February/March 2011

NAPRA National Drug Schedules Notice Board

NDSAC Initial Recommendation on naproxen sodium 220 mg per tablet
March 14, 2011

A meeting of the National Drug Scheduling Advisory Committee (NDSAC) was held on March 6, 2011, with the following Initial Recommendation made:

- Naproxen sodium 220 mg per oral dosage unit (when sold in products labeled with a recommended maximum daily dose of 440 mg, and in package sizes exceeding 6,600 mg) - Schedule III (from Schedule II)

Any objections to this Initial Recommendation must be received by the NAPRA office by April 12, 2011. Questions or comments should be directed to the Manager, Professional and Regulatory Affairs, Kathy Vesterfelt at (613) 569-9658, ext. 225 or kvesterfelt@napra.ca

Notice to interested parties — Proposal regarding the addition of Salvia divinorum and salvinorin A to Schedule III to the Controlled Drugs and Substances Act
February 19, 2011

This notice provides interested stakeholders with the opportunity to provide comments on Health Canada’s proposal to add the plant *Salvia divinorum* (*S. divinorum*) and its main active ingredient salvinorin A to Schedule III to the Controlled Drugs and Substances Act (CDSA). Stakeholders may also identify themselves for inclusion in any future consultation.

The plant *S. divinorum* is a species of sage belonging to the mint family. Its leaves are generally chewed or smoked to obtain psychotropic effects. While uncertainty remains surrounding the health risks of *S. divinorum*, known effects are reported to be short-acting in nature and include hallucinations, dysphoria, out-of-body experiences, unconsciousness and short-term memory loss. The effects, which vary from person to person, are also often described as unpleasant. Neither *S. divinorum* nor salvinorin A are currently included in any of the schedules to the CDSA.

Recently there have been reports suggesting that Canadian teens and young adults are using *S. divinorum* for its ability to produce hallucinations. *S. divinorum* is widely touted as a “legal” hallucinogen on the Internet, and has also been reported to be one of the most prevalent herbal products used as an alternative to illicit drugs.1 Results from the Canadian Alcohol and...
Drug Use Monitoring Survey (CADUMS) reveal that, in 2009, 1.6% of Canadians aged 15 years and older reported having used S. divinorum at least once in their lifetime, with a much higher rate of use (7.3%) in youth aged 15–24 years. The results from the Canadian 2008–2009 Youth Smoking Survey also show that 5% of 15-year-olds have used S. divinorum in the past year. Moreover, the 2009 Ontario Student Drug Use and Health Survey (OSDUHS) indicated that 5.4% of Ontario students in grades 7–12 reported ever using S. divinorum and 4.4% of these students reported using this substance in the past year. Because its psychoactive effects resemble those of other substances included in Schedule III to the CDSA such as lysergic acid diethylamide (LSD) and psilocybin, Health Canada is concerned that the ready availability and use of S. divinorum poses a risk to the health and safety of Canadians, particularly youth.

While S. divinorum and salvinorin A are not currently included in any of the United Nations drug control conventions, a number of countries have chosen to regulate one or both as controlled substances. Australia, Belgium, Denmark, Finland, Germany, Italy, Japan, South Korea, Spain and Sweden have all placed controls on the import and/or sale of S. divinorum and/or salvinorin A. Some American states have also implemented laws restricting their use, sale and/or distribution.
HEALTH CANADA ADVISORIES

All Health Canada Advisories, Warnings and Recalls for health professionals and the public may be accessed directly through MedEffect Canada at:

http://www.hc-sc.gc.ca/dhp-mpo/medeff/index_e.html

At this site, pharmacists should subscribe directly to MedEffect e-Notice to receive the latest advisories, warnings and recalls and the Canadian Adverse Reaction Newsletter (CARN) as they are issued by Health Canada. These alerts are an important source of information regarding the post-market safety and effectiveness of health and drug products and pharmacists are reminded of their responsibility to be aware of this vital information.

Pharmacy Managers are reminded to continue to maintain a system within the pharmacy for the communication of all important notices to employees from the MPhA and MedEffect Canada.

For Health Professionals and Consumers

March 2011

Multaq (dronedarone) - Updated Safety Information in Regards to Hepatocellular Liver Injury - Sanofi-aventis Canada Inc.

For Health Professionals [2011-03-15]
For the Public [2011-03-15]

February 2011

Methylene blue injectable in combination with serotonin reuptake inhibitors - Association with serotonin toxicity

Notice to Hospitals [2011-02-17]

PEGETRON REDIPEN (peginterferon alfa-2b) - Recall of Triad Group Alcohol Prep Pads, Alcohol Swabs, and Alcohol Swabsticks - Merck Canada Inc.

For Health Professionals [2011-02-04]
For the Public [2011-02-04]

December 2010

Thelin (sitaxsenan sodium) - Worldwide Product Withdrawal - Pfizer Canada Inc.

For Health Professionals [2010-12-20]
For the Public [2010-12-20]

Supplement to The Manitoba Pharmaceutical Association Newsletter March, 2011
Retain a copy for reference.
Recent Advisories Warnings and Recalls

Multaq (dronedarone) - Updated Safety Information in Regards to Hepatocellular Liver Injury - Sanofi-aventis Canada Inc.

For Health Professionals [2011-03-15]
For the Public [2011-03-15]

Important Information: Additional Recalled Lubricating Jelly Products [2011-02-17]

Methylene blue injectable in combination with serotonin reuptake inhibitors - Association with serotonin toxicity

Notice to Hospitals [2011-02-17]

Pharmetics Inc. Voluntarily Recalls a Number of Products from the Canadian Market [2011-02-08]

Important Information: Additional Health Products Co-packaged with Recalled Alcohol Prep Pads [2011-02-04]

PEGETRON REDIPEN (peginterferon alfa-2b) - Recall of Triad Group Alcohol Prep Pads, Alcohol Swabs, and Alcohol Swabsticks - Merck Canada Inc.

