SASKATCHEWAN COLLEGE OF PHARMACISTS

Newsletter

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VOLUME 25 NUMBER 2 SEPTEMBER 2004

Maximum Allowable Cost (MAC) Policy

We have received comments regarding the maximum allowable cost policy and our position. It has been said, since we appoint a representative to the Formulary Committee, that we support the MAC policy. We wish to clarify our position:

1. When the College appoints an individual to another body, that individual becomes responsible to that body and not the College. His responsibility is to do what is best for that body and its ownership. Thus, appointees to the Formulary Committee are accountable to the Minister of Health, not to their appointing organization, to do what is best for the public.
2. We have written to the Minister to voice our concerns regarding this new policy but unfortunately the Minister decided to proceed.

Briefly the concerns relayed to the Minister were:

1. Impact upon the time of the pharmacist and physician adversely affecting patient care;
2. Transparency and objectivity of the policy making process;
3. Criteria for selection of the class, and future classes;
4. Silo budgeting;
5. Technical and policy issues.

We offered examples of how "we can work collaboratively to introduce and enforce mutually agreeable policies that can achieve both the goals of reducing costs while advancing optimal drug therapy outcomes".

- expand and promote the trial prescription program to minimize wastage;
- drug use management strategies, including establishing a centre in collaboration with government, this College and the regulatory bodies of medicine and nursing;
- leverage the information available under Enhanced Information Collection (commonly known as ADAPT) for quality assurance and education purposes to influence prescribing and dispensing habits; and
- support enhanced prescriptive authority within the current scope of practice of the pharmacist. This would allow the pharmacist to extend prescription refills in emergency circumstances, dispense prescription drugs without a physician's authorization when the patient can safely use the drug in a self-care situation, and prescribe drugs within protocols established with physicians. The latter could include adjusting dosages such as in warfarin dosage adjustment programs in the province, and therapeutic substitution.

Unfortunately the Minister responded in part as follows:

"Dear Mr. Joubert:

Thank you for your faxed letter of June 15, 2004, regarding your Council's views on the Government of Saskatchewan's decision to adopt the policy of Maximum Allowable Cost (MAC). I am pleased to have this opportunity to inform you that the policy will be implemented on July 1, 2004, as planned, and to address some of the points raised in your letter. ..."

On a more positive note the letter concluded with:

> "In your letter, you mention your Council's desire to work collaboratively with government to achieve our mutual goals of reducing costs while advancing optimal drug therapy outcomes. I would be pleased to meet with you at a mutually convenient time to discuss these opportunities. Please contact my office to discuss arrangements for a meeting.
>
> Again, thank you for writing."

We plan to accept the Minister's invitation to meet.

Inside This Issue

SCP Council 2004-05

Division 1
Jeannette Sandiford, Weyburn
(term expires June 30, 2005)
Vice President

Division 2
Terri Bromm, Tisdale
(term expires June 30, 2006)

Division 3
Randy Wiser, Prince Albert
(term expires June 30, 2005)
Past-President

Division 4
Coralie Sorochuk, Saskatoon
(term expires June 30, 2006)

Divison 5
Bill Paterson, Regina
(term expires June 30, 2005)
President

Division 6
Corry MacWilliam, Swift Current
(term expires June 30, 2006)

Division 7
Debbie McCulloch
(term expires June 30, 2005)
President-Elect

Division 8
Melanie McLeod, Regina
(term expires June 30, 2006)

Ex Officio
Acting Dean Dr. Linda Suveges

Public
May Bridgewater
Lavonne Heck

Student Observer
Steven Yakiwchuk

SCP Staff

Andrea Brockmeyer,
Reception/Accounting Clerk
(on leave)

Jeanne Eriksen, Assistant Registrar

Paulette Francis,
Reception/Accounting Clerk

Pat Guillemin,
Administrative Assistant

Ray Joubert, Registrar

Cheryl Klein,
Senior Administrative Assistant

Heather Neirinck,
Administrative Assistant

Lori Postnikoff, Field Officer

Council Highlights – June 9, 2004

The Council of the Saskatchewan College of Pharmacists held its final meeting of the 2003-2004 year in Regina on Wednesday, June 9, 2004. This was a special meeting where we met with various groups to discuss issues of mutual interest.

The Saskatchewan Registered Nurses Association

First Council met with the Council of the Saskatchewan Registered Nurses Association (SRNA). The purpose of the meeting was to identify common values for our organizations and to discuss opportunities for collaboration, i.e. primary care and educational and governance opportunities. This meeting provided the opportunity for discussion around the new SRNA membership category of Registered Nurse (Nurse Practitioner) [RN(NP)].

IMS Health Canada

Later in the day Council met with representatives from IMS Health Canada, the Representative Board of Saskatchewan Pharmacists (RBSP), the College of Physicians and Surgeons of Saskatchewan (CPSS), and the Saskatchewan Medical Association (SMA). Physicians maintain their position that pharmacies and/or pharmacists should refrain from submitting prescriber information to IMS Health without the physician's consent and have requested that Council review their position on this matter. In order to be transparent and follow due process, Council invited all affected parties to meet to express their respective positions and provide information to Council for their deliberation.

