PARTNERS IN CARE: INTEGRATING TECHNICIANS HAS ALLOWED FOR GREATER CLINICAL FOCUS

PROTECTING THE COLD CHAIN

VOLUNTEER EXPERIENCES HELP MEMBERS GROW
MISSION:
The Ontario College of Pharmacists regulates pharmacy to ensure that the public receives quality services and care.

VISION:
Lead the advancement of pharmacy to optimize health and wellness through patient centred care.

VALUES:
Transparency - Accountability - Excellence

STRATEGIC DIRECTIONS:
1. Optimize the evolving scope of practice of our members for the purpose of achieving positive health outcomes.
2. Promote the use and integration of technology and innovation to improve the quality and safety of patient care, and to achieve operational efficiency.
3. Foster professional collaboration to achieve coordinated patient-centred care and promote health and wellness.
4. Build and enhance relationships with key stakeholders, including the public, the government, our members, and other health care professionals.
5. Apply continuous quality improvement and fiscal responsibility in the fulfilment of our mission.
The objectives of Pharmacy Connection are to communicate information about College activities and policies as well as provincial and federal initiatives affecting the profession; to encourage dialogue and discuss issues of interest to pharmacists, pharmacy technicians and applicants; to promote interprofessional collaboration of members with other allied health care professionals; and to communicate our role to members and stakeholders as regulator of the profession in the public interest.

We publish four times a year, in the Fall, Winter, Spring and Summer.

We also invite you to share your comments, suggestions or criticisms by letter to the Editor. Letters considered for reprinting must include the author’s name, address and telephone number. The opinions expressed in this publication do not necessarily represent the views or official position of the Ontario College of Pharmacists.
EDITOR’S MESSAGE

“...a key to successful initial uptake is having a clear understanding of ‘what’ we can do and ‘how’ we can do it.”

Della Croteau, R.Ph., B.S.P., M.C.Ed.
Deputy Registrar/Director of Professional Development

Although it has been a long time coming, first submitted to government in March 2011, our expanded scope regulation will be here very soon and we need to be sure that when it arrives, we are ready.

With this in mind, the College has been busy preparing materials to help educate members on the new expanded scope of practice. Central to this is a comprehensive Orientation Manual which is in the final stages of development as we gather feedback from current practitioners through a number of focus groups.

The Orientation Manual, which all members will be required to declare that they have read and understood, forms the basis for our extensive communication strategy. We anticipate hosting a number of ‘live’ orientation sessions throughout the province in the months immediately following receipt of our authorization from government.

These ‘live’ sessions will give members an opportunity to learn about their new role and responsibilities in an interactive environment where they can ask questions and engage in dialogue with colleagues and College representatives.

Appreciating that not all members will be able to attend one of these sessions, or prefer a different type of learning experience, we are also considering the development of an ‘online’ learning module to deliver this important material.

Regardless of how you choose to get yourself familiar with the expanded scope and its various new activities, we have learned from our colleagues in other provinces, that a key to successful initial uptake is having a clear understanding of ‘what’ we can do and ‘how’ we can do it.

As you will recall the new regulation provides pharmacists with the authority to:

• Initiate a Prescription (for smoking cessation therapy), and
• Adapt (dose, dosage form, regimen or route of administration) or Extend an Existing Prescription, and
• Perform a Procedure on Tissue below the Dermis, and
• Administer injections and inhalations (for the purposes of demonstration and/or education).

With respect to administering injection authority the College has been continuing its dialogue with government and other interested stakeholder groups regarding the public benefit of broadening the administration of injection authority to include routine injections and immunizations. Feedback in this regard has been positive and we are optimistic that this additional expanded scope will allow pharmacists to positively impact immunization rates in Ontario.

With all of the necessary preparation currently being done by the College we are confident that when the regulation is passed we will be ready to ‘hit the ground’ running. We hope that you will be as well.
...in order for the integration of registered technicians into our current operations to truly be successful, we have to change our traditional workflow.

Sherif Guorgui, B.Sc.Phm., R.Ph. President

With the expanded scope of practice near, I believe this is a good time to be reflecting on the challenges and opportunities currently facing the healthcare system as a whole and our profession in particular.

There is no doubt that economic constraints, coupled with an aging population is straining our healthcare system. This is not a situation reserved for Ontario, or even Canada for that matter, but rather a global reality that impacts pharmacy throughout the world.

Although we are still awaiting final government approval (as of this publication) for our new expanded scope of practice, it is imminent.

Therefore, we must start working now, so that we can prepare ourselves to effectively deliver on our new roles and responsibilities.

From the experience of other jurisdictions, such as British Columbia and Alberta, we realized that one of the initial barriers to embracing the new scope was the ability for pharmacists to find the necessary time to engage in these new clinical services. In these initial markets however, registered technicians were not yet available. This is not the case here in Ontario, with over 650 technicians currently registered with the College and hundreds more engaged in the process.

The proper incorporation of a registered technician into the workflow has proven to be an effective way to mitigate the very real time constraint facing pharmacists.

Technicians, as independent regulated healthcare professionals, have the skills, knowledge and judgement, to be accountable and responsible for the final technical check of the prescription preparation.

Allowing technicians to take on this role will free up pharmacists’ time considerably, so they can focus on the delivery of more patient-centred initiatives.

For the majority of us however, in order for the integration of registered technicians into our current operations to truly be successful, we have to change our traditional workflow. We need to separate the role of the technician, who can independently authorize the final technical check, from the pharmacist’s role of ensuring the therapeutic appropriateness of the prescription. For many of us, these functions are currently combined and done by a pharmacist positioned at the end of the process within the dispensary.

Although there are numerous ways to change our current workflow to maximize the benefits of incorporating registered technicians, moving the pharmacist from the end of the process to the beginning, may be the easiest to illustrate. Positioning the pharmacist here maximizes their engagement with the patient as they ensure the appropriateness of current drug therapy, provide any necessary consultation and identify any additional clinical services which may benefit the patient. The pharmacist can then sign off on the therapeutic appropriateness of the prescription, and hand it over to a registered technician to prepare and subsequently release to the patient assuming any necessary consultation has already been done by the pharmacist.

It is expected that evolving our practice to include pharmacy technicians will take some time as we learn to work together, understand each others’ roles and ultimately develop the trust necessary. The first step however, must be a willingness to change and realization of the imminent need to consider alternative workflows and business models.
COUNCIL APPROVES 3-YEAR STRATEGIC PLAN (2012–2015)

Council participated in a facilitated planning session to set the strategic plan for the College for the next three years. In developing the plan, which included a revised Mission Statement and Strategic Directions along with a newly created Vision and Values, Council members focused on the overriding mandate of the College, to protect the public interest and referenced various documents, including the recently-published Drummond Report.

Over the next few months, College staff will develop an operational plan to support the Strategic Plan for Council’s consideration at its June 2012 Meeting. The operational plan will be monitored at every Executive Committee meeting to ensure that Council objectives are met, and each quarter, College Council will receive an update respecting progress on each strategic direction.

STRATEGIC PLAN (2012–2015)

Mission: “The Ontario College of Pharmacists regulates pharmacy to ensure that the public receives quality services and care.”

Vision: “Lead the advancement of pharmacy to optimize health and wellness through patient-centred care.”

Values: Transparency - Accountability - Excellence

Strategic Directions:
1. Optimize the evolving scope of practice of our members for the purpose of achieving positive health outcomes.
2. Promote the use and integration of technology and innovation to improve the quality and safety of patient care, and to achieve operational efficiency.
3. Foster professional collaboration to achieve coordinated patient-centred care and promote health and wellness.
4. Build and enhance relationships with key stakeholders, including the public, the government, our members, and other health care professionals.
5. Apply continuous quality improvement and fiscal responsibility in the fulfillment of our mission.

REGULATION, TO INCLUDE IMMUNIZATION AND ROUTINE INJECTIONS, RATIFIED BY COUNCIL

In anticipation that government may wish to move forward with the inclusion of immunization as part of the expanded scope legislation a revised Bill 179 regulation and supporting list of substances, which allows administration of a substance by injection or inhalation for purposes of routine administration including immunization, was ratified by Council. The College will then be prepared to move ahead quickly should immunization and routine injections receive public policy approval.

Following the December 2011 Council meeting, the College had posted the revised Bill 179 regulation for comment, along with the expanded list of substances to be administered by injection and inhalation for routine purposes, including immunizations. The College received substantial feedback and although the majority of the respondents were in favour of the amendments, there were a few concerns relating to specifics which the College anticipates covering in future guidelines and policies.

As previously advised, it is not anticipated that an individual pharmacist would administer all the substances listed, as the use will be specific to the circumstances of practice. As well, the College will expect any pharmacist who administers drugs by injection or
inhalation to have the knowledge, skills, and judgment to do so and to be prepared to manage any adverse outcomes. A watching brief will be kept on this matter and the membership will be kept updated on developments.

