President's Bulletin

NOVA SCOTIA PHARMACEUTICAL SOCIETY APRIL 2001

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Regulatory Website
www.napra.org

The NAPRA (National Association of Pharmacy Regulatory Authorities) Website, launched several years ago, provides easy access to information, documents and forms related to the regulation of pharmacy in Canada. The Nova Scotia Pharmaceutical Society has a "sub-site" on the NAPRA site (click on "Nova Scotia" on the NAPRA homepage). The Nova Scotia sub-site currently offers sections including:

About Us: contains the Society's Mission Statement, background information, and information on the Society's Council, Committees, Administration, Delegates and Member Statistics.

News: includes the Presidents Bulletins

Provincial Information: contains the Nova Scotia Drug Schedules, Pharmacy Act, Regulations, NSPS Code of Ethics, and NSPS Guidelines/Policies on topics ranging from The Use of Automated Tablet Dispensers to Transmission of Prescriptions by Facsimile. This section also includes the Professional Library Requirements and Pharmacy Practice Audit and Self-Audit forms.

NSPS Annual Reports are contained in the **What's New** section.

Pharmacists are encouraged to visit the Nova Scotia section of the NAPRA website. Suggestions for additions to the site are welcome!

National Continuing Competence Program

In the fall of last year, the Society distributed the framework for a National Continuing Competence program to members. This basic framework was approved by the provincial regulatory authorities across Canada, and is an important component of the Mutual Recognition Agreement allowing freer movement of registered pharmacists across Canada.

During the April meeting of the National Association of Pharmacy Regulatory Authorities (NAPRA), a special Core Steering Committee was selected to oversee Phase Two of the development and implementation of the Program, based on the approved framework.

Implementation of the Continuing Competence Program in Nova Scotia will occur on a gradual basis (starting with self-assessment) and the Society will keep members up to date on both the development and implementation of this Program.

Meanwhile, please feel free to contact the Registrar should you have any questions or concerns.

ATTENTION!

This Bulletin is forwarded to every licensed pharmacist and active certified dispenser in Nova Scotia. Decisions of the Nova Scotia Pharmaceutical Society regarding matters such as regulations, drug schedules, pharmacy practice, etc., are published in this Bulletin. The Nova Scotia Pharmaceutical Society therefore assumes that all pharmacists/certified dispensers are aware of these matters.

Compounding Notes

The issue of compounding vs. manufacturing is addressed in Health Canada's "Policy Framework on Manufacturing and Compounding Drug Products in Canada" document (available on the Health Canada website: www.hc-sc.gc.ca). The policy states that a pharmacist can compound a product for a patient without a prescription as long as: the ingredients are all non-prescription products in non-prescription strengths, the compounded product is not commercially available, and the compounded product is provided to the patient as a result of an established pharmacist-patient relationship.

When compounding non-prescription products be mindful of the following:

First, Health Canada approves the sale of drugs for certain indications. If you are unsure if the product you are compounding has been approved for the indications intended, please check with Health Canada.

Second, remember to label the product appropriately. The label must include the ingredients used, with strengths, the total amount of the final preparation, directions for use, date prepared, and storage instructions. If appropriate, expiry dates should also be included. See below for information regarding expiry dates.

USP Package Standards/ Expiry Dates

The USP recently revised its product dating (expiry) standards for repackaged and compounded products. For non-sterile products, the expiry date should be no longer than one year and less if the ingredients expire before one year or if stability data indicates otherwise.

The full revisions appear in the first supplement to "The United States Pharmacopoeia, 24th Rev."

For more information on the stability of compounded products, the second edition of "Trissel's Stability of Compounded Formulations" by Lawrence A. Trissel is now available. The Dalhousie University Book Store will order this textbook upon request.

Gentian Violet

The Society has received several calls recently from pharmacists regarding the increased demand for Gentian Violet. Gentian Violet solution is sometimes used for the treatment of candidiasis associated with breastfeeding. Many lactation consultants and community health nurses are recommending the use of Gentian Violet to their breastfeeding patients. Because of reports in the past that indicated potential concerns of carcinogenicity, pharmacists are expressing concern about its increased use.

Because of these concerns, the Society sought the advice of an infectious diseases specialist at the IWK. The advice provided included the following:

Gentian Violet is effective for the treatment of candidiasis associated with breastfeeding and

can be used when conventional treatments fail. Although it does not legally require a prescription, it is recommended that Gentian Violet be used only with a doctor's advice.
Solutions of 0.5 to 1.0% solutions are commercially available. Take care not to provide Gentian Violet solutions containing methanol.