We continue to monitor legal challenges, especially to the Alberta privacy commissioner's ruling that prescriber information is private and should be protected, contrary to the federal privacy commissioner's ruling, which is also being challenged.

We also continue to monitor the Minister's announcement last fall of his intentions to pass new regulations pursuant to section 57 of the *Health Information Protection Act* to prohibit this practice except with consent. We have yet to review the final version of the proposed regulations under HIPA and are not aware if the provincial privacy commissioner supports the regulations. Council will return to this issue at the September meeting to finalize a decision.

Council Elections

The Council position for Division 2 remained vacant following the March election. During the last district meetings members were encouraged to seek election. One member had expressed interest and was invited to attend the June Council meeting as an observer. Council is pleased to announce that Terri Bromm has been appointed as the new Councillor for Division 2 effective July 1, 2004, to complete the current term of office, which expires June 30, 2006.

At the last meeting the election of the Vice-President was deferred at Council's request for time to consider the nomination. Jeannette Sandiford was acclaimed Vice-President for the term beginning July 1, 2004.

Crystal Methamphetamine

Council reviewed information regarding the production of methamphetamine. We received a request to restrict access to ephedrine and pseudoephedrine as precursors to the clandestine production of crystal methamphetamine as well as information regarding initiatives underway in Alberta.

Council directed that the Registrar issue a memorandum to all pharmacy managers seeking their cooperation and feedback on this issue. The memo stated Council's position that we continue to:

a) communicate our support to Health Canada for amendments to the precursor regulations;
b) encourage NAPRA to initiate a review of drug scheduling factors

to include drugs that are precursors to substances of abuse and misuse and review the current scheduling of products containing pseudoephedrine; and

c) to request that pharmacies voluntarily move all single entity products containing pseudoephedrine and ephedrine into the no-public access areas of their pharmacies while restricting the sale of all products containing pseudoephedrine and ephedrine to purchases by a single individual to a limit of 3600 mg of pseudoephedrine and 400 mg of ephedrine.

Plan B® De-regulation

We have received notice that the federal government is proceeding with the process of de-regulating Plan B® to non-prescription status. The National Drug Scheduling Advisory Committee (NDSAC) has recommended Schedule II (i.e. non-prescription, no public access) status. At the time of writing we await the final version with changes approved from the consultation period, which will be published in Canada Gazette Part II with the effective date. Council has directed that if and when this product becomes de-regulated and placed in Schedule II, pharmacists will not be required to provide evidence of certification to prescribe, but they must meet the standards for Schedule II products as outlined in the *Model Standards of Practice for Canadian Pharmacists.*

[Please refer to "Levonorgestrel" article on page 10 of this publication.]

District Meetings

Topics for the fall district meetings were discussed. The proposed topics include:

a) implementation of the new standards of practice in phases with extensive tools especially for documentation, supplemented with education for members and guidance on how to use technicians more effectively;

b) the Pharmacy Information Program and the Drug Plan Enhanced Information Collection (members of the Drug Plan staff will be in attendance to present and answer questions);

c) Privacy Legislation.

Please note the District Meeting schedule on page 5 for the date, time and location nearest to you.

Summary of Membership July 1, 2004

As of July 1, 2004 we have a total membership of 1371 members on the register. This represents a net gain of (4).

Of the total, 1134 members hold a Practising membership. The remaining members are: Non Practising members (58); Associate members (98) and Retired members (81).

	2001	**2002**	**2003**	**2004**
Practising Members	1083	1067	1116	**1134**
Total Members	1380	1328	1367	**1371**

For July 1, 2003 to June 30, 2004 (38) graduates of the College of Pharmacy and Nutrition at the University of Saskatchewan registered with our College. Thirty-two of these graduates held a conditional practising membership prior to receiving their Certificate of Qualification from the Pharmacy Examining Board of Canada. In addition, (6) new members from out of province registered with the SCP under the requirements of the Mutual Recognition Agreement and one out-of-country trained candidate met the requirements for registration and joined the College.

We wish to welcome our new members to the College and encourage them to become active in their profession both provincially by working with the regulatory and advocacy bodies and within their communities.

MEMBERSHIP/PERMIT RENEWAL SUMMARY AS OF JULY 1

MEMBERSHIPS	**2002**	**2003**	**2004**
Practising Members:	**1067**	**1116**	**1134**
(32 Conditional Practising included)			
Community	795	860	843
Hospital	149	171	174
Out of Province	32	33	34
Other	91	52	83
Non Practising Members:	68	66	**58**
Associate:	111	105	**98**
Retired:	82	80	**81**
TOTAL Membership	1328	1367	**1371**
Membership Terminations	107	75	65
PHARMACIES:			
Community			
Chain	122	129	138
Independent	209	202	190
Satellite	15	16	14
Internet		1	1
Dispensing Physician (1)	7	8	7
Publicly Operated	1	1	0
TOTAL Pharmacies:	**354**	**357**	**350**

NOTES: (1) One Dispensing Physician operates two pharmacies/clinics

Convocation Luncheon – May 27, 2004

The Saskatchewan College of Pharmacists was proud to host the 2004 Convocation Luncheon at the Saskatoon Centennial Auditorium to recognize the 2004 Pharmacy Class of the College of Pharmacy and Nutrition. President-Elect Bill Paterson assumed the role of Master of Ceremonies, and during the program offered the Chair's congratulations to the graduates.