**COMPETENCIES FOR PHARMACIST INJECTION EDUCATION APPROVED**

As outlined in the above-noted regulation pharmacists, as in other provinces, wishing to administer a substance by injection will be required to successfully complete an education program. Following preliminary consultation with other provinces, territories and the National Association of Pharmacy Regulatory Authorities (NAPRA) there was general agreement on the principle of establishing national competencies for education programs which would allow for labour mobility of pharmacists with injection training. Accordingly, Council approved the adoption of the 14 competencies developed by the Public Health Agency of Canada (objectives of the competencies and the complete immunization guide can be accessed at [http://www.phac-aspc.gc.ca/im/ic-c/index-eng.php](http://www.phac-aspc.gc.ca/im/ic-c/index-eng.php)) along with a 15th competency, which was developed in collaboration with other provinces and addresses injection of other substances, as the base competencies required for acceptable training programs.

**COUNCIL APPROVES AUDITED STATEMENTS FOR COLLEGE OPERATIONS IN 2011**

**AS PREPARED BY CLARKE HENNING LLP, CHARtered ACCOUNTS**

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<tr>
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<th>Budget</th>
<th>Actual</th>
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<tr>
<td><strong>Revenues</strong></td>
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<tr>
<td>Member fees – Pharmacists</td>
<td>$7,252,000</td>
<td>$7,462,843</td>
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<td>Member fees – Pharmacy Technicians</td>
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<td>105,600</td>
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<tr>
<td>Pharmacy fees</td>
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<td>Registration fees and income</td>
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<tr>
<td>Investment Income</td>
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<th>Budget</th>
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<tr>
<td><strong>Expenses</strong></td>
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<tr>
<td>Council and committees</td>
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<td>Administration</td>
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<tr>
<td><strong>Total</strong></td>
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**Excess (deficiency) of revenues over expenses from operations for year, before depreciation**

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<th>Budget</th>
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<tr>
<td></td>
<td>384,553</td>
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Depreciation

- 434,521

**Excess of revenues over expenses for the year**

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<td>384,553</td>
<td>698,090</td>
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The audit and resulting financial statements were prepared in accordance with generally accepted accounting principles and the College continues to remain in a sound financial position. Council was particular pleased to review the management letter from Clarke Henning which states that the auditors did not identify any issues of concern.
A process for communicating this information and ensuring that courses delivered meet the competencies will be developed and communicated to the membership.

NEW LIBRARY RESOURCES APPROVED

The Accreditation Committee recommended Council approval of two references (Lexicomp Patient Education as an acceptable patient counseling publication and SOLUTIONS in Health Inc. as a drug information service) that are required by legislation in a pharmacy library in order for pharmacists to meet standards of practice for patient care and ensure the safe use and distribution of drugs in Ontario. Council approved the additions. For a complete set of references, visit the College’s website at www.ocpinfo.com.

BRIDGING PROGRAM FOR INTERNATIONAL PHARMACY TECHNICIAN APPLICANTS APPROVED

An international pharmacy technician applicant who does not meet the transition pathway requirements (i.e. did not complete the Pharmacy Examining Board of Canada Evaluating Exam before January 1, 2012) must meet certain education requirements under the Registration Regulation (i.e. must have successfully completed a program that, at the time the applicant commenced it was approved by the Council as one whose graduates should possess knowledge, skill and judgment at least equivalent to a current graduate of a program accredited by the Canadian Council for Accreditation of Pharmacy Programs) in order to become registered. This is a non-exemptible requirement and accordingly, Council approved a bridging program for international applicants who are now beginning to explore registration through this route.

Until a more comprehensive international bridging program is developed, the proposed program includes the existing four continuing education courses in the transition bridging program, with the addition of the Orientation to the Canadian Healthcare System course. These courses will provide international applicants with some additional education to support their transition to practice in Ontario. In addition to completing the bridging program, international applicants will be required to complete the full SPT program, requiring a minimum of 12 weeks practice under the supervision of an approved preceptor, with completion of structured activities which include the independent double check exercise (for 500 prescriptions/orders).

For more information on this subject, please visit the College’s website at www.ocpinfo.com

DR. NANCY WAITE APPOINTED OCP PROFESSOR IN PHARMACY INNOVATION

As reported in fall 2011, College Council approved the establishment of the OCP Professorship in Pharmacy Innovation at the University of Waterloo (UW) through the donation of a one-time gift of $600,000. The University recently selected Professor Nancy Waite to assume the position of OCP Professor in Pharmacy Innovation and it is anticipated that there will be regular reports from her to College Council for the purpose of assessing progress. (See also story on page 22)

SUBMISSION RE: MANDATORY REVOCATION PROVISIONS AND TREATMENT OF SPOUSES BY HEALTH CARE PROFESSIONALS

On June 24, 2011, the Minister of Health and Long-Term Care asked the Health Professions Regulatory Advisory Council (HPRAC) to advise on the issue of mandatory revocation provisions and treatment of spouses by health care professionals under the Regulated Health Professions Act, 1991 (RHPA). To assist in their evaluation, HPRAC posed the following questions:

1. Should alternatives to the mandatory revocation provisions currently mandated in the RHPA with respect to the treatment of a spouse by a regulated health
professional be considered? If yes, please propose appropriate alternatives.

2. If there are appropriate alternatives to the mandatory revocation provisions currently mandated in the RHPA with respect to the treatment of a spouse by a regulated health professional:
   a. Do the alternatives pose a risk of harm to the public?
   b. Do the alternatives best serve the public interest?

3. Any other comments about the issue of mandatory revocation provisions and treatment of spouses by regulated health professionals?

The College’s Patient Relations Committee considered the matter and proposed a submission supporting the development of alternatives to the mandatory revocation provisions, in the event of the need for emergency or incidental care. Also emphasized was the need to re-balance the manner in which the sexual abuse provisions of the Health Professions Procedural Code are applied by ensuring that all provisions are reasonable and justifiable, and therefore less likely to be disregarded.

To view the College’s submission, as well as other responses, please visit the HPRAC website: http://www.hprac.org/en/projects/spousaltreatment.asp. Further information from the Ministry is anticipated later this year.

REPORT ON SECURE RETENTION AND PRESERVATION OF DISPENSING REPORTS AND PRESCRIPTIONS

Changes to the regulations under the Drug and Pharmacies Regulation Act (DPRA) require the records of prescriptions dispensed be retained for at least ten years. Moreover, the records should be kept, where possible, in electronic form. As a result of the type of questions that will likely arise, from members and software vendors, the College requested Mr. Ross Fraser to examine the issue and make recommendations regarding the requirements for e-signing and retaining prescriptions and dispensing records. Council received the report for information, noting that it will be used as background material for developing policies and guidelines respecting this matter.

PEBC AND COUNCIL APPOINTMENTS

Council welcomed returning public appointee, Mr. Aladdin Mohaghegh, who was reappointed to serve on College Council for a three-year term. Also noted was the appointment of Ms. Bonnie Hauser as the College’s representative on PEBC (Pharmacy Examining Board of Canada) for a three-year term. College Council took the opportunity to thank public member, Mr. Thomas Baulke, whose appointment will expire on June 10th and Mr. Peter Gdyczynski, whose appointment as the College’s representative on PEBC expired in March, for their hard work and dedication.

FUTURE COUNCIL MEETINGS
- June 11 and 12, 2012
- September 10, and 11, 2012

For more information respecting Council meetings, please contact Ms. Ushma Rajdev, Council and Executive Liaison at urajdev@ocpinfo.com.

REMINDER: UPCOMING COUNCIL ELECTIONS
SEE PAGE 20 FOR DETAILS
PARTNERS IN CARE

From left to right: Renee Hayden, RPhT, Operations Manager
Heather Monteith, RPhT, Pharmacy Liaison
Rudy Liem, Pharmacist, Pharmacy Services Manager
Lynne Hanlon, RPhT, Karen Skubnik, RPhT
Peter Adams, Pharmacist, Pharmacy Manager
Rachel McCallum, RPhT, Delia Littlejohn, RPhT
FOR PHARMACISTS WORKING WITH LTC AND RETIREMENT RESIDENCES, INTEGRATION OF PHARMACY TECHNICIANS ALLOWS FOR GREATER CLINICAL FOCUS

By Stuart Foxman

Preamble: The previous issue of Pharmacy Connection (Winter 2012), showcased an example of a community pharmacy practice that has successfully integrated registered pharmacy technicians. To follow up, the College recently visited two pharmacies that focus on long-term care delivery: Classic Care in London and Rexall in Sudbury.

Both pharmacies have been using registered technicians for sometime and are experiencing tangible benefits. The Classic Care Pharmacy in London (pictured on opposite page) includes a team of six registered technicians (three of whom were interviewed) working in collaboration with a pharmacy manager and pharmacy services manager. The team at the Rexall Pharmacy in Sudbury (pictured on the following page) includes a pharmacist and three registered technicians. Their stories are recounted here.

Should you have an example of integrating registered technicians into practice we’re interested in hearing from you. Please contact the College at pharmacyconnection@ocpinfo.com.
For Jason Chenard, RPh, the past year has seen a dramatic transformation in his Sudbury pharmacy. Chenard, the pharmacy manager, serves seven long-term care, nursing/assisted living and retirement facilities in and around Sudbury. During the past year his Rexall location has delivered the highest volume of patient-focused services, which includes MedsChecks and pharmaceutical opinions, for the chain in the country.

What accounts for the increased numbers? Having three registered pharmacy technicians on his team has changed the nature of the workflow, freed valuable time, and enabled the pharmacists to better utilize their capabilities.

