "unique identifier" by the physician are not authentic, secure or private and do not meet Health Canada's policy.** The graphic picture of a signature added by the physician's computer is analogous to a rubber stamp and therefore not acceptable. Prescriptions issued in this manner are not legal and do not meet the Health Canada Policy Standards, particularly for privacy protection, security and authenticity.

The future of the e-Rx initiative will be best realized within an integrated electronic health record system. There is much work to be done to deal with such a fundamental change in the information flow between pharmacists and practitioners. For example:

- Prescription data entry will become the responsibility of the prescriber, not the dispenser.
- How will the system handle modifications to the prescription made by the dispenser?
- How will the system handle dispenser refusal to fill situations?
- How will the system handle transfers of prescriptions from one dispenser to another?
- There needs to be freedom of choice of dispenser for the patient.

The full potential of e-Rx will also require the acceptance of both physicians and practioners.

SALE OF PSEUDOEPHEDRINE IN PRINCE EDWARD ISLAND

Pharmacy Only Sale: In Prince Edward Island, the sale of pseudoephedrine is directly covered by regulations to *The PEI Pharmacy Act.* The regulations and the *Act* restrict the retail sale to pharmacies only. Single ingredient pseudoephedrine must be sold as a NAPRA Schedule II product from behind the dispensary with pharmacist intervention. Combination products are Schedule III and may be sold in an area "immediately adjacent" to the dispensary.

Non Pharmacy Sale: The regulations and the *Act* restrict the retail sale in pharmacies only. Other provinces may not have as strong or as direct a regulatory link to legislation that prevents the sale of pseudoephedrine from outlets that are not licensed as a pharmacy. Although some court challenges to over rule the "Pharmacy Only" sale may have been successful in other provinces, these decisions do not apply in Prince Edward Island. Prince Edward Island pharmacists, noticing the sale of pseudoephedrine in a Prince Edward Island non pharmacy outlet, are encouraged to advise the retailer of the regulations governing the sale. The retailer can return the product to their wholesale, as it should not have been sold to someone who cannot sell the product by retail. Should the retailer choose not to discontinue the sale, the matter can be referred to the Registrar, Neila Auld and the PEIPB will follow up.

CHANGES TO THE DRUG ADVERTISING RESTRICTIONS UNDER THE FEDERAL *FOOD AND DRUGS ACT* AND THE CORRESPONDING REGULATIONS

Drug advertising in Canada has been far more restrictive than in United States. The restrictions are contained in the federal *Food and Drugs Act (FDA)* and its regulations. Advertising any drug to the general public as a treatment, prevention or cure of any of the diseases listed in schedule A to the FDA is not permitted. This will change **June 1st 2008.**

Changes will occur to the *Food and Drug Regulations (FDR),* the *Natural Health Products Regulations (NHPR),* and the *Medical Devices Regulations (MDR)* that will:

(1) Revise the list of Schedule A diseases; and
(2) Exempt natural health products (NHPs) and certain drugs from the prohibition of preventative claims for the diseases listed in Schedule A.

Schedule A to the FDA is a list of diseases, disorders or abnormal physical states (hereafter referred to as diseases) for which preventative, treatment, and cure claims are prohibited by subsections 3(1) and 3(2) of the FDA (hereafter referred to as section 3) in the labeling and advertising to the general public of any food, drug, cosmetic or medical device.

The broad terms "preventative" and "treatment" that are used in the FDA have always been interpreted by Health Canada to include "risk reduction" and "symptomatic treatment", respectively. Therefore, preventative, risk reduction, treatment, symptomatic, and cure claims are prohibited in the labeling and advertising to the general public for diseases listed in Schedule A. Examples of Schedule A diseases are cancer, appendicitis, gout, and heart disease.

NHPs and drugs that are subject to these new regulations will be permitted to carry preventative claims in the labeling and advertising to the general public for diseases that remain in Schedule A. For these NHPs and drugs, prevention of a Schedule A disease generally does not re3quire practitioner intervention, but treatment or cure of a Schedule A disease would. It should be noted that these products are subject to all other provisions in the FDA, the *Controlled Drugs and Substance Act* (*CDSA)*, and their regulations, therefore, any other restrictions on the labeling and advertising of claims or any conditions for the market authorization of these products will remain in place. Advertising and referencing prevention of Schedule A diseases would not be permitted for drugs covered under the CDSA of schedule F to the FDR (unless for veterinary use).