On hand to honour the seventy-two graduates were members of Council, members of the SCP (many of who had an active role as preceptors in the SPEP program), representatives of the Representative Board of Saskatchewan Pharmacists (RBSP), Dean Dennis Gorecki, Assistant Dean Linda Suveges, members of the faculty, parents, family and friends of the graduates.

Vice-President Debbie McCulloch presented the two major awards of the day.

The Saskatchewan College of Pharmacists Robert Martin Prize and Gold Medal was presented to **Sarah Scott Jacques** of Saskatoon. This prize is awarded annually to the most distinguished graduate of the Class. Sarah has received numerous academic awards and scholarships during her years at the College, today receiving her Bachelor of Science in Pharmacy with Great Distinction, with a four-year average of 90.91%.

Sarah has accepted a hospital pharmacy position at the Royal University Hospital in Saskatoon.

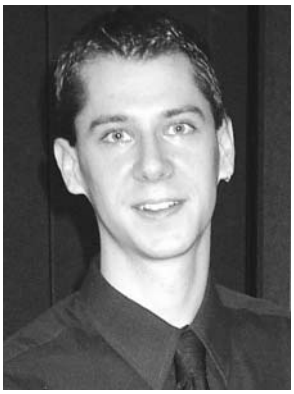
The Saskatchewan College of Pharmacists Campbell Prize was presented to **Darcy Alan Lamb** of Assiniboia. Darcy was honoured as the second most distinguished graduate of the class of '04. Darcy has received many scholarships and awards during his academic career and today received a Bachelor of Science in Pharmacy with Great Distinction with a four-year average of 86.96%.

Darcy will be completing a hospital pharmacy residency with the Regina Qu'Appelle Health Region.

We extended our congratulations and best wishes to Sarah and Darcy and all the graduates of the Class of 2004. We anticipate hearing great things as each of you pursue your chosen path.

◀ *Sarah Jacques SCP Robert Martin Prize & Gold Medal*

Darcy Lamb ▶ *SCP Campbell Prize*



COLLEGE OF PHARMACY AND NUTRITION

Our sincere thanks ...

to our many generous sponsors, donors, friends and participants who provided support for this year's 19th Annual Golden Suppository Golf Classic held on July 16th, 2004 at the Holiday Park Golf Course in Saskatoon. The proceeds from this event will be used to support the College Research Trust Fund for projects involving graduate student research and those of new faculty members, to assist them in establishing their research programs. This year's tournament raised in ***excess of $24,000*** *for this fund. The College wishes to acknowledge and express its most sincere appreciation to the various companies and individuals who have helped make this tournament the 'fun' and success it is.*

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... and appreciation!

From the Desk of the Dean

Dr. Linda Suveges
College of Pharmacy and Nutrition

I am pleased to write this message as the Acting Dean of the College of Pharmacy and Nutrition while Dean Dennis Gorecki is on administrative leave. Dr. Remillard will serve as Assistant Dean of Undergraduate Affairs during the next year and we appreciate his willingness to serve in this capacity. Our College's leadership team now includes an Associate Dean of Research and Graduate Affairs – Dr. Marianna Foldvari. Over the next five years, Dr. Foldvari will spearhead the implementation of the College's new *Research Plan* and *Graduate Education and Success Plan*. Drs. Shawna Berenbaum and Yvonne Shevchuk have kindly agreed to extend their terms as Heads of the Divisions of Nutrition & Dietetics and Pharmacy, respectively, to provide continuity during the year ahead.

The academic year is now upon us and I can report that we have another excellent group of first year undergraduate students joining the College – 90 in Pharmacy and 28 in Nutrition. The increase in enrolment in Pharmacy (from 80 to 90) will provide us with some challenges (such as size of available classrooms and availability of placements in structured practice experiences), but hopefully an increase in potential graduates will also assist with resolution of the current shortage of pharmacists. We also welcomed eight new graduate students from Canada, China, Iran and Egypt. In addition to welcome-week and the start of classes, our current activities are focusing on the site visit for the accreditation of the B.S.P. program, scheduled for the end of September. The Faculty and the Accreditation Self-Study Committee (comprised of practitioners, students, faculty and staff members) have worked very hard over the past several months to develop a Self-Assessment Report which provides detailed descriptions, analysis and appraisal of the College and the Pharmacy program, and outlines our plans to address any deficiencies.