For Health Professionals [2011-02-04]
For the Public [2011-02-04]

Foreign Product Alert - Slimming Factor [2011-02-03]

Foreign Product Alert - RockHard Weekend (lots 100159 and 100260 sold as blister packs, 3-count bottles and 8-count bottles) [2011-02-03]

Foreign Product Alert - Fruta Planta, Reduce Weight Fruta Planta [2011-02-03]

Exact Multi Greens Powder and Capsules Recalled as They May Pose Serious Health Risks to Canadians with Milk Allergies [2011-02-02]

Foreign Product Alert - Vigor-25, Man Up Now [2011-01-31]

Foreign Product Alert - Tiger King [2011-01-31]

Foreign Product Alert - Prolatis’ Duro Extend Capsules For Men [2011-01-31]


Nutrex Research Lipo 6x: Weight Loss Product could cause serious adverse reactions [2011-01-28]

It's Your Health - Disposal and Use of Medication [2011-01-26]

It's Your Health - Safe Use of Medicines [2011-01-25]

It's Your Health - Injectable Cosmetic Treatments [2011-01-24]

Update: Four Probiotic Natural Health Products May Pose Serious Health Risks to Canadians with Milk or Soy Allergies [2010-12-24]

Three Probiotic Natural Health Products May Pose Serious Health Risks to Canadians with Milk or Soy Allergies [2010-12-23]
Advisories, Warnings and Recalls for the Public - 2010

March 2011

Multaq (dronedarone) - Updated Safety Information in Regards to Hepatocellular Liver Injury - Sanofi-aventis Canada Inc.

For Health Professionals [2011-03-15]
For the Public [2011-03-15]

February 2011

Important Information: Additional Recalled Lubricating Jelly Products [2011-02-17]

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For the Public [2011-02-04]

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Foreign Product Alert - Fruta Planta, Reduce Weight Fruta Planta [2011-02-03]

January 2011

Foreign Product Alert - Vigor-25, Man Up Now [2011-01-31]

Foreign Product Alert - Tiger King [2011-01-31]

Foreign Product Alert - Prolatis' Duro Extend Capsules For Men [2011-01-31]


Nutrex Research Lipo 6x: Weight Loss Product could cause serious adverse reactions [2011-01-28]

It's Your Health - Disposal and Use of Medication [2011-01-26]

It's Your Health - Safe Use of Medicines [2011-01-25]

It's Your Health - Injectable Cosmetic Treatments [2011-01-24]

Bowers Medical Ltd. Recalls a Number of Triad Products [2011-01-14]

Reminding Canadians About Using Acetaminophen Safely [2011-01-13]

Important Information for Multiple Sclerosis Patients: COPAXONE® Co-packaged with Recalled Alcohol Prep Pads [2011-01-12]
Shandex Sales Group Urgently Recalls Alcohol Swabs [2011-01-11]
Synerate: Weight Loss Product Could Cause Serious Adverse reactions [2011-01-07]

December 2010

UPDATE: Four Probiotic Natural Health Products May Pose Serious Health Risks to Canadians with Milk or Soy Allergies [2010-12-29]

Three Probiotic Natural Health Products May Pose Serious Health Risks to Canadians with Milk or Soy Allergies [2010-12-23]

Thelin (sitaxsentan sodium) - Worldwide Product Withdrawal - Pfizer Canada Inc.

For Health Professionals [2010-12-20]
For the Public [2010-12-20]
ISMP Canada Safety Bulletin

Oral Clonidine Suspension: 1000-Fold Compounding Errors Cause Harm to Children

ISMP Canada has received 3 reports of children experiencing harm because of errors during preparation of oral clonidine suspension from clonidine powder. This bulletin provides information about the incidents, describes the dangers associated with clonidine overdose, and suggests strategies to prevent recurrence of this type of error.

Incident Reports

In each of the 3 incidents, a pharmacist working in a community pharmacy used clonidine powder (provided in containers labelled by weight, in grams) to prepare a suspension for pediatric use. The prescribed doses for clonidine ranged from 25 mcg (0.025 mg) to 125 mcg (0.125 mg). In each case, there was a mix-up during the conversions among grams, milligrams, and micrograms, and the concentration of the suspensions dispensed was 1000 times greater than intended.

Each child required emergency treatment and admission to hospital. Two of the children were admitted to the intensive care unit, and one of these required treatment of severe hypotension.

Background

Clonidine is a centrally acting alpha₂-adrenergic agonist approved for use in Canada for the treatment of hypertension (e.g., Catapres and generic agents; available as 0.1 mg and 0.2 mg tablets). In addition to its use in treating hypertension, clonidine (Dixarit and generic agents; available as 0.025 mg tablet) has also been approved for the relief of menopausal flushing in patients for whom hormone replacement therapy is unsuitable. With the availability of newer and better-studied anti-hypertensives, however, the use of clonidine has waned over the past couple of decades. With this less frequent use of clonidine has come reduced familiarity with the drug and its dosing.

Clonidine is also used for off-label treatment of several conditions in the pediatric population. In particular, it is often used as a first-line treatment option for pediatric patients with tics. The use of clonidine in combination with stimulant medications has been supported by various expert organizations that address ADHD and its comorbidities. Clonidine is often dosed in micrograms for pediatric use, whereas for adults, the dosing is typically expressed in milligrams.

The therapeutic window for children is narrower than that for adults, and compounding errors can lead to significant harm. Among children, ingestion of 10 mcg per kilogram body weight can result in severe overdose. In the 3 incidents described earlier, the children experienced symptoms consistent with clonidine overdose, including shallow breathing, sweating, and hypotension.

The most common signs of clonidine toxicity include profound hypotension, bradycardia, and central nervous system depression. Signs and symptoms similar to those exhibited with narcotic overdose may also occur, including respiratory depression (which may progress to apnea), miosis (i.e., constriction of the pupils), muscle flaccidity, and hyporeflexia. Although uncommon, early hypertension may also occur in cases of severe clonidine overdose because of activation of the peripheral alpha-adrenergic receptors. Symptoms of overdose generally arise within 30 minutes to 2 hours after ingestion, with hypotensive effects peaking in 2 to 4 hours.