Health Canada Warnings

Health Canada recommends the "removal from sale" of the following herbal products:

- Bao Ji Wan Pills (China)
- Chinese Modular Chest Relief Tablets (USA)
- Yang Ching Pearl Powder (China)
- Double Dragon Regal Medicated Oil (Singapore)
- Shi Long Oil (Singapore)

Health Canada would appreciate receiving information relating to the identification of all known importers of these products. Please contact Annette Daley, Atlantic Regional Office, 902-426-5350.

NOVARTIS has recalled Sandomigran DS 1mg tablets, Lot C0L01371, dispensed between January 23, 2001 and March 20, 2001. Patients should return their supplies to their local pharmacist for replacement. For further information call NOVARTIS Customer Relations at 1-800-465-2244.

Original Package Dispensing

Pharmacists are reminded that professional judgement and patient consultation must be used when dispensing medications which are prepackaged by the manufacturer in special compliance packs.

Improved compliance must be balanced against the fact that these packages are usually not child resistant. Keep in mind that current regulations state that child resistant closures must be used unless otherwise authorized by the patient or physician.

Faxed Prescriptions

Pharmacists are reminded that they can legally fill faxed prescriptions, but only under specific conditions. The prescription must be written on the form provided by the Society (or a form containing all the same elements) and must be faxed directly from the prescriber's office. The receiving fax machine MUST BE LOCATED WITHIN THE DISPENSARY!

Prescription orders written on "Prescription/Discharge Notes" forms and faxed from the Colchester Regional Hospital may be filled. These forms, if properly completed by the prescriber, contain all the elements required by the Nova Scotia Pharmaceutical Society's Facsimile Transmission of Prescription policy document, including the prescriber certification section.

Prescription Authority via Computer Fax Modems

Please be advised that, after consultation with the Therapeutic Products Division of Health Canada and NAPRA, the Society supports the use of computer generated faxed prescriptions under the following conditions:

- the prescription will be produced from the prescriber's computer system and transmitted to the appropriate pharmacy via fax modems/lines
- the prescription will contain all the elements required by the Food and Drugs Act and Pharmacy Act
- the prescription will bear the prescriber's name. As an alternative to an actual signature, a unique identifier for each prescription will be used for validation/accountability purposes

- the prescription will contain a standardized explanation of the unique identifier, along with a specific phone number for use by the pharmacist, if necessary, in the validation process
- the prescription will contain all the elements required by the "Nova Scotia Pharmaceutical Society Facsimile Transmission of Prescription" policy document, including the name of the pharmacy to which the prescription is being faxed. As noted above, a unique identifier will be used as an alternative to a signature
- an audit trail of all computer-generated prescriptions will be maintained by the prescriber.

ADR Reporting

Pharmacists are reminded of their responsibility to report all Adverse Drug Reactions to Health Canada (Atlantic Regional ADR Centre, 902-473-7171). ADR report forms are located in the CPS and are available on the internet at www.hc-sc.gc.ca/hpb-dgps/therapeut under Guidelines and Forms. A guideline for ADR Reporting is included with the Bulletin.

Interchangeability of Drugs

Products which have not been approved as "interchangeable" in Nova Scotia cannot legally be substituted. Please refer to your Nova Scotia Formulary to ensure that the brand of a product you wish to substitute has been approved as interchangeable.

Keeping the above in mind, pharmacists have the authority to undertake product selection, unless the prescriber has indicated "no substitution" and provided the price of the drug dispensed does not exceed that of the prescribed drug. When a brand other than the brand prescribed is dispensed, the pharmacist must inform the patient. This will provide the patient with the opportunity to ask questions and to tell the pharmacist if they are concerned. The end result is reduced patient confusion and improved patient compliance and satisfaction.

Prescription Label Policy

The Society recently reviewed its prescription label policy as a result of constructive criticism from a concerned member. The Council appreciated the member's comments, however, maintained that the policy supports prescription label consistency and seamless care.

The Council elaborated on the original policy with the following results:

For single entity drugs, the generic (non-proprietary) name and strength should appear on the label. In addition to the generic name, either the trade (brand) name or the manufacturer's name should also appear on the label. The pharmacist should use professional judgement and include the brand name in cases where brand name recognition is important. If possible, the generic name should appear first. Additionally, dosage forms/routes of administration should appear on the label, when appropriate.

Notice

Members are advised that Mr. Sean McSween is currently not licensed as a pharmacist in this province.