This summer, the College received its "Planning Parameters" from the University Provost's Committee on Integrated Planning. The parameters document provides an assessment of the *College of Pharmacy and Nutrition Plan 2003-07*, identifies those initiatives that will contribute to the University's overall goals and sets out the expectations of us during this first planning cycle. The Committee noted that our Plan is comprehensive, well-written, and orients the College's strategic goals and planning around the University's plans and initiatives. The expectations for the College focus on: a substantial increase in graduate student enrolment; modest growth in research productivity; a high level of involvement in health initiatives identified in the University-level plan, including those sponsored by a new Inter-professional Health Sciences Council; and, measures that will result in less reliance on the University's budget and that will provide a net increase in revenue for the College. The College is looking forward to pursuing the action plan that will enable us to achieve our goals in this planning cycle.

As the summer ends, the College would like to thank all those who participated as preceptors in the structured practice experiences program over the summer and during the 2003-04 academic year. We very much appreciate your commitment to the education of future pharmacists and we look forward to working with everyone in the future.

2004 FALL DISTRICT MEETINGS

District Meetings will once again be held across the province.
Please note the date, time and place in your area.

- Prince Albert
  Monday, October 18
  Marlboro Inn – Cavalier Room
- North Battleford
  Tuesday, October 19
  Tropical Inn – Cypress Room
- Kindersley
  Wednesday, October 20
  Kindersley Inn – Elm Room
- Swift Current
  Thursday, October 21
  Days Inn – Room "C"
- Regina
  Thursday, October 28
  Travelodge – Burlington Room
- Saskatoon
  Monday, November 1
  Saskatoon Inn – Courtyard Room
- Tisdale
  Tuesday, November 2
  Tisdale Recplex – Salopian Room
- Yorkton
  Wednesday, November 3
  Holiday Inn/Best Western – Harvest Room
- Weyburn
  Thursday, November 4
  Signal Hill Arts Centre – Studio (Second Floor)

What is a Natural Health Product?

Re-printed with permission from the Alberta College of Pharmacists

The new *Natural Health Product Regulations* (to the *Food & Drugs Act*) definition of "natural health product" (NHP) is rather complex. The definition has two components: function and substance. To determine whether an item fits the definition of a natural health product, ask the following questions:

- does the product perform a function listed in the definition (see below)?
- is the product included in Schedule 1 to the *Natural Health Products Regulations*?
- is the product not included in Schedule 2 to the *Natural Health Products Regulations*?

If the answer to these three questions is yes, the product qualifies as a natural health product and is subject to the NHP regulations.

You can refer to Schedules 1 and 2 and the full text of the regulations on Health Canada's website at *http://www.hc-sc.gc.ca/hpfb-dgpsa/nhpd-dpsn/regs_cg2.pdf*.

The schedules to the *Natural Health Products Regulations* are not to be confused with Schedules I and II of the *Drug Schedules Regulations, 1997* (provincial).

The regulations specifically state:

"natural health product" means a substance set out in Schedule 1 or a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in

a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or its symptoms in humans;
b) restoring or correcting organic functions in humans; or
c) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health.

However, a natural health product does not include a substance set out in Schedule 2, in any combination of substances that includes a substance set out in Schedule 2 or a homeopathic medicine or a traditional medicine that is or includes a substance set out in Schedule 2.

Examples of natural health products include:

- traditional herbal medicines
- traditional Chinese medicines
- traditional Ayurvedic medicines
- native North American medicines
- homeopathic medicines (listed in one of four homeopathic encyclopedias)
- vitamins, minerals, amino acids, essential fatty acids

There will probably be some products whose status is open to interpretation. For example, is a herbal tea a natural health product or a food? Such products will be included at the discretion of the Natural Health Product Directorate.

Drug/natural health product combinations will be regulated as drugs under the *Food and Drug Regulations*.

Natural health products compounded for a specific patient are not subject to these regulations.

Once a product has been assessed by Health Canada and granted a product licence, the product label will bear an eight-digit product licence number, preceded by the letters NPN. The NPN on the label will inform consumers that the product has been reviewed by Health Canada for safety, quality and health claims. Labels for homeopathic products will bear the designation DIN-HM.

All natural health products must have a product licence and a product number by January 1, 2010. However, there is a phased-in approach to this requirement, as follows.

Priority 1: June 1, 2004

NHP substances on the Therapeutic Product Directory's New Drug List

Priority 2: January 1, 2005

Isolates, amino acids, fatty acids, concentrated volatile (essential) oils, indicated for internal use, and extracts other than those prepared by traditional methods

Priority 3: June 1, 2005

Alga, bacterial, fungal, probiotics and non-human animal materials

Priority 4: June 1, 2006

Plants, plant materials, extracts prepared by traditional methods, and volatile (essential) oils other than those that are concentrated and indicated for internal use

Priority 5: January 1, 2007

Vitamins and minerals

Priority 6: June 1, 2007

Homeopathic medicines

Products that were granted a drug identification number (DIN) after 1994 have until December 31, 2009 to apply for a NPN since they have already proven their safety and efficacy.