Recommendations

Clonidine suspension is not commercially available, and suspensions must be compounded individually. The following strategies are suggested to prevent compounding errors with clonidine:

- Use a standard formula and worksheet to prepare oral liquid clonidine, preferably one based on commercially available tablets, such as the clonidine compounding formulation available from The Hospital for Sick Children in Toronto. This formulation does not necessitate weighing of powder; instead, it uses a specified number of tablets in a dose readily available from manufacturers. The tablets are labelled in terms of milligrams, which reduces the complexity of converting a powder weighed in grams to a dose prescribed in micrograms.

- Ensure that effective, independent double-checks are performed for critical steps in the process (identified on
the worksheet) to increase the chance that errors are identified.

- In cases where practitioners must work alone, explore options for independent double-checks. For example, pharmacists who work alone can consult drug information centres or collaborate with pharmacists in other pharmacies for a check on calculations.
- Encourage parents to bring to the pharmacist’s attention any refill prescription that seems to differ, in terms of appearance, taste, or instructions, from the previous prescription.\(^7,12,13\)

Other cases of clonidine overdose in children because of compounding errors have been reported.\(^7,12,13\) It is hoped that the sharing of information through this bulletin will help to inform practitioners and reduce the potential for recurrence of such incidents.

\textbf{Acknowledgements}
ISMP Canada gratefully acknowledges the expert review of this bulletin by (in alphabetical order):

- Ross Evans BScPhm MA (Journalism), Child and Parent Resource Institute, London, ON;
- Elaine Lau BScPhm PharmD MSc, Drug Information Coordinator, The Hospital for Sick Children, Toronto, ON;
- Ajit Ninan MD FRCPC DABPN, Assistant Professor, Department of Psychiatry, University of Western Ontario, and Chief of Treatment, Child and Parent Resource Institute, London, ON;
- Elaine Wong BScPhm, PICU/Medication Safety Pharmacist, Children’s Hospital of Eastern Ontario, Ottawa, ON;
- Ken Wou BSc(Pharm), Pharmacy Consultant.

\textbf{References} – please refer to page 3.

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**Community Pharmacy Incident Reporting Program**

ISMP Canada, with support from the Ontario Ministry of Health and Long-Term Care, developed the Community Pharmacy Incident Reporting (CPhIR) Program (www.cphir.ca) to allow community pharmacies to document and analyze factors contributing to errors in the medication-use system. Input from the Nova Scotia SafetyNET-Rx project, and implementation across the province of Nova Scotia, has also facilitated quality improvements to the program.

CPhIR assists community pharmacy teams to develop and implement system-based strategies for improving the quality of medication use in the community and for preventing medication-related incidents.

The program is designed to benefit provincial and national patient safety initiatives and contribute to the Canadian Medication Incident Reporting and Prevention System (CMIRPS) (www.ismp-canada.org/cmirps.htm).

If you would like more information about the CPhIR Program, please contact ISMP Canada by email: cphir@ismp-canada.org or by telephone: 1-866-544-7672.

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**Risk Assessment Program for Medication System Safety in Community Pharmacy**

The \textbf{Medication Safety Self-Assessment (MSSA) for Community/Ambulatory Pharmacy} was developed to assist and guide individual community pharmacies in identifying opportunities to improve their medication-use systems. The program’s self-assessment criteria are related to potential system improvements that have been identified through analysis of medication incidents. Completion of this MSSA can be an important element of a community pharmacy’s quality improvement initiatives.

The program’s web-based interface allows individual community pharmacies to compare their own results over time, thereby tracking the impact of any changes made, as well as to compare their results with the aggregate results of other participants in the program, both regionally and nationally. Several Canadian provinces have supported the use of this program as a component of quality improvement. The program is also available at a reasonable cost to individual community pharmacies.

For more information about the MSSA program for community pharmacy, please contact ISMP Canada by email: mssa@ismp-canada.org or by telephone: 1-866-544-7672.
Evaluation of Services Provided by ISMP Canada through the Canadian Medication Incident Reporting and Prevention System (CMIRPS)

In 2010, ISMP Canada engaged Prairie Research Associates (PRA) Inc. to conduct an evaluation of the work that ISMP Canada has delivered through the CMIRPS program. The evaluation (available from: www.ismp-canada.org/download/cmirps/rptISMPC_CMRIPS_Final_Report.pdf) focuses on the impact of the products and services offered by ISMP Canada, and the extent to which the work has resulted in changes to the healthcare system across Canada. The evaluation identified several potential enhancements to services, which are being incorporated into the organization’s future work plans.

ISMP Canada sincerely appreciates the time taken by the many Canadian practitioners who provided feedback and participated in the evaluation.

References

Extemporaneous Compounding Manual

**CLONIDINE 5 mcg/ml ORAL SYRUP**

**CLASSIFICATION**

ANTIHYPERTENSIVE

**YIELD**

100 ml

**PAGE**

1 of 1

### INGREDIENTS

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### MATERIALS

- mortar and pestle
- graduated cylinder
- amber prescription bottle - glass

### METHOD OF PREPARATION

1. In a glass mortar with a glass pestle, grind clonidine tablets to a very fine powder.
2. Add water and mix with pestle to smooth paste.
3. Add 30 mL of simple syrup in 10 mL portions. Mix well with pestle to incorporate simple syrup.
4. Transfer the mixture to the graduated cylinder.
5. Rinse the contents of the mortar into the graduated cylinder with enough simple syrup to bring the final volume to 100 mL.
6. Transfer the solution to an amber glass prescription bottle and label.

### PACKAGING

120 mL amber, GLASS prescription bottle with child resistant cap

### EXPIRY

28 days refrigerated

### LABEL

Clonidine 5 mcg/ml Oral Syrup

“X” mL

Batch #

Expires

### AUXILIARY LABELS

- Refrigerate

### REFERENCES


**Last Revised: September 24, 2007**
The Pharmacy Examining Board of Canada
Le Bureau des examinateurs en pharmacie du Canada

CALLING MANITOBA PHARMACISTS:
Recruitment of Registered Pharmacists as Assessors for the PEBC Qualifying Examination – Part II (OSCE)

The Pharmacy Examining Board of Canada (PEBC) invites qualified pharmacists and pharmacy technicians to consider participating as an assessor for the PEBC Qualifying Examination – Part II (OSCE and/or PT-OSPE). (See Assessor Eligibility and Selection Criteria.)