Curad Triple Antibiotic Band-Aids

Curad Triple Antibiotic Band-Aids contain neomycin, polymyxin B and bacitracin. Neomycin is listed in Schedule F of the Food and Drugs Act. Accordingly, these Band-Aids require a prescription!

Physician License Revoked

The College of Physician and Surgeons of Nova Scotia has provided notice that the license to practice medicine of **Dr. William H. Michael Christie** was revoked pursuant to Section 66(2) of the Medical Act.

Pharmacists Disciplined

Case #1

Mr. Yuet Man To, PhC of Neil's Harbour, Nova Scotia, pled guilty to a charge of professional misconduct in that:

- on or about September 18, 1995, August 19, 1996, October 23, 1998, July 20, 1999 and January 28, 2000 (inspection dates), the dispensary/pharmacy at Highlands Pharmacy, Nova Scotia fell below the acceptable standards in that it was cold, dirty, unsanitary and cluttered, despite several directives from the Society to improve the standards;
- on or about September 18, 1995, August 19, 1996, October 23, 1998, July 20, 1999 and January 28, 2000 (inspection dates), expired drugs were stocked on active shelves in the dispensary/pharmacy, despite several directives from the Society to remove all expired stock from all active shelves; and
- on or about July 4, 1995, September 23, 1995, March 1, 1996, August 19, 1996, February 6, 1999, July 20, 1999 and September 29, 1999, Mr. To advised the Society that he would take or had taken the necessary steps to bring the standards of his pharmacy to the acceptable standards, in particular with respect to expired stock and/or cold, dirty, unsanitary and/or cluttered conditions, when in fact an inspection conducted August 19, 1996, October 23, 1998, July 20, 1999 and January 28, 2000 indicated otherwise.

Mr. To respectfully agreed to the following sanctions:

- a letter of discipline will be placed in Mr. To's file at the Society,
- a record of the discipline will be published in the Presidents Bulletin with reference to his name,
- Mr. To must advise the Society of the steps he plans to undertake to ensure this conduct is not repeated,
- the Society will conduct random inspections to ensure compliance with the required standards
- Mr. To must pay a find of $2000.00 in costs

The above sanctions have been completed to the satisfaction of the Society and Mr. To is licensed and in good standing with the Society.

Case #2

Ms. Hila Lamey, PhC of Glace Bay, Nova Scotia pled guilty to a charge of professional misconduct in that:

- on or about September 30, 1999, Ms. Lamey incorrectly filled a prescription using Paxil instead of clonazepam,
- as a result of the incorrect filling, the patient took the wrong medication for three nights until the error was discovered by a nurse providing treatment to the patient,
- on or about September 30, 1999, at the time the prescription was incorrectly filled, or reasonable soon thereafter, Ms. Lamey did not provide the patient or the patient's agent with patient counseling as required by Regulations 14.4 and 14.4.1 of the Regulations to

the Pharmacy Act, despite the fact that the drug was new to the patient.

Ms. Lamey respectfully agreed to the following sanctions:

- a letter of discipline will be placed in Ms. Lamey's file at the Society,
- a record of the discipline will be published in the Presidents Bulletin with reference to name,
- Ms. Lamey must advise the Society of steps undertaken to prevent a further occurrence,
- Ms. Lamey must pay a fine of $2000.00 in costs.

The above sanctions have been completed to the satisfaction of the Society and Ms. Lamey is licensed and in good standing with the Society.

Complaints

Eighteen complaints were referred to the Complaints Committee in 2000. Of these, one was dismissed and three were referred to the Discipline Committee.

Incorrect Label – Prescription for antibiotic labeled twice daily instead of once daily.

Incorrect Drug – Incorrect drug dispensed on balance owing.

Incorrect Quantity – Prescription for 120 tablets dispensed as 60 tablets. Pharmacist was not involved with the incident resolution.

Professional Advertising – Two complaints concerning the use of qualifying words.

Confidentiality – Two complaints: **1.** Customer suspected store employee was not a pharmacy staff member yet had access to his personal health record. **2.** Customer complaining about the lack of privacy for patient consultation.

Patient Counseling – Complaint from physician suggesting pharmacist counseled her patient to discontinue a medication prescribed by her without her consent. Complaint not substantiated – PhC acted in best interest of patient.

Compounding Error – Patient complained of suspected compounding error

Destruction of a Narcotic without Authorization – Pharmacist destroyed a narcotic compound without receiving authorization from Health Canada.

Narcotic Dispensed without a Rx – Pharmacist dispensed narcotic without receiving a triplicate prescription.

Others – Pharmacy operating as Lock and Leave without Lock and Leave permit.