Chenard’s message to his fellow pharmacists: “We are in a process of change, and have to break old habits. We need to share the workload, and work more clinically for the betterment of the patient. We can’t do it all – trust the technicians.”

Peter Adams, RPh, shares that sentiment. Like Chenard, he works with long-term care and retirement homes, about 40 in southwestern Ontario as the pharmacy manager at London Classic Care Pharmacy, a division of Centric Health. With his technicians assuming many of his former responsibilities, his focus has fundamentally changed. “I can do more follow-ups, concentrate on the finer points, and institute continuous quality improvements,” says Adams.

“During the past year his Rexall location has delivered the highest volume of patient-focused services, which includes MedsChecks and pharmaceutical opinions, for the chain in the country.”
Since the start of 2011, the College has registered over 650 pharmacy technicians, and several thousand others are on the road to regulation. Across Ontario, many pharmacies have already integrated these technicians to great effect, bringing a range of benefits — among them, pharmacies like the Sudbury Rexall and Classic Care London, which serve a variety of long-term care facilities. What rewards have those types of practices reaped, and how have the roles changed within the pharmacy?

While the integration of pharmacy technicians is still at a relatively early stage, many positive impacts have quickly become apparent. “Before I was very reactive, now I’m more proactive,” says Adams.

In both pharmacies, the technicians note a strong sense of partnership with their pharmacists. Karen Skubnik, RPhT, who works at Classic Care, talks about a “cohesive team”, and how technicians like her can “lessen the technical load”.

At the Sudbury Rexall, Miranda Foster, RPhT, mentions how she gained a clearer picture of her responsibilities after becoming regulated, and points to her rapport with the pharmacists. “We collaborate,” she says simply.

How does that collaboration work? In Sudbury, one stream of work involves the refill of weekly strips, where technicians do the sign-off. Lisa Daub, RPhT, says that the task involves reviewing the technical details of weekly strip packaging — correct patient, correct drug and correct Hours of Administration (HOA). “We make sure everything is accurate,” she says.

Technicians are aware of a residence’s policy regarding medication...
The greatest efficiency has been found by placing the pharmacist at the beginning of the process. The pharmacist reviews and signs off on the clinical appropriateness of the prescription first and once complete hands it over to an assistant to prepare, and a technician to do the final technical check.

I’ve gladly deferred tasks to our registered technicians so I can focus more clinically.

Pharmacist Jason Chenard

How will you use your extra time?

When the resident of a Sudbury area nursing home was feeling fatigued, he received a timely visit from a local doctor and pharmacist. “We ran blood work, and his sugars were in the 30s,” says Jason Chenard, RPh. “So we started him on insulin, and over about three visits his lab results had normalized. He’s now on 60 units of insulin in the evenings and is feeling much better.”

Now, assuming there are no changes to the order, pharmacists only need to be involved in checking the clinical aspect of these prescriptions as part of their regular three-month review. Typically this is also the time that a pharmacist conducts a MedsCheck, to review each patient’s regimen and ensure that every drug on the currently scheduled medications to avoid interactions. The technician would know to flag this to the pharmacist.

Regulation has allowed for the technicians to take on this role. Before that, Chenard says that checking the weekly strip packaging would often take more than one pharmacist, a day or more. Now, assuming there are no changes to the order, pharmacists only need to be involved in checking the clinical aspect of these prescriptions as part of their regular three-month review. Typically this is also the time that a pharmacist conducts a MedsCheck, to review each patient’s regimen and ensure that every drug on the

(e.g. HOA). “We’re the eyes to make sure it’s compliant, and if not we’ll flag it,” says Foster. Using their professional judgment, technicians can raise possible issues with the pharmacist, says Chenard and together they’ll discuss the situation and make a decision. One example: a patient who has been prescribed a new antibiotic, which should be given outside of the HOA of currently scheduled medications to avoid interactions. The technician would know to flag this to the pharmacist.

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registered pharmacy technicians on staff, freeing up time. Chenard knows that the long-term care residences that he serves have their own in-house physicians. And in the retirement residences that he also works with, residents tend to be more independent. But residents in the assisted living homes — often because of mobility or cognitive issues, or the weather during long winters — can find it tougher to get into the community to access health care services.

“There’s a definite barrier for them getting in touch with a physician or pharmacist, or getting to a walk-in clinic, so we come to them,” says Chenard.

The residents are encouraged to keep their family physician, if they have one. But on the regular visits, the doctor who works collaboratively with Chenard will order labs and x-rays and prescribe medication as needed, while Chenard will select the drug and dose and counsel the patient.

As registered technicians assume a greater role in the dispensary, Chenard says that pharmacists will increasingly have to ask themselves this question: “With the time, what do you want to do with your expanded scope?” For him, the answer was clear — spend more time at the bedside doing counseling and education. “It’s just part of being a pharmacist,” says Chenard, “it’s what we do.”

We’ve been able to reach 100% of MedsChecks in long-term care homes quarterly . . . We weren’t able to do that before, and couldn’t without the registered technicians.

Pharmacist Rudy Liem
A second stream in the workflow within the Sudbury operation is required whenever there’s a new prescription or change to an existing patient’s drug or dosage. Here, the greatest efficiency has come from placing the pharmacist at the beginning of the process. The pharmacist reviews and signs off on the clinical appropriateness of the prescription first, and once complete hands it over to an assistant to prepare, and to a technician to do the final technical check.

EVERYONE’S JOBS HAVE EVOLVED

Foster says that her job has changed completely since she became regulated, with her professional accountability allowing for more responsibility. Yet in many ways the pharmacist’s role has evolved too.

“I’ve gladly deferred technical tasks to our registered technicians so I can focus more clinically,” says Chenard.

Since adding the technicians, he has doubled the time he spends with patients and the health care team in the residences. Before, he may have identified approximately 20 more critical pharmaceutical opinions a month. Now, with increased time spent evaluating the appropriateness of patients’ therapies, he makes recommendations at the rate of closer to 100 a month.

In London, Classic Care has seen similar outcomes. With the technicians picking up on weekly strip packaging checks, the pharmacy is focused on hiring more clinically-focused instead of operationally-focused pharmacists. In fact, one operational pharmacist just switched to a clinical role, and now she spends all of her time doing MedsChecks and patient education.

“We’ve been able to reach 100% of MedsChecks in long-term care homes quarterly, and the depth and quality of the MedsChecks has increased significantly,” says Classic Care pharmacist Rudy Liem, RPh, the pharmacy services manager. “We weren’t able to do that before, and couldn’t without the registered technicians.”

Not only have the technicians reduced the need for operationally-focused pharmacists, but Liem acknowledges a difference in how they handle their function. “I find that the registered technicians that I work with are more engaged in the technical process and perform it with more dedication,” he says.

LEARNING TO EMBRACE THE ROLE

Liem has an admission. When he first heard about the registered pharmacy technician role several
You need to be open to the new role and to recognize and respect them (technicians) as professionals.

Pharmacist Peter Adams
years back, "I felt very apprehensive because I didn’t understand the role."

Liem faced his trepidation by getting involved and ended up being one of the first instructors at London’s Fanshawe College teaching the Professional Practice component of the pharmacy technician bridging course. Liem says it’s vital for pharmacists to learn what the technicians can and can’t do: “Once you know, you have to embrace the role.”

His pharmacist colleagues agree. “You need to be open to the new role and to recognize and respect them [technicians] as professionals”, Adams explains. Chenard adds, “Trust them, they are more capable and competent than you think”.

That process isn’t always easy. In a previous job, Skubnik suspected that the full benefits of the RPhT role had not been fully considered. She believes that that was partly related to an understandable discomfort with integrating former pharmacy assistants into this new role with a new and unfamiliar scope of practice.

Foster too, at a past job, felt that her pharmacist was not always comfortable with the technician’s new role, and just “couldn’t let go,” she says. Now Foster, who feels validated through the regulation process and takes great pride in her work enjoys a respectful rapport with the pharmacist.

With the contingent of registered technicians only growing, “you need to see how to fit that role into your practice,” says Liem. “They’re invaluable.”

While advising pharmacists to have faith in their abilities, registered technicians are also urging their own counterparts to get on the road to regulation.

Michelle Gagne, RPhT from Sudbury believes that one of the challenges continues to be a lack of understanding amongst assistants of the process and benefits of regulation, stating simply, “they still don’t know what to do.” Her advice: “go for it.”

Skubnik describes becoming registered as “the difference between having a job and a career – there’s much potential growth for the profession.”

To Chenard, it’s important for pharmacists to remember that registered technicians are professionals too, accountable within their scope of practice. “Every one I’ve worked with has demonstrated their capabilities quickly,” he says. “They are very efficient and safe. It was evident early on that I could trust them, and that allowed me to be at ease.”
As we continue to examine pharmacy practices that have successfully integrated registered technicians into their workflow some common themes are emerging. One of these is the need for pharmacists, designated pharmacy managers and pharmacy owners to have a clear understanding of the role and responsibilities of registered technicians.

Although there are many tasks that a registered technician is authorized to perform perhaps the most significant, with respect to how it could potentially impact the workflow within a pharmacy, is a technicians’ ability to independently perform the ‘final technical check’ of any new or refill prescription.