In 2008, the health care environment has changed substantially from when Schedule A and section 3 were added to the FDA. Medical science has advanced, pre-market review of drugs and NHPs is required, a prescription drug regime exists, and publicly funded health care is available. Information

about diseases where self-help is appropriate is increasingly available to the Canadian public who thus have the opportunity to make more informed decisions about their health. The public's desire for this approach is reflected in an increasing emphasis on alternative health care and a greater involvement of patients in their choice of treatment.

The new list of Schedule A diseases coming into effect on June 1, 2008 is as follows:

- Acute alcoholism
- Acute anxiety state
- Acute infectious respiratory syndromes
- Acute psychotic conditions
- Acute, inflammatory and debilitating arthritis
- Addiction, except nicotine addiction
- Appendicitis
- Arteriosclerosis
- Asthma
- Cancer
- Congestive heart failure
- Convulsions
- Dementia
- Depression
- Diabetes
- Gangrene
- Glaucoma
- Haematologic bleeding disorders
- Hepatitis
- Hypertension
- Nausea and vomiting of pregnancy
- Obesity
- Rheumatic fever
- Septicaemia
- Sexually transmitted diseases
- Strangulated hernia
- Thrombotic and embolic disorders
- Thyroid disease
- Ulcer of the gastro-intestinal tract

Further information and detail can be obtained through the Health Canada website using the following ling (The pertinent section starts at page 2629 [page 11 of 411]):

http://canadagazette.gc.ca/partII/2007/20071226/pdf/g2-14126.pdf

QUESTIONS AND ANSWERS

I own a small community pharmacy. I do not have the room or expertise to do specialty compounding. If I get a prescription for a specialty compound, can I fill the prescription using product compounded by another pharmacy?

Pharmacists who do not provide specialty compounding services have two options:
1. Refer the patient to a pharmacy that can prepare the product.
2. Obtain the specialty compound by contracting with another pharmacist who provides the service. A contract between the two pharmacies must be signed and retained by both pharmacy managers if the service is contracted out.

WHOLESALING & ESTABLISHMENT LICENSING

The following is an excerpt from correspondence the Board has received regarding the requirement for Establishment Licensing. Pharmacies are reminded that selling/transferring prescription drugs **not pursuant to a prescription**, is considered "wholesaling" and specific federal laws must be adhered to.

Re: Wholesaling & Establishment Licenses – Drugs

As a follow up to a previous Health Canada correspondence forwarded to Pharmacy Associations across Canada on the issue of regulatory responsibilities with respect to wholesaling by pharmacies, this letter serves to provide further guidance to your members on this matter.

"Wholesale" is defined in section C.01A.001 of the *Food and Drug Regulations* as;

"..to sell any of the following drugs, other than at retail sale, where the seller's name does not appear on the label of the drugs:
(a) a drug listed in Schedule C, D, or G to the Act or in Schedule F to these Regulations or a controlled drug as defined in subsection G.01.001 (1); or
(b) a narcotic as defined in the Narcotic Control Regulations."

Section C.01A.004. (1) Subject to subsection (2), no person shall, except in accordance with an establishment license, …wholesale a drug…"

An Establishment License holder is subject to the Good Manufacturing Practices section (Division 2) of the *Food and Drug Regulations* as it applies to wholesalers. Requirements include, but are not limited to:

- Maintain adequate distribution records to ensure a rapid and effective recall,
- Store drugs under acceptable conditions and maintain records to that effect,
- Maintain documentation to show that personnel are adequately qualified and trained, and
- Use and maintain standard operating procedures for their work.

When pharmacies form buying groups for mutual benefit where one pharmacy engages in bulk purchasing of drugs (to receive volume discounts for example) and then proceeds to divide them up between the members, these activities are considered to be wholesaling and would be subject to the Establishment License requirements. Similarly, if a pharmacy routinely purchases pharmaceuticals and then resells or distributes them to one or more pharmacies, it is also considered wholesaling and subject to Establishment License requirements including Good Manufacturing Practices.

Pharmacies engaged in wholesaling activities need to apply for a Health Canada Establishment License. Wholesaling with an Establishment License would constitute a violation of the *Food and Drugs Act*.

Guidance on Good Manufacturing Practices, Establishment Licensing requirements and the application forms can be found on the Health Products and Food Branch Inspectorate web site at:

www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate

Further information on this matter; feel free to contact me at (709) 772-6471.