- Pharmacy license holder failed to forward triplicate prescription copies within 7 days of filling to Prescription Monitoring Program.

- Pharmacist dispensed a brand name drug not approved as interchangeable by the NS Formulary.

- Pharmacist failed to provide patient focused care in partnership with physician and patient resulting in negative impact on patient care.

Regulatory and Standards of Practice Issues

The Society is working closely with NAPRA on the following regulatory issues:

- **Regulation of Internet Pharmacy:** The provincial Registrars are working on standards for e-pharmacy operations, which will require all traditional pharmacy license requirements to be fulfilled, including all standards relating to pharmacist-patient relationships, the provision of information and the resolution of drug-related problems.
- **Electronic transmission of Rx's:** Pharmacy standards for electronic transmission of prescriptions are currently being developed in

conjunction with the federal government and the Canadian Institute for Health Information (CIHI).

- **Drugs for Veterinary Use:** The Registrars have referred the issue of the appropriate scheduling and standards of practice for the sale of Schedule F, Part II for veterinary use to the National Drug Scheduling Advisory Committee for review.
- **Medication Incident Coalition:** NAPRA is a participant in a federal government sponsored coalition of stakeholder organizations involved in preventing/processing/resolving medication errors.
- **Bill C-11:** NAPRA, along with the Coalition of Regulatory Agencies (CORA) will participate in a presentation to the Standing Committee of the federal government regarding the Immigration and Refugee Protection Act, as it applies to foreign-trained pharmacists.
- **Natural Health Products:** NAPRA, on behalf of the provincial regulatory bodies was asked by Health Canada to make recommendations on the regulation of alternative and complementary health products and practitioners.
- **Privacy Issues:** The Registrars are developing national "Guidelines for Pharmacists Complying with Provincial Privacy Legislation".
- **Medication Packaging and Labeling Project:** The regulatory bodies, under NAPRA, are working with the Canadian Public Health Association's Steering Committee on "Medication Packaging and Labeling". This steering committee is developing guidelines for manufacturers of pharmaceutical products and packaging to ensure that package design and labeling, as well as package inserts, are suitable for and easy to understand by seniors with low literacy skills. These guidelines are expected to be useful to pharmacists who provide patient information sheets as part of their counseling process.
- **Specialty Certification:** NAPRA and the provincial regulatory bodies continue to work in the area of specialty certification. A discussion paper called "A Specialty Certification Program for Canadian Pharmacists" has been developed and has been circulated to all federal and provincial advocacy groups (CPhA, PANS, etc.). The Society is excited about this issue and is eager to move the certification program forward.

Clinical Issues

Celebrex/Sulfa Allergies

Pharmacists are reminded that Celebrex is a benzenesulfonamide derivative and therefore may cause allergic reactions in patients with sulfa allergies.

Meridia

Meridia, the new obesity drug, is now available in Canada. It works by inhibiting the reuptake of serotonin and norepinephrine. The usual starting dose is 10mg once a day, taken in the morning.

Meridia can cause increased blood pressure and heart rate, constipation, dry mouth and insomnia. It should not be combined with drugs that increase serotonin or norephinephrine levels (MAO inhibitors, St. John's Wort, SSRI's, etc.). Cytochrome P450 drugs that decrease Meridia's metabolism should also be avoided (cimetidine, etc.)

Monistat Vaginal Cream and Warfarin

Miconazole and other "azole" antifungal drugs, when taken systemically, can interact with warfarin, by inhibiting its metabolism and therefore increasing warfarin blood levels.

Recently, the US Food and Drug Administration made a decision to require new warnings on the packages of Monistat Vaginal Cream and Suppositories about this warfarin interaction. Although the chances of interactions are rarer with creams/suppositories than with oral products, it may be prudent to warn your warfarin patients to watch for increase bleeding/ bruising while using Monistat.

Proper Splitting of Tablets

Pharmacists must provide appropriate medications in their proper form to their patients. Only drug products that are scored should be used for tablet splitting (i.e. into half or quarter tablets).

Drugs that are not scored will likely not split properly to provide a uniform dose. Coated tablets can also present problems, because once the drug is split any effect the coating provides may be compromised.

Before splitting tablets, pharmacists must make sure that:

- the drug literature indicates splitting of the specific brand of tablet can be accomplished safely and effectively;
- if a change in the prescription occurs due to using a strength higher than originally called for, the prescriber must approve the change, and
- detailed patient counseling is provided to ensure the patient understands changes made to the prescription, and if the patient is responsible for tablet splitting, explain splitting techniques and tools.

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