Since 2001, the PEBC Qualifying Examination for pharmacists has consisted of two components: Part I, the multiple-choice question examination given in two half-day sessions; and Part II, a performance assessment, approximately 3 hours in length, given on a third day. Part II is a performance-based examination of a particular kind, known as an Objective Structured Clinical Examination (OSCE). It is designed to assess communications/interpersonal skills, the application of knowledge to simulations of commonly encountered patient scenarios and other aspects of professional competence that do not lend well to written examinations. The competencies to be assessed through both the written and practice-based exams are those adopted (or adapted) by all member provinces of the National Association of Pharmacy Regulatory Authorities (NAPRA).

In 2010, PEBC implemented the new PEBC Qualifying Examination for pharmacy technicians, also consisting of a multiple-choice examination (Part I) and performance-based examination (Part II), the Objective Structured Performance Examination (PT-OSPE). The examination will be implemented in provinces as they move forward with regulation of pharmacy technicians. Once registered, pharmacy technicians will also be integrated into PEBC processes.

It is particularly important that practising pharmacists be involved in assessing candidates for pharmacist licensure as the examination reflects both the health care needs of the public and the standards of the profession. Likewise, it is important that certified pharmacy technicians be involved as assessors in the PT-OSPE, once they are registered.

The complete list of interested assessors is submitted for annual review by the licensing bodies, for confirmation that all assessors are members in good standing on an ‘active’ register and are not under investigation.

Many assessors find that involvement as an assessor is both personally and professionally rewarding. Although many return year after year there is always a need for new assessors. Each year, PEBC invites interested pharmacists who have been licensed in Canada for at least three years and are currently providing or directly supervising patient care services (including dispensing, clinical and/or drug information services) to apply as assessors for both the OSCE and the PT-OSPE. PEBC also invites interested pharmacy technicians who are registered in Canada to apply as assessors for the PT-OSPE.

If you are interested in participating as an assessor or if you would like more information, please complete and return the attached ‘Assessor Recruitment Response Form’. (If you have previously participated but have moved to a different city, please fully complete the response form, indicating where and in what capacity you participated.) You will be contacted by the examination centre nearest to you approximately two months in advance to determine your interest and availability. The exam centre will then select the number of assessors required and confirm whether or not you will be as assessor.

More information can be found on the PEBC website at www.pebc.ca.
Professional Competencies for Pharmacy Technicians

PEBC very much appreciates the interest shown by practicing pharmacists and newly certified pharmacy technicians in PEBC’s Pharmacy Technician Qualifying Examination – Part II (PT-OSPE). As this is an emerging new profession, it is important that all participants in the examination support the vision for the new profession and the expanded role of the regulated pharmacy technician in the pharmacy and in the health care system as a whole.

PEBC has based the examination on the NAPRA competencies, as outlined in the document: www.napra.org/Content_Files/Files/Professional_Competencies_for_Canadian_Pharmacy_Technicians2007.pdf. Standards of practice are now being developed and will continue to evolve as the profession evolves. More information about the role and regulation of pharmacy technicians is available on the provincial regulatory bodies’ websites. If you have questions or concerns about the PEBC examination, the competencies being assessed or your eligibility to be an assessor, please contact our Chief Administrator, Cheryl Gnanapragasam, (e-mail address: Cheryl.Gnanapragasam@cancercare.mb.ca) or our Chief Examiner, Dora Ma, (dma@sbgh.mb.ca).

2011 Dates & Locations
PEBC Qualifying Examination – Part II (OSCE)

Pharmacist OSCE

Sunday, May 29
Locations in May: Vancouver, Edmonton, Calgary, Saskatoon, Winnipeg, Toronto, Kingston, London, Hamilton, Ottawa, Montreal (bilingual), Halifax and St. John’s

If you are eligible and interested in participating as an assessor for this examination, please complete both pages of the Response Form in full (including the Assessor Eligibility & Selection Criteria page) and submit by mail or email to:

Kerri Arsenault – Site Administrator
43 Blairmore Gardens
Winnipeg, MB
R2C-4X2
heehaw@shaw.ca
Phone: 222-6987

You may also submit an application online at:
www.pebc.ca/EnglishPages/OSCEAssrs/Recruitment.html OR
www.pebc.ca/FrenchPages/FAssessors/FAssrSurvey.html

Your early response on or before March 15, 2011 is greatly appreciated.
Assessor qualifications are listed on the ‘Assessor Eligibility & Selection Criteria’ found on the next page. Assessors are trained prior to the examination, so it is not necessary to have experience as an assessor. The most important qualification is current practice experience:

- performing or directly supervising patient care activities such as dispensing, compounding, clinical and drug information services (for both OSCE and PT-OSPE assessors)
- working with and/or directly supervising pharmacy technicians (for PT-OSPE assessors)

The examination day is approximately 11 hours long. A service fee of $385 for pharmacist-assessors / $260 for pharmacy technician-assessors is offered for participating in a full-day examination. (Fees are under review for 2011.) Eligible travel expenses are reimbursed (at the most economical travel rates) with receipts and/or documented mileage, up to a maximum as designated by the examination centre.

If you are interested in participating as an assessor, please complete the following information (page 1 and page 2) and return it by mail, fax or e-mail to the address/number indicated on the previous page.

This response is not considered to be a commitment or agreement to participate, but is an indication of your interest. You will be contacted by the Chief Administrator or Chief Examiner of the nearest examination centre, to follow up with you about participating in an examination.