A simple way of illustrating this point is to consider a prescription for 100 tablets of Drug ‘X’ for Mrs. Smith. A registered technician can, independent of a pharmacist, authorize that, as per the original prescription, the bottle contains 100 tablets of Drug ‘X’ and is labelled correctly for Mrs. Smith. This step in the product preparation is often referred to as the ‘final technical check’. Prior to having
TECHNICIAN INTEGRATION

registered technicians, this step could only be done by a pharmacist.

Although a technician can sign off on the technical check of a prescription, we must remember that only a pharmacist may authorize that the prescription is appropriate for the patient. This step is often referred to as the ‘therapeutic check’. In addition, it is the pharmacist who is required to provide appropriate patient consultation.

There is a clear division of roles and responsibilities between the pharmacist and registered technician. One of the challenges community pharmacies have had in making this distinction has been that for many, the current workflow combines these two steps into one. The pharmacist, at the time of doing the ‘final technical check’ of the product preparation, is also ensuring the therapeutic appropriateness (therapeutic check) of that prescription.

By clearly defining the roles and separating the functions a variety of new workflows become possible as the pharmacist is no longer tied to having to perform the ‘final technical check’ of the prescription.

Transferring this responsibility to a registered technician will enable the pharmacist to spend more time on clinical patient-related activities.

REMINDER:

UPCOMING COUNCIL ELECTIONS – DISTRICTS N AND H (HOSPITAL)

You will have received your electoral declaration by now. The workplace we currently have recorded as your Declared Place of Practice (for Elections) will be used for election purposes. If your information is up to date, you do not need to contact the College. If the information is incorrect, or you are unclear as to which postal code you will be voting in, please access the College website (www.ocpinfo.com), click on the Member Login icon, login in using your User ID (OCP number) and password, and you will be able to verify and/or change your information for voting purposes (primary workplace).

IMPORTANT DATES:

Nominations open: June 1, 2012
Nominations close: June 15, 2012
Voting closes: August 1, 2012

For further information, contact: Ryan Hosein
Client Services Representative
416-962-4861 ext. 2250 • email: rhosein@ocpinfo.com

EXCITING OPPORTUNITY TO JOIN THE COLLEGE!

Your contributions can help ensure that future pharmacists and technicians are prepared to provide the public with quality services and care.

For more details, visit the College’s website and click on ‘CAREERS’ at the bottom of the page.
It has come to the attention of the Office of Controlled Substances (OCS) that some of the requests for authorization for destruction of unserviceable narcotics and controlled drugs are being sent to the incorrect location and this is resulting in delays or loss of the request. We would like to take this opportunity to clarify the current procedures and contact information for pharmacists to request authorization for destruction of narcotic and controlled drugs under the Controlled Drugs and Substances Act.

Permission to destroy controlled drugs and narcotics may be obtained by completing the destruction authorization form or providing the following information to the OCS:

- Name and full address of the pharmacy
- Telephone and fax number of the pharmacy
- Name and license number of the submitting pharmacist
- Date
- Substance name
- Quantity
- Strength
- Expiry Date (when possible)
- Lot # (when possible)

The above information should be sent to the National Compliance Section by fax, email or mail:

National Compliance Section
Office of Controlled Substances
Health Canada
123 Slater St
AL3502B
Ottawa, ON K1A 0K9
Phone: (613) 954-1541
Fax: (613) 957-0110
Email: national_compliance_section@hc-sc.gc.ca

**TIPS FROM THE COLLEGE:**

Methods of Denaturing Controlled Substances

Destruction is defined by the Office of Controlled Substances as altering or denaturing a substance to the point that its consumption is rendered impossible or improbable. Some recommended methods of denaturing are adding sufficient water or soap solution to partially dissolve and bind the contents. Where a large amount of liquid product is present, the use of products like kitty litter can be used to bind the end product. The use of bleach is NOT recommended as it may result in a dangerous chemical reaction. Pharmacists may also want to contact their Ministry of Environment licensed waste management contractor for advice. Under the standards of practice and regulations by the Ministry of the Environment, denatured or destroyed drugs must be disposed of in an environmentally safe manner. Pharmacies may want to take advantage of the Orange Drop Program (www.makethedrop.ca) operated by Stewardship Ontario, to remove and destroy the denatured drugs and sharps material from their site. Drugs should never be washed down the toilet or thrown out with the regular garbage.
Dr. Waite, an Associate Professor and Associate Director, Practice-Based Education at the University of Waterloo’s School of Pharmacy, enjoys observing how other cultures successfully manage their health and happiness. “Their strategies may differ from ours, she says, “but they still work.”

Her sense of adventure and curiosity about novel approaches will serve her well in her new position. Earlier this year, Dr. Waite was awarded the first Ontario College of Pharmacists Professorship in Pharmacy Innovation.

How can pharmacy programs better prepare graduates for the increasingly expanded roles they’ll be assuming in the health care system? That’s the question that Dr. Waite is eager to address through the OCP Professorship, created with a $600,000 gift from the College.

As the holder, Dr. Waite will provide leadership in both educational and research initiatives. The intention is to ensure a curriculum that produces pharmacists who will not only flourish in their professional environment, but will

From the Amazon jungle to the Himalaya mountains, Dr. Nancy Waite has had some spectacular travels.

By Stuart Foxman
How can pharmacy programs better prepare graduates for the increasingly expanded roles they’ll be assuming in the health care system?

function well during periods of transition and ultimately lead change in the profession.

Dr. Waite is accustomed to ambitious undertakings. She was the second member of the faculty when Waterloo’s School of Pharmacy was launched in 2007, and oversaw development of the new curriculum. It is a blend of best education practices, unique approaches that are possible when a new program starts with a blank slate and Waterloo’s traditional strengths in co-operative education.

In designing the curriculum, Dr. Waite was guided by this philosophy: be bold. Elements were included such as ordering lab tests, prescribing medication and administering vaccines, not knowing for sure which would be applicable in a wider scope of pharmacy practice. “But we knew that the clinical care piece was growing,” she says.

Along with overseeing the curriculum development, Dr. Waite is responsible for experiential programming, including co-op and community service learning, practice-based courses/labs, residencies/fellowships, and continuing professional development.

For her achievements, she earned the Association of Faculties of Pharmacy in Canada – Bristol-Myers Squibb Excellence in Education Award for 2011.

Under the OCP Professorship, Dr. Waite will examine the evidence of the effectiveness of some of Waterloo’s teaching approaches. First-year students, for example, team up with one of about 20 social service agencies to complete a six-month project. It can touch on anything from a health fair to supportive housing to a women’s shelter. Dr. Waite feels that it’s important for the students to understand the community in which their patients live, and what being part of the community is all about. Now, she’ll take a closer look at the learning outcomes of those opportunities.

Another research area of interest is the way that various pharmacist interventions can improve how patients manage their medications, and decrease negative health outcomes. “Where are the places that pharmacists can play a bigger role? One is continuity of care, as patients are discharged from hospital into the community,” Dr. Waite says.

Dr. Waite earned her BScPhm at University of Toronto, and her PharmD and Fellowship at Wayne State University in Detroit. Prior to working at the University of Waterloo and the University of Toronto, she was Manager, Department of Pharmacy Practice and an Associate Professor at the Albany College of Pharmacy in New York.

A former member of the OCP Council, Dr. Waite is honoured to hold the inaugural OCP Professorship in Pharmacy Innovation, and grateful for the College’s focus on this area. “The College is all about protecting the public,” she says, “but it’s also about moving the practice forward — and that will call for innovation.”
OUT OF AFRICA: VOLUNTEER EXPERIENCES HELP MEMBERS GROW
FOR THESE COLLEGE MEMBERS, DEVELOPMENT WORK IS A CHANCE TO GIVE BACK PERSONALLY AND PROFESSIONALLY.

By Stuart Foxman

As a community pharmacist, Martha Bailkowski is used to busy days, but never like this: 1,000 people waiting in the heat, some of whom walked three days to get there.

The scene wasn’t her Toronto pharmacy, but a village in northern Ghana. Bailkowski volunteers with GRID, or Ghana Rural Integrated Development, a Canadian charitable organization. GRID runs health care clinics in Ghana, with the Ghana-based group, and for the past three years Bailkowski has taken part in medical missions there.

For College members, development work is a chance to give back, but Bailkowski feels that she gains too, personally and professionally. “You learn and grow so much,” she says. “When you can understand and look after each other better, that must make you a better pharmacist.”

Her latest mission included a group of 30 health care professionals — physicians, dentists, nurses, an optometrist, three other pharmacists, and a pharmacy technician. Everyone pays their own way. After landing in Ghana’s capital city of Accra, they embarked on a 13-hour bus ride to the tiny village of Carpenter.

That was home base, but the group held clinics in four villages, two a day. The patients needed everything from wound care to treatment for infections. To dispense, Bailkowski
Volunteer pharmacist Martha Bailkowski (also seen on page 24) counselling a patient with the help of a translator.

PHARMACY VOLUNTEERS

had a laptop and printer hooked up to a generator. She could choose pictograms for the labels, like a rising or setting sun to indicate when to take the medication. Each prescription went into a Ziploc bag. Bailkowski used translators for patient counseling; one spoke 13 dialects: “Every village had their own,” she says. Working so closely with the rest of the team, and seeing their faith in her, has had a lasting impact. “I feel confident in my role as a pharmacist,” says Bailkowski, “but didn’t always feel confident in my interprofessional collaboration. So that really helped.”