Melanie Watson

It is with great sadness that we report the passing of Melanie Watson on July 19, 2004. As you may remember in January 2003 Melanie retired from her position as Assistant Director of the Continuing Professional Development for Pharmacists unit at the College. Melanie, who joined the CPDP office (formerly known as the Continuing Education Unit) in 1995, had worked closely with the SCP members and staff especially during the planning and implementation of the Saskatchewan Learning Portfolio for Pharmacists. Melanie attended many SCP District Meetings to inform members as to new initiatives and to answer their questions, usually with a few tips to make the process more user friendly.

We extend our deepest condolences to Melanie's husband, Don, and their sons.

A Cautionary Note for Pharmacists and Other Trustees – From the Privacy Commissioner

[Excerpt from the FOIP Folio (Freedom of Information and Protection of Privacy) May 2004 issue. This newsletter is produced by the Office of the Saskatchewan Information and Privacy Commissioner ("OIPC"). It is intended to keep you up-to-date on reports and recommendations from the OIPC. It will feature best practices, tips and shortcuts and access/privacy developments in Saskatchewan and other parts of Canada and sometimes beyond.]

Past issues of the FOIP FOLIO have highlighted interesting legal privacy cases in other parts of the country. You can add to that list a civil action launched in the Provincial Court of Alberta in Action #PO 49010043 (Calgary). This reflects a claim for general damages by a woman who alleges that her pharmacist disclosed her personal health information to her estranged husband without her consent. The disputed claim alleges that the Defendants breached Alberta's Health Information Act ("HIA") including: disclosure without knowledge or consent, failure to take reasonable steps to protect privacy and confidentiality and failure to establish policies and procedures to facilitate the HIA in that province. The Plaintiff is suing for $12,500 in general damages, special damages of $1,500, punitive and aggravated damages and costs. The original complaint was dealt with by the Alberta Information and Privacy Commissioner in his Investigation Report H2002-IR-002, available at www.oipc.ab.ca.

The message for Saskatchewan trustees is that there are real and possibly expensive consequences for a failure to establish policy and procedures for HIPA compliance.

Contact information for the Office of the Saskatchewan Information and Privacy Commissioner ("OIPC") is:
Toll Free Telephone Number:
1-877-748-2298
Saskatchewan Information and Privacy Commissioner
#100, 1230 Blackfoot Drive
Regina, Saskatchewan S4S 7G4
Phone: (306) 787-8350
Fax: (306) 798-1603

Health Canada

Information About Clozapine

To Pharmacy Licensing Bodies
(NAPRA, OCP, OPQ)

Dear Pharmacists:

Re: Information about the monitoring of patients taking clozapine

Further to the issuance of safety information regarding the dispensing of clozapine in 2003, Health Canada released new information on the dispensation of clozapine products in Canada: a 2004 Health Canada Dear Health Care Professional letter including a new statement for the Patient Registration Form and the patient information leaflet on consent, a Public Advisory and a Notice to Hospital. All of these documents are posted on the Health Canada website.

Health Canada is overseeing the distribution of the Notice to Hospital to Canadian hospitals and the Public Advisory to Canadians and targeted associations. The three market authorizations holders of clozapine assumed the responsibility of the distribution of the Dear Health Care Professional letter to pharmacists, psychiatrists and general practitioners across Canada.

Please note that "the switching of a patient from one brand of clozapine to another must not be done by a pharmacist unless he/she obtains a new, registry-specific patient registration form filled out by the prescribing physician".

Given the crucial role of the pharmacists in the safety of patients taking clozapine, Health Canada requests your assistance in the posting of the clozapine documents on our website and the dissemination of the revision to the clozapine Product Monographs.

We also invite you and your members to join the Health_Prod_Info mailing list which electronically disseminates the *Canadian Adverse Reaction Newsletter* and notices of homeopathic medicine or a traditional medicine, that is manufactured, sold or represented for use in health professional communications or consumer advisories from the Marketed Health Products Directorate. It is a simple and efficient way to be kept informed of updated safety information on health products. To receive the Newsletter and Advisories free by e-mail, go to: http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/subscribe_e.html.

Thank you in advance for your cooperation in this matter.

Marketed Health Products
Directorate
Email: MHPD_DPSC@hc-sc.gc.ca

Note: References have been deleted. Copies of the publications may be found at www.hc-sc.gc.ca

Canada

An Establishment Licence for Pharmacy Non-Retail Sales of Pharmaceuticals

We have been informed via NAPRA of the following information. It was directed to the NAPRA office from James Bellis, Acting Manager of the Establishment Licensing Unit of the TPD of Health Canada.

A Drug Establishment Licence is required for all businesses in Canada engaged in any of the six activities related to the manufacturing and testing of all drugs in dosage form and bulk intermediates of Schedule C (radiopharmaceutical) and D (biological) drugs from the "Food and Drugs Act" and Schedule F to the Regulations. The six activities are: fabrication, packaging/ labelling, importation, distribution, wholesale, and testing.

From the *Food and Drugs Regulations:*

C.01A.01 – Wholesale – "means to sell any of the following drugs, other than at retail sale, where the seller's name does not appear on the label of the drugs: (a) a drug listed in Schedule C, D or G to the Act or in Schedule F to these Regulations; or (b) a narcotic as defined in section 2 of the *Narcotic Control Regulations*."