Please check the appropriate YES or NO responses and provide the information requested:

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<th>Based on NAPRA’s new professional competencies:</th>
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| I meet the qualifications indicated (checked) on the ‘Assessor Eligibility and Selection Criteria’ |     |    |

| I am currently involved in additional professional activities (in addition to my regular work), as follows (describe briefly if applicable): |

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13-Jan-11
Assessor Eligibility & Selection Criteria

Objectives are to:

- Ensure that assessors have current practice experience in a patient care setting, working along with or directly supervising pharmacists (OSCE) or pharmacy technicians (PT-OSPE)
- Ensure that assessors are well-equipped to assess candidates’ performance
- Avoid perceived or actual conflict of interest or bias
- Protect the security of the examination, avoiding intentional or unintentional use or distribution of PEBC exam information other than for actual administration of the PEBC examination.

Eligibility - Assessor Qualifications - please check all that apply:

- Is a “member in good standing” of one or more provincial regulatory authorities.
- Has been fully licensed in a Canadian jurisdiction for at least three years (for the Pharmacist OSCE)
- Is not, or has not been in the past three years, a subject of disciplinary action or unresolved investigation by any pharmacy or other professional body.
- Currently practices in a patient care environment, providing or supervising pharmacy services on a regular basis, either full- or part-time. Such services may include: dispensing, compounding, patient teaching, medication reconciliation, responding to patients’ requests, consulting with other health professionals regarding patients’ needs (e.g., drug information), etc.
- Currently works along with and/or directly supervises pharmacy technicians (for the Pharmacy Technician OSPE).
- Currently works along with and/or directly supervises recently licensed pharmacists (for the Pharmacist OSCE).
- Is willing to sign and comply with the assessor confidentiality, security, conflict of interest and code of conduct agreements (sample enclosed).
- Is willing to participate on the basis of the offered service fee, and limited remuneration for travel (NOT accommodation) to the nearest examination centre as shown on the response form.
- Has no limitations that would impair the ability to accurately observe, hear, record and assess candidates’ performance over a 10 to 12 hour period.
- Is NOT involved in coaching current or prospective candidates to pass or perform well on PEBC examinations

In one location, the examination is offered in both French and English. Standardized patients and exam staff respond to the candidate in the candidate’s preferred language; assessors record performance in the same language. Therefore, assessors and standardized patients must be fully bilingual. Please indicate (check) the language(s) in which you are fully fluent, verbally and in writing:

- English
- French

Please provide details if you are involved in teaching pharmacy or pharmacy technician students in an academic setting or bridging program:

NOTE: the following are NOT eligible due to potential or perceived conflict of interest; please check all that apply:

- Graduate students in the same faculty.
- A prospective candidate OR an immediate family member/close associate of a pharmacy student or of a candidate eligible to take the examination.
- Involved in the development of the curriculum for - or involved in the training/assessment of - practical/professional skills of groups of students (e.g., professional practice labs, or other small group sessions involving the use of standardized patients, role-playing scenarios or simulations) in the last two years of the academic / training program.
- Involved in the development, review, administration or dissemination of practice exams, cases or preparatory courses or materials (designed to specifically prepare candidates for the examination) at any time during a three-year period from the time of participation in a PEBC Examination.
Technical Discussions on Regulatory Modernization

Updating or rewriting regulations is, at best, a daunting task. Understanding the far-reaching implications any changes to Canada’s Food and Drug Regulations explains, in large part, why Health Canada’s Legislative and Modernization Office has embarked on a lengthy and thorough process to do just that.

In recent months, beginning in the fall of 2010, NAPRA participated in a general information session to receive the high level overview of the review process. An invitation was also received to participate in a series of workshops entitled the Technical Discussions on Regulatory Modernization. NAPRA’s participation was requested on the basis of providing the association’s perspective and to complement the discussion between industry representatives and drug and medical device reviewers. The sessions occurred in October 2010, November/December 2010 and January 2011. Although significant contributions were made in areas ranging from pre- and post-market activities, NAPRA was pleased to learn that additional consultations with health care regulators and the federal government will follow the conclusion of these sessions.

NAPRA Board Approves Busy Slate of Projects for 2011 and 2012

NAPRA’s Board of Directors journeyed to Canada’s far eastern shores for their semi annual Board meeting held in St. John’s, Newfoundland November 6-7, 2010.

Discussions during the fall meeting focus on the activities the association will continue from the previous year and the roster of new projects planned for the subsequent year. In short, 2011-2012 will be a very busy period for the association. Some of the projects to be completed are: the association’s strategic planning exercise for 2012-2015; the development of the Standards of Practice for Pharmacy Technicians document; the initial phase of the National Drug Schedules review; advancing the IPG Project; and, starting in 2012, the review of supporting documents for the Mobility Agreement of Canadian Pharmacists.

In addition to these projects, NAPRA will continue its on-going activities related to conducting drug scheduling reviews, liaison activities with government and other external stakeholders, participating in the Blueprint Steering Commit
Regulation of Pharmacy Technicians Continues to Advance

Kathy Vesterfelt, Manager of Professional and Regulatory Affairs for NAPRA participated in meetings with representatives of some pharmacy regulatory authorities to continue the discussions on the regulation of pharmacy technicians and related issues. The group met in October 2010 and more recently in January 2011. At the November 2010 meeting, NAPRA’s Board agreed to create a formal committee of the Board called the National Ad Hoc Committee on Pharmacy Technicians to address issues related to pharmacy technicians. The first task of the group is to work on the national Standards of Practice for Pharmacy Technicians.

In other related pharmacy technician news, on December 3, 2010 the Ontario provincial government proclaimed the new Registration Regulation under the Pharmacy Act to allow pharmacy technicians to be recognized as a new class of registrant. The Ontario College of Pharmacists is the first jurisdiction to register technicians. The College of Pharmacists of British Columbia – who also had their enabling regulations passed by the provincial government in 2010 – will begin registering pharmacy technicians in 2011.

NAPRA Meets with Health Product and Food Branch Inspectorate

Carole Bouchard, Executive Director as well as Registrars representing NAPRA’s member pharmacy regulatory authorities (PRAs) met with representatives of Health Canada’s Health Product and Food Branch Inspectorate (HPFBI) in October 2010. The discussions focused on the issue of counterfeit products, internet pharmacies and the development of a related policy. The meeting also served as a venue to exchange information on regulations/procedures and the current landscape of internet pharmacies. The next steps are to exchange comments on a few documents and determine where joint initiatives may be warranted.