Ghana is in the back of her mind all the time – the people, their needs, and the rewards of helping out. In Carpenter, she had to shower outdoors, just cold water, but it was magical: “The stars and moon are so clear, you almost feel like you can reach out and touch them.” She finds herself looking up at the moon here, and thinking, “Oh my gosh, this is the moon that’s shining over Ghana right now. It’s like you’re transported back.”

When fellow pharmacy volunteer Aly Haji reflects on his own African volunteer work last year, he’s humbled – and amazed – by what he achieved.

Just some of what he took on at the Aga Khan Hospital in Dar Es Salaam, Tanzania: researched and co-authored a hospital formulary; co-authored antibiotic guidelines; enhanced the computerized physician order entry system; designed a drug information system and trained staff; designed a compounding centre; and worked with the chief pharmacist and other department heads to implement medication safety policies.

Quite impressive for four months – especially considering that Haji was between his second and third year at the Leslie Dan Faculty of Pharmacy, University of Toronto. “I can’t believe I did it all,” says Haji. “It’s a good thing I’m in pharmacy, because I got heartburn from this. It was very stressful.”

Stressful, yes, but immensely satisfying. Haji is proud to have the skills to make a difference.

THEY ARE WAITING
A poem by Martha Bailkowski

They are waiting
The lame, the sick,
The broken-hearted
Quietly, patiently
For the West to come
And bring the hands that heal.

We come
To help the lame
Heal the sick
Mend the broken hearted
Thoughtfully, eagerly
We come to ease their pain.

They ponder
The reality that is their future
Babies must be strong today
In order to survive tomorrow
And can our kind and generous hearts
Give that child a future?

We remember
The long days
And the hot nights
The seemingly endless lineups
How do they face another day?
The miracle of the loaves and fishes.

They have so little
We receive so much
A little girl sees her fingers
A young boy tends his cows
We see them in our mind’s eye
And smile.
and knew he would have a chance to build on those skills in Tanzania.

Haji, whose parents are pharmacists, is inspired by College members who make volunteer and development work part of their professional life. With the continually increasing scope of practice in pharmacy, he feels it’s critical to broaden your horizons. The assignment at the Aga Khan Hospital was a perfect opportunity.

The scope of his original duties evolved, into areas that he never would have touched here as a pharmacy student. Educationally, the experience was unequalled. It gave Haji a huge amount of confidence in working in a pharmacy setting, and in dealing with what he calls “overwhelming” situations.

Mostly, it reinforced the idea that as a future pharmacist he can make an impact on the lives of patients not only in Ontario but also globally. “Pharmacists,” says Haji, “can play a huge role in public health in developing countries.”
QUALITY AND SAFETY IN COMPOUNDING NON-Sterile PREPARATIONS
OVERVIEW

Patients are put at risk when compounded preparations are below regulatory standards. Multiple studies have shown pharmacy-compounded products (for example, bio-identical hormones, nitroglycerin ointments) are at risk for quality issues resulting in sub-potency, supra-potency, and even contamination.1,2,3 This article outlines important considerations when compounding non-sterile preparations by referring to the newly revised United States Pharmacopeia (USP) Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations (as of May 2011) and the Ontario College of Pharmacists (OCP) Guidelines for Compounding Preparations. The USP <795> Chapter defines the specific criteria required to compound preparations of acceptable strength, quality, and purity with appropriate packaging and labeling in accordance with regulatory agencies. In Canada, drug manufacturing is regulated by Health Canada and compounding is an authorized act regulated by provincial authorities.4 The 2006 OCP Guidelines for Compounding Preparations (available at http://www.ocpinfo.com and currently under review) set standards for the quality and safety of compounding practices in Ontario pharmacies.5

The following section supports the preparation of non-sterile compounds within the context of USP specifications and provincial regulatory standards. Relevant medication incidents voluntarily reported to ISMP Canada (for instance, via the Community Pharmacy Incident Reporting (CPhIR) Program at http://www.cphirca) are used to highlight potential outcomes that may result when non-sterile compounding guidelines are not followed.

Before compounding a non-sterile preparation, the need for the compounded product is confirmed by checking for commercially available preparations in the Health Canada’s Drug Product Database (http://webprod3.hc-sc.gc.ca/dpd-bdpp/index-eng.jsp), and contacting manufacturers. To comply with the Health Canada policy on compounding, this confirmation is required in order to validate the lack of product availability and avoid duplicating an approved drug product.4
After confirming the need to compound a preparation, designated managers need to ensure compounders (who are responsible for compounding preparations that are accurate and adhere to provincial standards) have accurate knowledge and expertise. The compounder must use professional judgement when deciding whether they have the expertise to compound a specific product. This includes understanding chemical and physical properties of ingredients, using appropriate equipment, and performing necessary calculations.

Compounders need to prepare non-sterile preparations in designated areas. Designated areas are described as an appropriate environment (i.e. adequate space, lighting, and storage) to prevent cross-contamination and the inadvertent addition of extraneous material to the medication. The OCP Guidelines for Compounding Preparations supports this practice by including provisions for sanitation. OCP recommends the pharmacy have a written sanitation program that specifies cleaning and disposal requirements. The written program should also address hygienic behaviors (such as, wardrobe, hand washing, management of injuries) of pharmacy staff engaging in compounding activities. Furthermore, the designated area should have access to potable water (i.e. drinking water) for hand and equipment washing.

Sample Case: A pharmacist intended to compound an oral suspension of clonidine (using clonidine powder) for a 15-year-old male. The pharmacist incorrectly compounded the clonidine suspension (due to mixing up during calculations/conversions among grams, milligrams, and micrograms) resulting in a preparation 1,000 times more concentrated than prescribed. Before the error was discovered, the patient was admitted to hospital multiple times.

Designated managers need to provide compounders with necessary resources to consistently and accurately produce the intended preparation. Formulations should be accessed from a reputable source. If no formulation is available, a formula should be completed using knowledge in pharmacology, chemistry, and therapeutics. As seen in the Sample Case described above, a miscalculation led to dispensing a preparation 1,000 times more concentrated than the intended prescription. This incident emphasizes the importance of independent double checks and following standardized procedures to confirm accuracy and quality of compounded preparations. Along with defined policies and procedures, compounding preparations require the use of proper resources. This includes using equipment that is clean, and properly maintained. Compounding ingredients must be purchased from reliable sources that are of appropriate identity, quality, and purity.

Sample Case: A male patient received a prescription for a 1% hydrocortisone in clotrimazole [cream]. The compounded preparation contained a piece of wax paper. The prescription was prepared from pre-made stock. The pharmacist did not notice the wax paper in the compounded product and the patient used the preparation containing the wax paper.

Quality control procedures are required to ensure accuracy and completeness. In the Sample Case described above, the pharmacy used pre-made stock to fill the prescription. Unfortunately, the pre-made stock contained wax paper that was included in the dispensed container. Although the wax paper did not cause harm to the patient, compounders are responsible for ensuring the final product appears as expected. If discrepancies are found in the final preparation, compounders need to resolve such discrepancies in preparation and/or appearance before dispensing to the patient.

Sample Case: A patient was prescribed sulfatrim oral suspension to be taken over a period of 90 days. A compounded oral suspension of sulfatrim is only stable for 20 days from its day of preparation. The pharmacist prepared and dispensed a 90 day supply of sulfatrim oral suspension. The medication error was caught during dispensing and the patient was given a 20-day supply with the remaining amount credited as refills.

As seen in the Sample Case described above, sulfatrim or co-trimoxazole oral suspension was not commercially available at the time of dispensing due to drug shortages, resulting in the need for the pharmacy to compound or prepare the oral formulation. The pharmacist in this particular near-miss situation almost dispensed a compounded preparation intended to be used past the acceptable beyond-use date. This illustrates the need for compounders to understand the concept of beyond-use dates.
What is the difference between expiry dates and beyond-use dates?

The manufacturer or distributor gives an expiry date to a drug product based on known stability data. It indicates the expected timeframe in which a drug product meets the therapeutic and stability requirements based on the published monograph or literature. Beyond-use dates, on the other hand, provide the date after which a compounded preparation shall not be used and are determined from the date when the preparation is compounded. Compounders provide the beyond-use date (based on the manufacturer’s stability information and the literature with respect to stability, compatibility, and degradation of ingredients) to limit patient use of the compounded preparation. All compounded preparations must contain a beyond-use date.

How do I figure out the beyond-use date for a compounded preparation?

The beyond-use date is determined from the date of compounding by applying drug-specific and general stability resources, when available. These resources should consider the nature of the drug, degradation, packaging containers, storage conditions, and the duration of therapy. USP <795> states that when a manufactured product is used as an active ingredient in a compounded preparation, the product expiry date cannot be used solely to assign a beyond-use date. Beyond-use dates should be assigned conservatively, while using professional judgment based on pharmaceutical education and experience. For non-sterile compounded preparations that are packaged in tight, light-resistant containers and stored at proper temperatures, consider the recommendations in Table 1 for beyond-use dates when established stability information is not available. It is presumed that recommended beyond-use dates are for compounded preparations that are suitably preserved, where applicable, to protect against bacteria, yeast, and mould contamination.