Krista Ricketts, Senior Compliance Officer
Health Products and Food Branch
Inspectorate Atlantic Region

An update from Health Canada – June 2008

A patient just presented an electronically-generated prescription with an electronically-generated prescriber's signature. The signature is legible, but is this an acceptable form of prescriber authorization?

An electronic prescriber's signature is only acceptable if the signature is unique. Health Canada considers a unique electronic signature to be equivalent to a paper-and –pen signature. It must be a fresh, new signature written on the prescription with an electronic pen pad, similar to signing a pen and paper prescription. It is an illegal electronic signature if it is cut and pasted into an electronic prescription.

To ensure the signature is unique, the pharmacist should compare the signature each time with an old prescription. The signatures should be slightly different if they are unique, as is an original signature each time.

If you don't have an old signature with which to compare the current signature, please call the prescriber to determine if a new, original electronic signature is generated for each new prescription.

A computer-generated prescription that is given to the patient or faxed to the pharmacy must have an original prescriber's signature or a unique electronic signature.

Is it legal to complete a prescription transfer by fax?

A prescription transfer must involve direct communication between two pharmacists. The pharmacist who transfers to another pharmacist must enter on the patient record the following information:

- Date of transfer
- Identification of the pharmacist from whom the prescription was transferred
- Identification of the community pharmacy to which the prescription was transferred
- Identification of the pharmacist to who the prescription was transferred

The pharmacist who transfers to another pharmacist must transfer all remaining refill authorizations.

The prescription transfer may be completed by fax only if direct communication has occurred between the two pharmacists directly. The faxed prescription must contain all of the required information cited above.

What is the proper way of documenting part-fills for controlled drugs and substances (including narcotics)?

In the past Health Canada has expected pharmacists to document part-fills of controlled drugs and substances (including narcotics) by recording the quantity dispensed on a given date on the reverse side of the original prescription, along with the handwritten initials of the pharmacist responsible for dispensing the part-fill. In addition, a "paper trail" copy of the prescription, for information purposes, had to be included in the daily prescription file on each part-fill date.

Health Canada is now determined that the software commonly used in community pharmacies in Prince Edward Island has automated many recordkeeping functions. It is now not necessary to add part-fill documentation to original prescriptions when second and subsequent part-fills are processed, provided that the software program allows tracking between the part-fills (quantity, date, and prescription number) and the original prescription. A "paper trail" copy of the prescription must continue to be filed in the daily prescription file on each part-fill date.

In the case of methadone prescriptions pharmacists may continue to document each part-fill on the reverse side of the original prescription. A "paper trail" copy filed on each part-fill date is not required for methadone part-fills.

RECORDING OF CEUs

Beginning with re-licensing for 2009/2010 year there will no longer be "carry-overs" of CEUs accumulated beyond the required 20CEUs. Additionally, the Professional development log, available on-line or by request **must be emailed to the Board office or mailed through Canada Post. We will no longer accept faxed forms.** They are often illegible and when there is trouble with either the sending fax machine or the receiving one, they are not received. A reminder also that they can be sent in at any point in the year and must be received by January 31. The late fee is $500.

Attending or participating in continuing education is not "about getting 20 points. It is about maintaining a solid and broad knowledge base for practice. It is for this reason that we also require you to indicate the particular competency element from the Standards of Practice achieved. Pharmacists should recognize where they are lacking in particular element and seek CE training in those areas.

ISMP MEMBERSHIP

The Board has purchased annual access to the newsletters of the *Institute for Safe Medication Practices (ISMP) Canada.* They will be forwarded to pharmacists through the NAPRA email system and also faxed to pharmacies.

In addition we have approached ISMP to provide a training session for their *Medication Safety Self-Assessment (MSSA) for Community Pharmacies"*. It would be made available/accessible for pharmacists across PEI. It meets the needs for a quality assessment of pharmacy systems and acts as an educational tool of what constitutes a safe medication system. Specifically, the community pharmacy MSSA can be used to identify opportunities for improvement in a community pharmacy medication system and also track improvement efforts over time. A web-based program provides immediate results in tabular and graphic form of one's own results as well as a comparison with aggregated results of other respondents on both a national and regional basis (if sufficient numbers). ISMP Canada provides support for questions, provides self-assessment booklets/PDF versions, and passwords for on-line access. ISMP is also active in encouraging medication incident reporting so it can keep the profession informed. The fee for access to this overall program is $400 for the newsletters (giving the Board authorization to distribute them) and $1600 for pharmacists having access to MSSA. The Board is working on a training session/sponsor for PEI before we purchase access. More information can be found at www.ismp-canada.org.