Practitioners and Pharmacists (from the Establishment Licence guidance document)

The activities of a practitioner, pharmacist or a person under the supervision of a practitioner are exempt from the licensing requirements of Division 1A only if all three of the following criteria are met: (i) the activity is pursuant to a prescription; (ii) the activity is limited to compounding or importing; (iii) the activity is related to a drug that is not commercially available in Canada.

The term "practitioner" as defined in Division 1 of the *Food and Drug Regulations*, means: "a person authorized by the law of a province of Canada to treat patients with any drug listed or described in Schedule F to the Regulations."

Drug establishments are inspected by Health Products and Food Branch Inspectorate inspectors to assess whether the facility is operating in compliance with the requirements of Part C, Division 2 of the Food and Drug Regulations pertaining to Good Manufacturing Practices (GMP). A Drug Establishment Licence will only be issued once the inspectors have assessed the firm as being in compliance with these requirements.

This requires a pharmacy manager to have an Establishment Licence to conduct any of the six activities outlined above, including pharmacy to pharmacy sales, bulk ordering for more than one pharmacy, or distribution to more than one pharmacy.

Not only does the need to have an Establishment Licence impact community pharmacies but it also has implications for Regional Health Authorities (RHAs). To clarify, Health Canada personnel informed us of the following. A RHA that repackages drugs for distribution amongst facilities within the RHA and/or a hospital that purchases drugs for all the hospitals within the RHA and then distributes those drugs in the original manufacturer's container to other hospitals within the RHA would be considered a wholesaler and would require an Establishment Licence. This is also true when drugs are being distributed not only within the same RHA but also to hospitals in adjacent communities in different RHAs. The RHA is obtaining, storing and distributing drugs and there is a charge for the transactions; therefore, it falls under the scope of this section of the "Food and Drugs Regulations".

Link to the Establishment Licence application form: *www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/del_app_v4_nov2003_ e.pdf*

Link to the Establishment Licensing guidance document: *www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/gui_doc_el_elf_tc_e. html*

Generic Hydromorphone

Cst. Chris Lair, a member of the RCMP, has been studying the street use of hydromorphone in Prince Albert and northern Saskatchewan over the past three years. He has been recognized by the Provincial Court of Saskatchewan as an expert in the area of street use techniques and trafficking techniques in the drug hydromorphone.

Recently, information has been received from independent street users that generic hydromorphone pills are extremely difficult to use intravenously compared to brand name Dilaudid® pills. Cst. Lair confirms that during drug search warrants and undercover purchases of hydromorphone, the generic form is never seen, although some pharmacies had been dispensing this preparation. Users report that twice as many pills of the generic must be used intravenously to receive the same effect.

Based on this information, Cst. Lair prepared both drugs using the methods employed by street users. He found the information received from the street users to be quite accurate and the generic is much more difficult to prepare. Based on these findings, a recommendation was made to the Prince Albert-Parkland Medical Health Officer, Dr. Leo Lanoie, and to local pharmacies that, if appropriate, physicians prescribe only the generic and pharmacies only stock the generic. Shortly after this initiative was undertaken, the street price of hydromorphone doubled, and availability on the street sharply declined. The supply and price have now stabilized to pre-initiative levels as users now report that they are going elsewhere to obtain their prescriptions as the generic hydromorphone has a much lower street value. It would be appreciated if physicians and pharmacies keep this information in mind when prescribing and dispensing hydromorphone.

Destruction of Prescription Hard Copies

REMINDER …

Schedule F

C.01.041. (2) Where the prescription for a Schedule F Drug is written, the person selling the drug shall retain the prescription for at least two years from the date of filling.

Schedule G

G.03.009 A pharmacist shall maintain a special prescription file in which shall be filed in sequence as to date and number all written orders or prescriptions in writing for controlled drugs dispensed and the written record of all controlled drugs dispensed pursuant to a prescription or order verbally given.

G.03.010 A pharmacist shall retain in his possession for a period of at least two years any records which he is required to keep by this **Part.**

Narcotic Regulations

40. (1) A pharmacist shall maintain a special narcotic prescription file in which shall be filed in sequence as to date and number all written orders or prescriptions for narcotics dispensed and the written record of all verbal prescription narcotics dispensed pursuant to a verbal order or prescription as provided in section 39.

(2) A pharmacist shall retain in his possession for a period of at least two years any records which he is required to keep by these Regulations.

For example, when a prescription for a one-month supply of a Schedule F drug authorizes 11 refills, the pharmacist has authority to dispense up to twelve months supply. This in essence means that pharmacists should maintain the files for three years (two years after date of last fill). Prescriptions for controlled substances that have appropriate refill authorization and narcotic prescriptions with part fill authorization must be kept for two years from the most recent entry on the record, which in most cases would mean two years from the last refill/part-fill.

There have been instances where members have been audited by third-party payers, and to their detriment, they did not have records going back for the time specified in the legislation.