Moving Forward with Natural Health Products Policy Review

In April 2009, NAPRA’s Board of Directors approved a re-examination of NAPRA’s current Policy for Natural Health Products (approved 2006). A Working Group was established to advance the policy’s examination and determine options for the Board’s consideration. Work continued in the fall of 2010 with the Working Group meeting face-to-face in December. Next steps include the preparation of materials to be presented to the Board for their consideration in April 2011 and the corresponding preparation of the implementation/communication plans to support the Board’s decision.

Policy Summit Workshops

Kathy Vesterfelt, Manager of Professional and Regulatory Affairs attending the Canadian Centre for Continuing Education in Pharmacy (CCCEP)/Canadian Pharmacists’ Association (CPhA) Policy Summit meeting held in Toronto in October on behalf of the association.

The two-day workshop – entitled Advancing Innovation and Excellence in Pharmacy Practice – focused on a goal to develop a policy framework in four critical areas of professional development in pharmacy.
CLEAR Conference Presents Opportunity for Learning, Networking and Special Recognition

Kathy Vesterfelt, Manager of Professional and Regulatory Affairs had the privilege to travel to Nashville, Tennessee to attend the CLEAR Conference. Over the course of the three-day conference, attendees participated in a variety of interesting sessions. It was a great opportunity to learn and network with peers in the field of regulation from around the globe.

In addition, there was a very special award presented. Deanna Williams, Registrar for the Ontario College of Pharmacists received the 2010 Regulatory Excellence Award from the Council on Licensure, Enforcement and Regulation (CLEAR) at its annual conference held on September 25, 2010 in Nashville Tennessee.

The CLEAR Regulatory Excellence Award recognizes an individual demonstrating an outstanding contribution to the enhancement of occupational or professional regulation, regulatory processes, or consumer and public protection. The individual must have demonstrated exceptional leadership, vision, creativity, results and outcomes above and beyond the regular functions of the job or expectations, and beyond what is normally achieved. Ms. Williams received her award for her role in leading the College and the profession beyond the minimum legislative requirements established by Ontario’s Ministry of Health and Long Term Care in regard to quality assurance and the provision of quality services to the public of Ontario.*

NAPRA is pleased to extend its congratulations to Ms. Williams on her award.

(*Source: Council on Licensure, Enforcement and Regulation website http://www.clearhq.org)

NAPRA Continues Participation with the Canadian Network of National Association of Regulators

CNNAR once again hosted its annual conference in Toronto in November 2010. Kathy Vesterfelt, Manager of Professional and Regulatory Affairs and Louise Travill, Project Manager for the International Pharmacy Graduates’ (IPG) Project attended on behalf of NAPRA. This year’s conference was of particular relevance to NAPRA given the event’s theme – Focus on Qualification Assessment and Recognition – and its direct relation to NAPRA’s IPG Project. Overall, the conference presented very useful and insightful information for the NAPRA attendees.

The Pharmacy Examining Board of Canada and NAPRA Meet

NAPRA President Dianne Donnan and The Pharmacy Examining Board of Canada’s President (PEBC) Peter Gydczynski settled on Toronto as the meeting place for their most recent bilateral meeting in September 2010. The Presidents were joined by Carole Bouchard, NAPRA’s Executive Director and John Pugsley, PEBC’s Secretary-Registrar for the afternoon. The two associations utilized their time to advance discussions on a couple of key issues of relevance for both organizations, namely: the results of the pilot project for pharmacy technician examinations; the PEBC practice survey for pharmacists and an update on NAPRA’s IPG Project.

2011-2012 Projects

(from page 1) tee and serving as the national voice for our members on pan-Canadian issues in pharmacy regulation.

More information on NAPRA’s projects will be forthcoming in future issues of this newsletter.
Canadian Centre for Language Benchmarks Presses Ahead with Pharmacy Occupations Project

The Canadian Centre for Language Benchmarks (CCLB) received funding from HRSDC to determine language benchmarks for pharmacists. The CCLB used, and tied into their project plan, the points covered in the Blueprint for Pharmacy document. The project is currently underway and will continue until June 2011. In addition to lending its support of the project, NAPRA also promoted the project and provided CCLB with on-going feedback from the pharmacy regulatory authority (PRA) members. NAPRA’s Executive Director, Carole Bouchard, Project Manager for the IPG Project, Louise Travill, as well as representatives from some PRAs, will continue to monitor the project’s advances and participate on the project’s advisory committee.

Action Plan for Pan Canadian Framework Involves NAPRA

Pharmacists are one of eight professions highlighted in the Pan Canadian Framework for the Assessment and Recognition of Foreign Qualifications sponsored by Human Resources and Skills Development Canada (HRSDC). Moving into the next phase of the Framework’s lifecycle – the development of the action plan – NAPRA was approached by HRSDC to review a draft action plan and discuss items to include in the document. As an additional step, NAPRA will provide HRSDC with information on how NAPRA members see the principle of a one year timeline.

NAPRA Offers Unique Learning Experience for University of Saskatchewan Student

Fourth year University of Saskatchewan student Fatima Khan spent a five-week rotation at NAPRA learning about the regulatory side of pharmacy and policy work. During her time at NAPRA, Ms. Khan assisted on two major projects: a research report on the over-the-counter (OTC) scheduling practices in other jurisdictions; and the development of part of the content for the readiness assessment tool prototype. Ms. Khan will complete two additional rotations prior to her final examinations. All of the staff at NAPRA wish Fatima the very best as she concludes her degree and pursues her career opportunities.