Should consideration be given to the suitability of containers used for non-sterile compounded preparations?

Sample Case: A child was prescribed an oral Prevacid® suspension. The pharmacist compounded the oral preparation and put it in a plastic amber bottle, instead of a glass amber bottle. Also, the mother was not aware that the oral preparation had to be refrigerated (no auxiliary label was placed on the prescription container) and stored it at room temperature. The issues were resolved before the child took the medication.

Compounders are responsible for selecting the appropriate container for non-sterile compounded preparations. In the Sample Case described

### TABLE 1: RECOMMENDED MAXIMUM BEYOND-USE DATES FOR NON-STERILE COMPOUNDED PREPARATIONS

<table>
<thead>
<tr>
<th>NON-SterILE PREPARATION</th>
<th>BEYOND-USE DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-aqueous Formulations (such as ointments, suppositories, troches, and others where no water is contained)</td>
<td>Not later than the time remaining until the earliest expiration date of any ingredient or 6 months, whichever is earlier</td>
</tr>
<tr>
<td>Water-containing Oral Formulations</td>
<td>Not later than 14 days for liquid preparations when stored at controlled cold temperatures (i.e. temperature thermostatically maintained between 2°C and 8°C)</td>
</tr>
<tr>
<td>Water-containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations (such as preparations for topical application, like creams, gels, ointments, etc.)</td>
<td>Not later than 30 days</td>
</tr>
</tbody>
</table>
above, Prevacid® (lansoprazole) oral suspension was dispensed in a plastic amber bottle and no instructions were given to refrigerate the compounded medication. Plastic containers can contribute to decreased stability of some compounded products. Ensom et al. showed oral lansoprazole preparations were stable for a longer period (91 days with or without refrigeration) in amber glass containers, compared to plastic containers (14 days when refrigerated). This highlights the importance of using the correct container for non-sterile compounded preparation. Compounders are encouraged to review relevant resources before compounding and packaging non-sterile preparations.

**IMPORTANT CONSIDERATIONS**

Inappropriate compounding practices can put patients at risk for potentially harmful outcomes. Compounders unable to compound a drug product for the patient should refer the patient to a compounder with the ability to prepare the product. The references provided in this article can be used as a starting point to ensure quality and safety in the preparation of compounded products. Compounding ingredients (i.e. active pharmaceutical ingredients and excipients) have defined chemical and physical properties that are published in manufacturer monographs. However, the compounding process can change ingredient properties resulting in altered quality, stability, and potency. These changes are highly dependent on the compounding formulation (i.e. capsules, solutions, ointments, etc.). It is vital for compounders to understand the impact of these alterations on the final product before patients are dispensed the compounded preparations.

The information in this article is adapted from the newly revised 2011 USP Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations (which has incorporated USP Chapter <1075> Good Compounding Practices[10] and the 2006 Ontario College of Pharmacists (OCP) Guidelines for Compounding Preparations.[5] It does not represent the entire USP Chapter or the entire OCP Guidelines. For further information, please consult the complete version of USP Chapter <795> and the OCP Guidelines for Compounding Preparations respectively.

The authors acknowledge support from the Ontario Ministry of Health and Long-Term Care for the development of the ISMP Canada Community Pharmacy Incident Reporting (CPhIR) Program (http://www.cphir.ca). The CPhIR Program also contributes to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (http://www.ismp-canada.org/cmirps.htm). A goal of CMIRPS is to analyze medication incident reports and develop recommendations for enhancing medication safety in all healthcare settings. The incidents anonymously reported by community pharmacy practitioners to CPhIR and the assistance from the editorial team at the OCP were extremely helpful in the preparation of this article.

**REFERENCES**

Protecting the Cold Chain

By Barbara Cadotte
Senior Policy Advisor, OCP

A cold chain is a temperature-controlled supply chain for products such as pharmaceuticals, vaccines and blood products that require a specific temperature range during distribution and storage.

The cold chain is necessary to preserve the potency of substances while they are in transit. In addition to temperature, products may also be sensitive to variations in humidity and light, and it is appropriate to include these in the category of those products requiring a cold chain. Products that have not been maintained at the appropriate temperature and under the appropriate conditions are considered to be unsafe for use.

This article will provide an overview of the legislative and policy framework that governs the safety and security of temperature-sensitive products and a brief introduction to the cold chain journey, including the issues associated with the ‘last mile.’ Some best practices for protection of cold chain products in the pharmacy are identified as well. As this is an issue that falls within the accreditation requirements for pharmacies in Ontario, information on the inspection process will also be included. Tips on implementing good cold chain practices appear in the side bar to this article.

LEGISLATIVE AND POLICY FRAMEWORK

An increasing number of medications require cold chain protection and it is expected that the number of pharmaceuticals and biologics that require cold-chain monitoring will continue to increase over the next several years. All persons and companies who are involved in the storage and transportation of drug products, for either human or veterinary use, should be aware of their responsibilities to keep products safe. The federal Food and Drugs Act and Regulations set out the requirements for the labelling, storage and
transportation of temperature-sensitive drugs in Canada. Health Canada has also provided guidelines to assist fabricators, packagers/labellers, distributors, importers and wholesalers to understand and meet their obligations when handling, storing and distributing such products.

The Drug and Pharmacies Regulation Act establishes accreditation requirements for pharmacies in Ontario, including the requirement for a refrigerator in the dispensary maintained at a temperature between 2° and 8°C to store drugs and other medications requiring refrigeration. The Designated Manager (DM) is responsible for ensuring that all drugs and medications purchased by a pharmacy for use or sale are of an acceptable standard and quality. The DM is also accountable for ensuring that there are appropriate policies and procedures in place to manage the cold chain once the pharmacy takes custody of the product. Where there is a remote dispensing system operated by the pharmacy, the DM ensures that systems are in place to track the movement of drugs and other medications between and among the pharmacy and its remote dispensing locations.

**THE COLD CHAIN JOURNEY**

Environmental controls are key to maintaining drug safety, quality and efficacy. The cold chain distribution process officially begins when a product is released from a manufacturer’s warehouse. From that point on, the cold chain is a complex series of multiple touchpoints, facilities, vehicles, modes of transportation, and personnel that ultimately ends with the administration of a medication to a patient. In the near future, this may occur at a pharmacy, but generally today this requires additional movement of the medication from the pharmacy to the place of administration, generally a physicians’ office, other facility or the patient’s home. All temperature-sensitive pharmaceutical and biologic products (those that require refrigeration to avoid heat damage, and those that must avoid freezing) are at risk of temperature damage if handled improperly anywhere along this journey.

**VACCINES**

Vaccination is one of the most effective public health interventions for promoting good health and preventing disease, and pharmacists have always played a role in advocating for patient immunization by providing general information and educating patients on risks and benefits, as well as by hosting immunization clinics. In both Canada and the United States, the scope of pharmacist practice is moving toward medication therapy management and away from the traditional practice of only dispensing medications. Several provinces and states have already conferred

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**COOL VS. COLD: WHAT’S THE DIFFERENCE?**

<table>
<thead>
<tr>
<th>Category</th>
<th>International Storage and Shipping Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen</td>
<td>-25°C and -10°C</td>
</tr>
<tr>
<td>Cold</td>
<td>Any temperature not exceeding 8°C <em>(in Ontario a pharmacy is required to have a refrigerator with a temperature between 2°C – 8°C)</em></td>
</tr>
<tr>
<td>Cool</td>
<td>Between 8°C and 15°C</td>
</tr>
<tr>
<td>Temperature controlled</td>
<td>Thermostatically controlled temperature of 20°C to 25°C</td>
</tr>
<tr>
<td>Room temperature</td>
<td>Temperature prevailing in a working area; not thermostatically controlled</td>
</tr>
<tr>
<td>Warm</td>
<td>Between 30°C and 40°C</td>
</tr>
<tr>
<td>Excessive heat</td>
<td>Above 40°C</td>
</tr>
</tbody>
</table>
upon pharmacists the authority to administer vaccines, and this scope of practice has been proposed for consideration in Ontario.

The issue of cold chain protection for vaccines is an important one. If vaccines are stored or administered at temperatures that are too high or too low, efficacy can be negatively affected and the patient may be inadequately protected or harmed due to the use of an ineffective vaccine. The optimum temperature for refrigerated vaccines is generally between +2°C and +8°C. For frozen vaccines, the optimum temperature is -15°C or lower and there may be additional restrictions on their use. For example, the Zostavax® vaccine must be maintained at a temperature of -15°C or colder and, once it is reconstituted, must be used within 30 minutes. Protection from light and humidity is also a necessary condition for some vaccines.

**Vaccine Storage**

Maintaining vaccines at the appropriate temperature from the time they leave the manufacturer to the time of administration is a very important aspect of immunization delivery programs. In Ontario, Public Health Standards outline the expectations for boards of health, including their mandate to ensure safe vaccine storage and handling procedures. Publicly funded vaccine must be stored in refrigerators that have been inspected annually by public health units wherever they are, including physician offices, nursing agencies, etc. During the inspection, the health care providers’ level of compliance with vaccine storage and handling requirements will be assessed and information and resources provided as required. The inspector will review:

i. Vaccine storage;
ii. Vaccine storage and handling equipment;
iii. Vaccine refrigerator temperatures;
iv. Vaccine temperature log book;
v. Vaccine handling;
vi. Vaccine inventory; and
vii. Availability of vaccine storage and handling resources material.