PHARMACISTS TRANSFERRING FROM ONE JURISDICTION TO ANOTHER

As a licensed pharmacist transferring into PEI from another province or jurisdiction, the **complete** registration process must be completed **prior to** commencing employment. This includes application, letter of standing, jurisprudence examination and applicable fee. You are a Pharmacist, not a student and not an intern. The Board is flexible in allowing jurisprudence to be written in another province and also works with the applicant to make the exam available for a sitting at their earliest convenience. In practicing, colleagues and the public would view you as a pharmacist. In the future, the pharmacist-in-charge, the permit holder and the pharmacist will be held accountable for failure to complete the proper licensing process. Other provinces have taken pharmacists to task for failure to complete the licensing process.

POOR LITERACY CAN EQUAL POOR HEALTH

Poor reading skills can make the difference between taking three pills once a day or one pill three times a day.

Canada spends $2 billion a year on hospital admissions as a result of people taking their medications incorrectly in their home. People with low literacy skills experience more health problems; prescription labels and written instructions about medications are useless to patients who can't understand them.

And health information on the Internet is often at an even higher level, making it incomprehensible to most of the people accessing medical information online.

A recent Ontario literacy council report showed that at least 42 per cent of Canadians hide their low literacy skills and are lies likely to feel confident to ask questions of their health-care providers. The study found they may also overestimate their literacy skills and few health-care workers are aware of how common literacy problems are, or how to identify people who have poor reading and writing skills.

"Literacy is hidden. It's a shameful thing. People who have literacy issues don't disclose it. They don't disclose it to the

people who really need to know it, who are their family practitioners or their pharmacists," said Julie Patterson, a literacy and health program manager at the North Bay Literacy Council.

In addition to following the steps in Standard 7 of the *Standards for Pharmacist Practice* (Pharmacist's duty to provide sufficient information to patients in relation to Schedule 1 drugs and Schedule 2 drugs), take into consideration the possibility of low literacy when counseling patients. Verbal instructions, having the patient repeat back and/or paraphrase instructions, and using diagrams when possible may increase patient understanding and compliance.

OFF-LABEL USES OF DRUGS – EXERCISE CAUTION

Pharmacists are reminded that it is good practice to critically evaluate and reflect on information gained through continuing professional development regardless whether the learning activity is accredited or non-accredited. It is through reflection that you can consider the new information – the validity of the information, how it fits with other knowledge you have, if you need further information, and how you may incorporate this new knowledge into practice. You may want to seek additional information from independent, objective, and peer-reviewed scientific literature.

You may want to be particularly diligent when considering information provided regarding off-labels uses of approved drugs. It is not illegal to dispense drugs prescribed for unapproved drugs. It is not illegal to dispense drugs prescribed for unapproved indications, nor is it illegal or contrary to accreditation guidelines for a continuing education program to discuss unapproved indications. (It is contrary to the *Food and Drug Act* for pharmaceutical manufacturers to promote their approved drugs for unapproved conditions.) However, lack of approval means that Health Canada has not reviewed the safety and effectiveness of this drug for this indication.

You are reminded that the *Standards for Pharmacist Practice* state that a pharmacist must not dispense a drug until the pharmacist has determined that the prescription is appropriate. The Standards go on to say that when determining the appropriateness of a prescription, the pharmacist should consider whether the prescription orders a drug for indication that is approved by Health Canada, considered a best practice or accepted clinical practice in peer-reviewed clinical literature, or part of an approved research protocol.

With regards to prescribing, the Standards state that a pharmacist must not prescribe a drug or blood product unless the intended use:

1. is an indication approved by Health Canada,
2. is considered a best practice or accepted clinical practice in peer-reviewed clinical literature, or
3. is part of an approved research protocol.

MULTIMED BLISTER PACKS

When dispensing multimed compliance blister packs to patients please ensure the contents are properly indicated on the package. This is of particular importance in those packages that have a fold over cover. Hospitals have been reporting that they have seen these covers that contain the labels/drug information removed by the patient. When presented in outpatients or admitted, the hospital staff cannot identify the contents, the dose or the directions. On dispensing, the pharmacist should ensure the patient is appropriately counseled on the use of the pack, as well as the medication enclosed. It may be advantageous to have the medication identified on the other section of the blister pack as well.