Canadian Patient Safety Institute—Symposium Marks Tenth Anniversary

NAPRA once again was among the attendees at the Canadian Patient Safety Institute’s (CPSI) annual symposium in Halifax. Celebrating its tenth and final event, the organizers developed a programme highlighting some of the featured speakers over the last ten years with a view to present an “update” on their original presentation in consideration of changes during the past decade. Carole Bouchard, NAPRA’s Executive Director and Dianne Donnan, NAPRA President attended the sessions as well as the association’s Annual General Meeting (AGM). This last symposium once again provided useful insight on various perspectives on patient safety.
Canadian Centre on Substance Abuse Board of Directors Dinner

NAPRA’s Executive Director, Carole Bouchard, was once again invited to attend the Board dinner for the Canadian Centre on Substance Abuse (CCSA). For this year’s event, guest speaker R. Gil Kerlikowske, Director White House Office of National Drug Control Policy delivered a speech on the United States’ 2010 National Drug Control Strategy, noting that it is a major shift away from the “war on drugs” philosophy that dominated the government’s approach in recent years. Additionally, one component of the Strategy is to place a special emphasis on pharmaceutical drugs and their place in the spectrum of tactics necessary to address abuse prevention and promote safe disposal. As the dinner attendees represented a wide range of people working in diverse fields (such as law enforcement and health care professionals), it also provided an ideal opportunity to promote the role of NAPRA’s members.

IPG Project
(continued from page 6)

and scope of the two assessment tools. Their recommendations will soon be presented to the IPG Steering Committee for approval.

Systems Development
A competitive procurement process to select an information technology services company was recently completed. The successful bidder was CORADIX Technology Consulting of Ottawa. The company will provide systems strategy, design and development services for the duration of the project. Initial efforts have centered on establishing and procuring the software applications that are integral to development of the IPG Gateway system. Development of the website also started. The initial launch will be a microsite (only a couple of pages), and as the project moves forward, the website will be expanded into a more comprehensive, bilingual presence.

Blueprint
(continued from page 6)

The project is a multi-year, multi-phased project designed to establish and maintain a plain language website in addition to developing new tools which will provide international pharmacy graduates (IPGs) with a single point of access to information they need in order to apply to become licensed to practice pharmacy in Canada.

While NAPRA undertakes initiatives when representing all of Canada’s pharmacy regulatory authorities, there are also a number of activities conducted by our members that respond to many of the actionable items in the five key areas of the Blueprint’s Implementation Plan. Some projects include:

- the advent of the regulation of pharmacy technicians
- the continued legislative and regulatory modifications to authorize pharmacists to deliver expanded pharmacy services
- on-going development and maintenance of professional development activities.

These projects, and many others like them, account for a significant investment in human resources and millions of dollars that contribute to the realization of the vision put forward in the Blueprint document.
Members of the International Pharmacy Graduates’ Gateway to Canada Project committees and project staff continue to make great strides to advance all aspects of the project. Here are some updates:

**Communications & Marketing**

The project now has a visual identity. Watch for it in the future!

**Pathway to Licensure**

Developing a pan-Canadian approach to licensure is a key part of the IPG Gateway. The objective is to both standardize the licensure requirements and align the steps in the licensure process, where possible. By doing this, it will help to make the process easier to navigate and reduce duplication for the international pharmacy graduate (IPG) when submitting licensure documentation. The pharmacy regulatory authorities (PRAs) will have access to standardized documentation/information in the IPG national licensing data repository. Representatives of the PRAs and the Pharmacy Examining Board of Canada (PEBC), met several times in the fall of 2010 where the discussions centered on the aspects of the licensure process that were considered the most feasible to align (e.g., identification, education documents, etc). In the coming months, discussions will continue on other areas of the licensure pathway.

**Assessment Tools**

Key deliverables of the IPGs’ Gateway to Canada Project include two self-assessment tools for foreign trained pharmacists. The first tool is intended to help the IPG determine their level of readiness to proceed with licensure and to work as a pharmacist in Canada. The second tool, initially described as a “prior learning assessment”, will enable IPGs to identify gaps and help them to develop learning plans to address those gaps. The IPG Advisory Working Group was tasked with validating the objective.

**STAKEHOLDER SPOTLIGHT: Canadian Pharmacists’ Association—Blueprint for Pharmacy**

“This optimal drug therapy outcomes for Canadians through patient-centred care”

This is the vision of the Blueprint for Pharmacy – Designing the Future Together. This initiative, led by the Canadian Pharmacists Association and in collaboration with many Canadian pharmacy stakeholders, officially launched in 2008. The plan designed to support and carry out the vision highlights actions and deliverables in five key areas:

- Pharmacy human resources
- Education and continuing professional development
- Information and communication technology
- Financial viability and sustainability
- Legislation, regulation and liability

NAPRA and its members support the Blueprint’s vision and its underlying principles. More specifically, NAPRA sits as on the Blueprint Steering Committee – the governing body for the entire initiative – in an advisory capacity. Additionally, NAPRA’s Board of Directors takes into account the Blueprint’s Implementation Plan when discussing and evaluating priorities for the organization.

One activity that is a shared objective of both the Blueprint and NAPRA is to examine ways of improving the path to licensure for international pharmacy graduates. To that end, NAPRA secured $3.7 million in funding from the Government of Canada to bring this project to fruition.

See Blueprint on page 5
NEWS RELEASE
FOR IMMEDIATE RELEASE
January 25, 2011

NAPRA Welcomes New Member –
Nunavut Department of Health and Social Services

OTTAWA – Nunavut’s Department of Health and Social Services is the thirteenth pharmacy regulatory jurisdiction to become a member of the National Association of Pharmacy Regulatory Authorities (NAPRA). NAPRA’s Board of Directors passed a motion to accept the request for membership sponsored by Barbara Harvey, Registrar, Health Professions for the Government of Nunavut.

“The addition of Nunavut to NAPRA’s membership fulfills one of our long-held goals to be a truly national association representing all of Canada’s pharmacy regulatory authorities,” said Dianne Donnan, NAPRA’s President. “This enables us to ensure that, going forward, NAPRA’s policies, guidelines and standards and capacity to address common issues includes the participation of members from coast to coast to coast.”

Citing one of they key benefits for the Government of Nunavut, Ms. Harvey indicated that NAPRA membership would provide the territory with a national link to the pharmacy regulators across Canada. She further added, “I believe Nunavut can bring a unique perspective to the organization and we are very interested in working together in the future on a number of national issues and concerns.”