**The Last Mile**

There are many hand-offs in the process of moving a product from a manufacturer to the end user. The “last mile” of the cold chain refers to that point in time just before the product is administered to a patient. Generally, it is at this time that a product leaves the carefully controlled cold chain, and there is less control over the conditions in which it is kept. This can be a critical period, when temperature-sensitive products may be most vulnerable to degradation, particularly when medications are to be transported to a facility, a physician’s office for injection at a future date, or provided directly to patients to be stored and administered in the home.

The pharmacy should develop written standards of practice covering the process for shipping and transport as both a reference and staff training tool. To ensure that products retain their potency during that last mile, it is recommended that the pharmacist provide both written material and counseling about the risks related to transportation and storage.

**Best Practices in Cold Chain Management**

There are several steps the pharmacy can take to help protect patients against unsafe or ineffective medicines due to cold-chain failure:

- Deal with reputable companies: these organizations will generally have agreements in place between the appropriate parties that outline the chain of storage and transportation conditions for the products that ultimately come to your door.
• Conduct a regular review of the standard operating policies and procedures in place within the pharmacy to ensure that temperature-sensitive products are properly received, stored and dispensed, and ensure that key staff members are trained on their duties and receive the appropriate oversight and monitoring.

• Protect deliveries from poor weather during unloading and examine containers to ensure there is no damage. Cold chain products requiring special monitoring will have temperature sensitive tags which should be checked before accepting at the pharmacy to ensure the cold chain was maintained during transportation.

• The contents of a shipment should promptly be transferred to the appropriate, environmentally controlled storage area.16

• The use of commercial grade equipment is recommended. The equipment must be well maintained, equipped with alarms and free from excessive frost build up. Frequent opening of the door can lead to temperature instability and no vaccines or medications should be stored on the door. There should be a back up power source in the event of a power failure and the door should be opened only when absolutely necessary. Very sensitive products should be kept in a separate refrigerator.17

• Ensure that the pharmaceutical packaging for home delivery meets the specifications needed for the product.18

**ESSENTIAL EQUIPMENT:**
1. Dedicated purpose-built refrigerator for storing biological products;
2. Freezer;
3. Temperature monitoring devices;
4. Insulated containers (coolers);
5. Ice packs (frozen);
6. Gel packs (stored at biological refrigerator temperatures); and
7. Insulating material.

**RECEIVING PRODUCTS:**
• Identify products requiring cold chain protection and check for any signs of damage;
• If the product has a temperature monitoring device or indicator, determine that it is working properly and registering temperatures according to the label on the product;
• Identify controlled drugs and substances subject to specific security requirements and ensure they are stored in accordance with legislative requirements.

**STORING PRODUCTS:**
• The product label should specify any special storage conditions, otherwise, confirm requirements against the product monograph;
• The refrigerator and freezer should be well maintained and kept free of frost buildup;
• To minimize temperature fluctuations caused by opening the door, the refrigerator should not be used to store anything other than products requiring cold chain protection;
• Do not store products on door shelves or crispers;
• Storage conditions should be checked, monitored and recorded:
  - Temperatures should be controlled and monitored using calibrated monitoring devices;
  - Records of temperatures and alarms, if any, should be maintained;
  - Humidity monitoring devices should be used in the appropriate locations;
  - The monitoring equipment should include an alarm to alert personnel in the event that control is compromised;
  - Calibration and functioning of all equipment should be checked on an annual or semi-annual basis;
  - Regular maintenance protocols should be in place for all refrigeration equipment;
• An alternate storage or a backup power source should be in place in the event of a power failure;
• Rotate stock according to expiry date so that products closer to the date are used first.

**TIPS TO SHARE WITH PATIENTS:**
• An ice pack is only sufficient for short-term transport and should not be placed directly against the product;
• Keep the product in its original packaging during transport;
• Consider the length of time required to reach final destination, if not transporting the product directly home, it may be more appropriate to pick it up later;
• If overnight storage is needed, place the product in the center shelf of a refrigerator.
A COLLEGE INSPECTION

The pharmacy is only one link in the cold chain, and pharmacy staff members have little control over what happens to a product prior to arrival at the door. However, the pharmacy has an obligation to ensure the appropriate practices are in place to receive, handle and store products once they are delivered to the pharmacy. The accreditation provisions of the Drug and Pharmacies Regulation Act provide the College with the authority to inspect pharmacies. Inspections focus on the operational requirements of the pharmacy, to ensure that the operation is safe and the public is protected, and to assist members to comply with legislated requirements. Inspectors are also a resource for the pharmacy and can provide information and advice regarding the pharmacy’s operations. With respect to cold chain management, an inspector will confirm that the refrigerator in the pharmacy meets the temperature requirements and that nothing other than drugs or medications requiring refrigeration are stored in the refrigerator. The inspector will also confirm that the contents are stored appropriately. Where the pharmacy operates a remote dispensing location, the inspector will confirm that the location has an alarm system that provides immediate notification to the DM of any alteration in the temperature of the location outside of the approved standards.

CONCLUSION

Most pharmacies manage the storage and handling of cold chain products appropriately and according to requirements established through legislation and policy. In order to protect the safety and efficacy of medications, and ultimately for the benefit of patient health and well-being, continuing vigilance of every link of the cold chain should be fully integrated into pharmacy practice. This article has provided an overview of some of the important elements leading to good cold chain practices; however every pharmacy needs to customize their practices to fit their patients and their needs.

REFERENCES

Member: Trevor Wrightman

At a motion on December 20, 2011, a Panel of the Discipline Committee considered allegations of professional misconduct against Mr. Wrightman which related to failing to meet the conditions of the Meds Check Program (‘Program’) when billing for services in relation to the Program and falsifying Program forms.

In resolution of the matter, Mr. Wrightman entered into an Undertaking, Agreement & Acknowledgment with the College whereby he resigned permanently as a member of the College, irrevocably surrendered his certificate of registration and does not now own or at any time in the future will acquire any ownership interest in any pharmacy in the Province of Ontario. Mr. Wrightman also paid the amount of $12,500.00 as an ex gratia payment to the Minister of Finance and $3,000.00 to the College for costs.

Accordingly, the parties made a joint submission to the Discipline Committee to issue an order for a stay of the allegations of professional misconduct against Mr. Wrightman. On the basis of the Undertaking, Agreement & Acknowledgment Mr. Wrightman entered into with the College, the Discipline Committee accepted the joint submission of the parties and issued an order staying the allegations of professional misconduct against Mr. Wrightman.

Member: Jerry Malkin

At a motion on February 27, 2012, a Panel of the Discipline Committee considered allegations of professional misconduct against Mr. Malkin which related to dispensing Schedule 1 and/or Schedule F drugs, controlled drugs, narcotics, and/or targeted substances without a prescription and/or proper authorization.

In resolution of the matter, Mr. Malkin entered into an Undertaking, Agreement & Acknowledgment with the College whereby he resigned permanently as a member of the College, irrevocably surrendered his certificate of registration and will not have, keep or acquire, now or at any time in the future, any ownership interest, direct or indirect, controlling or otherwise, in any pharmacy in the Province of Ontario. Mr. Malkin also agreed to pay costs to the College in the amount of $7,000.

Accordingly, the parties made a joint submission to the Discipline Committee to issue an order for a stay of the allegations of professional misconduct against Mr. Malkin. On the basis of the Undertaking, Agreement & Acknowledgment Mr. Malkin entered into with the College, the Discipline Committee accepted the joint submission of the parties and issued an order staying the allegations of professional misconduct against Mr. Malkin.

Member: Peter Jarcew

At a motion on March 2, 2012, a Panel of the Discipline Committee considered allegations of professional misconduct against Mr. Jarcew which related to being found guilty of an offence relevant to Mr. Jarcew’s suitability to practise, in particular sexual assault contrary to section 271 of the Criminal Code of Canada.

In resolution of the matter, Mr. Jarcew entered into an Undertaking, Agreement & Acknowledgment with the College whereby he resigned permanently as a member of the College, irrevocably surrendered his certificate of registration and will not have, keep or acquire, now or in the future, any ownership interest, direct or indirect, controlling or otherwise, in any pharmacy in the Province of Ontario.

Accordingly, the parties made a joint submission to the Discipline Committee to issue an order for a stay of the allegations of professional misconduct against Mr. Jarcew. On the basis of the Undertaking, Agreement & Acknowledgment Mr. Jarcew entered into with the College, the Discipline Committee accepted the joint submission of the parties and issued an order staying the allegations of professional misconduct against Mr. Jarcew.

The full text of these decisions is available at www.canlii.org

CanLii is a non-profit organization managed by the Federation of Law Societies of Canada. CanLii’s goal is to make Canadian law accessible for free on the Internet.
Get Involved!

There are many ways to get involved with the College. One of them is by participating on a College committee as a non-council member. Under the Regulated Health Professions Act, the College requires the appointment of members who are not elected members of Council to its various statutory committees.