Pharmacy managers should also keep in mind that the Canada Revenue Agency does consider prescriptions to be financial records and can request an audit going back over six years.

Drugs and the Elderly: Improving Drug Management in Saskatchewan's Long-Term Care System

(The Health Quality Council requested we publish this article so that our members are aware of the study and if interested may wish to participate.)

A recent Canadian study found potentially inappropriate prescriptions in nearly a fifth (18.3%) of clients in one Ontario long-term care facility. In a second study, also in Ontario, 21 per cent of nursing home residents received a prescription for at least one inappropriate drug. But what is the prescribing picture in Saskatchewan's long-term care setting? A new study by the Health Quality Council (HQC), due to be released in fall 2004, will report on how we are currently doing in this province and on activities underway to bring our drug management in line with leading practices.

Hallucinations, falls, fractures, and heart failure – these are just a few of the dangers associated with inappropriate drug management. Seniors are at particular risk, both because they often need more drug therapy than the rest of the population, and because as people get older, drugs can have a more pronounced effect. Medication-related problems lead to more visits to doctors and other health professionals, increased hospitalizations, additional lab work and monitoring, still more prescriptions – and, in some cases, death.

In the first phase of HQC's study, the project team will look at prescribing patterns using a list of key evidence-based indicators chosen by an expert advisory group, Researchers will analyze de-identified administrative data in areas such as hospital discharges and out patient drug prescriptions. The study will focus on a one-year period, January 1, 2001, to December 31, 2002. Plans for phase 2 include identifying leading practice sites, and working with pilot sites to improve drug management if needed.

"We know from the literature this is a national problem," says Lisa Clatney, HQC Researcher. "The aim of this project is to identify areas where we could be doing a better job, and then work with our health system partners to improve drug management in long-term care."

For more information on the project, please contact Catherine Delaney, a Knowledge Exchange Consultant with HQC by telephone (306-668-8810 ext 109) or email (*cdelaney@hqc.sk.ca*). Information is also available on the Health Quality Council's web site, *www.hqc.sk.ca*

Levonorgestrel

The basis for scheduling decisions of the National Drug Scheduling Advisory Committee (NDSAC) is the assumption that pharmacists are complying with our Standards of Practice. The Standards do play a big role in the committee's deliberations, and if there is a reason to believe that there are problems with compliance/implementation of the standards, it would change the decision-making parameter.

The following letter is from Barbara Wells, former Executive Director of NAPRA, to Ms. Karen Ash, Health Canada.

Dear Karen,

I am writing on behalf of the National Association of Pharmacy Regulatory Authorities (NAPRA) to confirm our support for the National Drug Scheduling Advisory Committee's (NDSAC) recommendation for Schedule II status along with your proposal to exempt Levonorgestrel when sold in concentrations of 0.75 mg per oral dosage unit, from Part II of Schedule F.

We noted in the summary of feedback you received about this proposal that there were questions and concerns expressed about the expectations for care and proper training of pharmacists in providing Emergency Contraception (EC). It is important to clarify that when the National Drug Scheduling Advisory Committee (NDSAC) made its decision to assign Schedule II status for this drug, it was with the understanding that pharmacists would be in compliance with NAPRA's "Model Standards of Practice for Canadian Pharmacists" (publicly available at http://www. napra.org/docs/0/95/123.asp).

These very comprehensive national standards require pharmacists to take steps to ensure that the drug is appropriate for the patient, that the patient is counselled on proper use, that confidentiality and privacy recruitments are respected, and that if warranted, referrals to other healthcare professionals or agencies are made, to name just a few expectations. It is possible that some pharmacists may possess the necessary knowledge already to meet these requirements in the context of EC and not require extra training. However, some may need special continuing education, or information to meet these expectations for a specific drug like EC. Examples might be: what to do if a minor requests EC? Would frequency of use suggest that birth control counselling is in order? What if the request is made by a rape or incest victim – what should the pharmacist do?

In your summary you mention frequently the availability of training programs by the Canadian Pharmacists Association. We are aware of a number of continuing education programs focused on helping pharmacists meet the necessary standards of practice for EC and certainly encourage and applaud these efforts. However, it should not be somehow misconstrued that the Committee's decision for Schedule II was contingent on pharmacists taking any prescribed, special training. Perhaps a more accurate message would be that pharmacists are expected to meet NAPRA's "Model Standards of Practice for Canadian Pharmacists" when dispensing EC and that there are programs offered by CPhA and others available to assist pharmacists in meeting these standards specifically for EC.

Thank you for this opportunity to comment."

The Canadian Diabetes Association is Changing its Meal Planning System!

The introductions of new medications and new methods for the management of diabetes have prompted changes in diabetes education. To meet these new needs, the Canadian Diabetes Association has been working on revising its meal planning system to make it more compatible with *Canada's Food Guide to Healthy Eating* and with the systems used in Quèbec and the USA. The biggest change will be in food groups containing carbohydrate (e.g. grains and starches, vegetables, fruits, and milk), where one serving of a food in all of these groups will contain 15 grams of carbohydrate.