About NAPRA
Established in 1995, NAPRA is the national voluntary association of provincial and territorial pharmacy regulatory bodies as well as the Canadian Forces Pharmacy Services, whose mandates are the protection of the public. NAPRA’s members regulate the practice of pharmacy and operation of pharmacies in their respective jurisdictions in Canada.

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COMMUNIQUÉ DE PRESSE

POUR DIFFUSION IMMÉDIATE
Le 25 janvier 2011

L’ANORP souhaite la bienvenue à un nouveau membre :
le Ministère de la Santé et des Services sociaux du Nunavut

OTTAWA – L’Association nationale des organismes de réglementation de la pharmacie (ANORP) souhaite la bienvenue à son treizième membre: le Ministère de la Santé et des Services sociaux du Nunavut. Le conseil d’administration de l’ANORP a accepté la proposition d’accéder à la demande d’adhésion présentée par madame Barbara Harvey, registraire des professions de la santé du gouvernement du Nunavut.

La présidente de l’ANORP, madame Dianne Donnan, a affirmé que l’adhésion d’un nouveau membre permettra à l’Association de réaliser l’un de ses objectifs, qui est d’être une véritable association nationale représentant tous les organismes de réglementation de la pharmacie du Canada. Ainsi l’ANORP sera en mesure d’établir des politiques, des lignes directrices et des normes et d’examiner des questions d’intérêt commun avec la participation de membres représentant toutes les régions du Canada.

Madame Harvey a expliqué qu’en devenant membre, le Nunavut pourra entre autres entretenir des liens avec les organismes de réglementation de la pharmacie répartis dans tout le Canada. « Le Nunavut est en mesure d’apporter un point de vue particulier à l’Association. Nous avons très hâte de travailler en collaboration et de nous pencher sur un certain nombre de questions et problèmes d’intérêt national », a-t-elle ajouté.

Qu’est-ce que l’ANORP?

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Dr. John Wade Research Award 2011 - Request for Applications

The Manitoba Institute for Patient Safety (MIPS) is an independent, non-profit organization. The Institute’s role is to promote, coordinate and facilitate activities that have a positive impact on patient safety throughout Manitoba while enhancing the quality of healthcare for Manitobans. More information on the Manitoba Institute for Patient Safety and its activities are available at http://www.mbips.ca/.

The Dr. John Wade Research Award is offered as a benefit to Premier Members of MIPS.

The institute is pleased to announce that Manitoba Blue Cross is sponsoring this prestigious award for 2011. This generous sponsorship allows MIPS to substantially increase the value of the Dr. John Wade Award.

Andrew Yorke, President and CEO of Manitoba Blue Cross, told the institute:
“Proactive strategies in healthcare, including a focus on patient safety, are a natural extension of Manitoba Blue Cross’ position within the delivery of supplementary health benefits and its overall approach to wellness within Manitoba communities. The support of the Dr. John Wade Research Award delivers on Blue Cross’ position of caring within Manitoba. More than just a company, Blue Cross works hard to reflect the unique Manitoba spirit of caring and concern for others. Throughout his career, Dr. Wade lives this very message and Manitoba Blue Cross is proud to extend its support to further research in patient safety and honour Dr. Wade’s many contributions.”

Criteria, Guidelines and Terms

A. Criteria:
Applications are welcomed from Manitoba-based researchers and health care employees who are staff or members of the following MIPS Premier Member Organizations:
1. College of Physicians and Surgeons of Manitoba
2. College of Registered Nurses of Manitoba
3. Manitoba Health
4. Manitoba Pharmaceutical Association
5. Regional Health Authorities of Manitoba
6. St. Boniface General Hospital
7. Winnipeg Regional Health Authority
Premier Member Organizations may send up to three (3) applications.

The award of $7,500.00 is granted to only one project per year to a Premier Member organization.

Eligibility for funding criteria includes:
- Unique, creative research questions or projects that will contribute to the development and understanding of patient safety culture in Manitoba healthcare organizations.
- Project may be used to support the development of a larger project/proposal.
- Applied research.
- A literature review.
Submission of a Final Report to the MIPS Research Committee by December 30, 2011 following parameters outlined in the funding letter.

- Acknowledgement of the Manitoba Institute for Patient Safety in all publications/presentations.
- MIPS strongly encourages applicants to secure matched funds or in-kind resources.

There is also $500.00 toward the development of a poster presentation, to be used by the investigators, and by MIPS upon request, for the purpose of knowledge transition.

The poster must be developed and the invoice submitted to receive the $500.

B. Guidelines and Terms:

- Application Forms are found at www.mbips.ca.
- Five print copies and the electronic copy must be received at the MIPS office by April 29 at NOON.
- Please mail or courier to MIPS at 102-175 Carlton Street Winnipeg, MB R3C 3H9
- The completed application form must be sent electronically from the Official Premier Member Organization Representative as registered with MIPS to the Manitoba Institute for Patient Safety Research Committee, c/o Vi Pelc vpelc@mbips.ca
- E-mail Subject Line: Wade Application
- Submission Deadline: Friday, April 29, 2011 at NOON.
- Funds will be administered through the Premier Member Organization.
- All award recipients will be notified by e-mail within three weeks of submission deadline.
- MIPS will share findings through communication vehicles such as MIPS website, Member Updates, and the Annual Report.
- Recipients will be asked to display their poster at the MIPS Annual General Meeting.
- The Award may not be granted every year.
Dr. John Wade Research Award
Application Form

Date:
Name and Position of Principal Investigator:
Co-Investigator(s):
Premier Member Organization:
Title of Project:
Contact Information:
E-mail:
Phone:
Fax:
Work Mailing Address:

Name and Approval of Member Representative:

Name____________________________________

Yes I approve this application. (Please mark with an X) __________

All submissions will be acknowledged by MIPS when received.

On a separate page, please describe (1000 words max.):
- The problem,
- Background knowledge,
- Hypothesis, research/project,
- Objectives,
- Research/project methods,
- Anticipated results with benefits to patient safety culture in Manitoba healthcare settings, and
- How the funds will be used.