Sitting on a committee provides tremendous learning and insight about the College and its role in regulating the profession in the public interest. The College encourages all members, including Pharmacy Technicians, to consider becoming involved. The number of days required to serve on each committee varies according to the frequency of meetings and agenda.

The statutory committees that require participation by a non-council member include:

- The Accreditation Committee, considers matters relating to the operation of pharmacies in Ontario including; operational requirements, ownership, supervision and the distribution of drugs in the pharmacy.

- The Discipline Committee, hears allegations of professional misconduct against members as referred by various Committees of the College.

- The Fitness to Practise Committee, considers incapacity matters referred by the Inquiries, Complaints and Reports Committee.

- The Inquiries, Complaints and Reports Committee, screens matters related to public complaints or information the College receives through reports.

- The Patient Relations Committee, develops and monitors a Sexual Abuse Prevention Plan as well as monitors the College’s Patient Relations Program.

- The Quality Assurance Committee, develops and maintains the College’s Quality Assurance Program, which includes; continuing education, a two-part register, minimum practice requirements and a practice review process.

- The Registration Committee, establishes the conditions and qualifications for registration.

To be considered for a position, please submit a letter of interest stating the committee(s) on which you would like to serve, along with a brief resume and any other information you deem useful. Non-council committee members are required to serve a one-year term and the President, in conjunction with the chairs of the committees, makes committee appointments at the beginning of each Council year. You will be contacted after the September Council meeting has taken place if you have been appointed to serve on a Committee.

If you are interested in being considered for an appointment to a committee, or for more information on non-Council Committee representation, contact Ms. Ushma Rajdev, Council & Executive Liaison, at 416-962-4861, ext. 243, email urajdev@ocpinfo.com.

To be eligible for consideration for appointment, you must:

- hold a valid Certificate of Registration as a pharmacist or as a pharmacy technician
- either practise or reside in Ontario
- not be in default of payment of any fees prescribed in the By-Laws
- not be the subject of any disciplinary or incapacity proceeding
- not have your Certificate of Registration revoked or suspended in the six (6) years preceding the date of the appointment
- not have your Certificate of Registration subject to a term, condition or limitation other than one prescribed by regulation and
- not have a conflict of interest in respect of the Committee to which you are to be appointed
Pharmaceutical manufacturers often use similar packaging and labeling for consistency when marketing their products. The resulting look-alike packaging and labeling are factors often associated with medication errors.

**CASE:**

An eighty-five year old patient requested a refill of her Midamor® 5mg tablets. During the preparation, the pharmacy assistant selected Midodrine® tablets in error. These tablets were then labeled as Midamor® and passed on to the pharmacist for checking. The pharmacist did not open the vial during the checking process and therefore did not detect the error. Midodrine® tablets were therefore dispensed to the patient instead of Midamor®. Fortunately, the patient detected the change in tablet appearance and contacted the pharmacy for an explanation before taking the incorrect medication. Upon investigation, the error and contributing factors were identified.

**POSSIBLE CONTRIBUTING FACTORS:**

- The packaging of Midamor® and Midodrine® are similar in size and shape. (see photo)
- The labeling is similar in appearance.
- Similarity in drug names.
- The two products were stored next to each other due to the similarity in names.
- The pharmacist did not check the contents of the vial before dispensing.
- Neither the pharmacy assistant nor the pharmacist checked the drug identification number (DIN) of the product being dispensed.

**RECOMMENDATIONS:**

- Avoid storing different products with similar appearance next to each other.
- Consider changing the brand of one of these products to reduce the potential of a mix up.
- When checking prescriptions for accuracy, the pharmacist should check the packaging and all digits of the DIN of the product being dispensed.
- The prescription vial should also be opened to confirm the correct contents.
- Manufacturers must take steps to ensure that packaging, labeling and product appearance are distinct and clearly identify different products. Tall man letters is one strategy which may be used. Tall man letters are uppercase letters that are used within a drug name to highlight its primary dissimilarities with look-alike drug names. For example, HumaLOG® may be differentiated from HumaLIN® and MidAMOR® may be differentiated from MidODRINE®.

Please continue to send reports of medication errors in confidence to Ian Stewart at ian.stewart2@rogers.com.
CONTINUING EDUCATION

Visit the College’s website: www.ocpinfo.com for a complete listing of upcoming events and/or available resources. A number of the programs may also be suitable for pharmacy technicians.

For local live CE events in your area, contact your regional CE coordinator by going to www.ocpinfo.com and searching on “Regional Coordinators”.

GTA

June 4- June 8, 2012
Improving Your Practice/Teaching Through Evidence-Based Clinical Practice
McMaster University, Hamilton
Contact: Deborah Maddock 905-524-9140 Ext 22900
http://ebm.mcmaster.ca/online_registration.html

June 13-15, 2012
OSCE-ology
Leslie Dan Faculty of Pharmacy, University of Toronto
Contact: Ryan Keay @ 416-978-7562
http://cpd.phm.utoronto.ca

June 14, September 9, September 23, 2012
(Multiple locations and dates)
Injection and Immunization Certificate Program
Ontario Pharmacists Association
Contact: education@dirc.ca

June 14-16, 2012
OPA Conference 2012 London, Ontario
Ontario Pharmacists Association
Contact: Stefani Margulies 416-441-0788 or 1-800-268-8058 Ext 4247
smargulies@opatoday.com

September 26, 2012
Root Cause Analysis Workshop for Pharmacists
Institute for Safe Medication Practice (ISMP Canada), Toronto, ON
http://www.ismp-canada.org/education/
Contact Medina Kadija at mkadija@ismp-canada.org

October 24-26, 2012
Primary Care: Providing Patient Care in a New Practice Environment
University of Toronto - Toronto, ON
http://cpd.phm.utoronto.ca/primarycare.html

INTERESTED IN EXPANDING YOUR NETWORK AND GIVING BACK TO THE PROFESSION?

OCP IS LOOKING FOR REGIONAL CE COORDINATORS

OCP is looking for regional CE coordinators in regions 4 (Pembroke and area), 9 (Lindsay area), 10 (North Bay area) 14 (Barrie area), 17 (Brantford area), 25 (Sault Ste Marie area), 27 (Timmins area) and associate CE Coordinator for Region 11 (Markham).
A complete list of regions by town/city is available on the College’s website, www.ocpinfo.com, by searching ’CE Region Assignments’.

As a Regional CE Coordinator, you will identify the CE needs of local pharmacists in your region and organize CE events with fellow team members. Interested pharmacists should submit their resume to Rahila Ovais at rovais@ocpinfo.com
October 2012 (date to be determined)
Nutrition for Pharmacists Certificate Program
Ontario Pharmacists Association
Contact: education@dirc.ca

October 2012 (date to be determined)
Infectious Disease Program
Ontario Pharmacists Association
Contact: education@dirc.ca

November 2012 (date to be determined)
Certified Geriatric Pharmacist Preparation Course
Ontario Pharmacists Association
Contact: education@dirc.ca

December 2012 (date to be determined)
Psychiatry Certificate Program
Ontario Pharmacists Association
Contact: education@dirc.ca

Canadian Society of Hospital Pharmacists (CSHP)
Online education program accredited by CCCEP
www.cshp.ca

Canadian Healthcare Network
On-line CE Lessons
www.canadianhealthcarenetwork.ca

Centre for Addiction and Mental Health (CAMH)
On-line courses with live workshops in subjects including mental health, opioid dependence, motivational interviewing, interactions between psychiatric medications and substances of abuse.
www.camh.net

Clinical Tobacco Interventions for Health Care Professionals
Online CE
www.opacti.org

Continuous Professional Development - Leslie Dan Faculty of Pharmacy, University of Toronto
Infectious Diseases Online Video Lectures and Slides, Influenza DVD
http://cpd.phmutoronto.ca/cimi.html

Ontario Pharmacists Association (OPA)
Online certificate programs in therapeutic areas including Pain and Palliative care and Diabetes level 1
Online complimentary programs in therapeutic areas including Methadone, Smoking Cessation, Practical Management of Cough and Cold, Ulcerative colitis and Vitamin D in osteoporosis.
www.pharmacisteducation.ca
Contact Penny Young 416-441-0788 ext. 2209, pyoung@dirc.ca

RxBriefcase
On-line CE Lessons (Clinical and Collaborative care series) and the Immunization Competencies Education Program (ICEP)
www.rxbriefcase.com

ON-LINE/WEBINARS/ BLENDED CE

Canadian Pharmacists Association
Home Study Online education programs accredited by the Canadian Council on Continuing Education in Pharmacy (CCCEP), including Diabetes Strategy for Pharmacists, QUIT: Quit Using & Inhaling Tobacco and Respiratory care
The Niagara Apothecary

The Apothecary is open from Mother’s Day to Labour Day, daily from 11 a.m. to 6 p.m.; Labour Day to Thanksgiving, weekends only. Retired pharmacists are available to provide information and answer questions about this heritage building.

Admission is free; donations welcome.

Make plans to visit this summer!

For more information visit the Apothecary’s website at:

www.niagaraapothecary.ca

REMINDER:

UPCOMING COUNCIL ELECTIONS - SEE PAGE 20 FOR DETAILS