At the present time, the feedback on the first draft of the proposed new system has been consolidated and a second draft of the system is being readied. An "almost final" version will be presented at the CDA/CSEM professional conference in late October, with the final basic version expected in January or February 2005. A larger, more detailed manual will be ready about one year later.

Consumers may notice that the Association's Food Choice Values and Symbols will no longer appear on food packaging. New labelling regulations will provide more nutrition information that can be used to make good food choices.

For more information, please go to the Association website at *www.diabetes.ca*.

CSHP NEWS

The Saskatchewan Branch of the Canadian Society of Hospital Pharmacists (CSHP) has been diligently planning the upcoming **Annual General Meeting (AGM) and Educational Sessions** for **October 23 and 24, 2004,** in Moose Jaw. Exceptional educational sessions and a chance to visit the luxurious spa are in the works! The brochures for the conference will be distributed in September, but ... mark your calendars now! For additional information please contact Educational Services Chair, Mr. Jim Oxley, Pharmacy Dept., Moose Jaw Union Hospital, Ph 306-694-0397; Fax 306-694-0325 or email *joxl@fhhr.ca*.

PROFESSIONAL OPPORTUNITIES

PHARMACIST WANTED

Gray Chemists is a pharmacy located in a medical center with ten family physicians, a dentist, optometrist and a doctor of urology. Pharmacy hours of operation are Monday to Friday, 9 AM to 5:30 PM, no weekends or holidays. Pharmacist required for 3 days a week.

For more information contact Nicole:
Gray Chemists
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Prince Albert, SK S6V 7H9
Ph: 306-764-2300 • Fax: 306-922-5130

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PHARMACIST

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4614 Lazelle Ave.
Terrace, B.C. V8G 1S5
Phone: (250) 635-2156

Email: *lkrause@northerndrugs.com*

www.northerndrugs.com

Integrity of the Triplicate Prescription Database

Pharmacists are reminded to send the second copy of the triplicate prescription, not gathered via the on-line adjudication system, to the College of Physicians and Surgeons for input into their database in a timely manner. The guidelines state, "Members are asked to send the prescription copy to the College at least once per week."

A recent call to our college office from a pharmacist concerning a person, whose triplicate prescriptions were not adjudicated on-line by SPDP at the patient's request, revealed that the information was not getting to the College of Physicians and Surgeons in a timely manner for review.

Pharmacists are reminded that they may confirm information regarding a patient's care with the physician. In order for the physician to ensure the individual is receiving the best possible care and is disclosing all information regarding the use of narcotic and controlled drugs, they must have access to the most up to date and timely information from the Triplicate Prescription Database at the College of Physicians and Surgeons.

SCP Guidelines for Post-Exposure to Blood

In the next Pharmacy Reference Manual updates you will receive the SCP *Guidelines for Post-Exposure to Blood*.

This document was prepared from information received from Health Canada, Workplace Health and Public Safety Program, Healthy Environments and Consumer Safety Branch and the recently released document *Guidelines for the Management of Potential Exposures to Hepatitis B, Hepatitis C, HIV and Recommendations for Post-Exposure Prophylaxis, January 2004*, from the Saskatchewan Subcommittee on HIV/AIDS, Saskatchewan Health.

Materna® Reformulation Causing Drug Schedule Change

Materna®, an iron-containing prenatal vitamin and mineral supplement, has been revised as below:

The Schedule II listing reads:

"Iron and its salts and derivatives (in preparations with more than 30 mg elemental iron per solid dosage unit or 5 ml oral liquid)".

Materna® "old" **DIN 02231880** (100's) contains 60 mg of elemental iron and therefore is a **Schedule II product**. This product remains Schedule II until such time as all inventories are depleted.

Materna® "new" (revised) **DIN 02248555** contains < 27 mg of elemental iron.

This means that the new revised product is now **Unscheduled** and can be sold from any retail outlet.

Confidential Information

As noted in the privacy legislation all personal health information must be kept confidential and this includes prescription vials and containers.

Pharmacies must shred their own confidential information or send it to a confidential shredding company. Pharmacy managers are reminded of the requirement to de-identify prescription vials and all containers carrying patient information before discarding.

E-Link Web Mail

This is a reminder to all members that E-Link is now running and accessible by all members. The National Association of Pharmacy Regulatory Authorities (NAPRA) provides this email facility.

The College will be using this mail facility to distribute information in a timely and efficient manner. From time to time you may also receive other broadcast bulletins and notices, in particular from NAPRA.

E-Link will provide you with a reliable, secure email system that supports a full-featured, web-based mail client accessible anywhere, anytime, from any Internet-connected computer by pointing your browser (Internet Explorer, Netscape, Safari) to *http://www. napra.ca/express*.

If you should forget your password please contact our office and ask for Cheryl Klein or send a message to *support@scp.napra.ca*.

We encourage you to use the E-Link service as your primary email account. You may automatically forward your email to another account, which will enable you to automatically receive communications from the College at another email account. We encourage you to logon to the E-Link system.