July 2011

For a complete listing of the most recent changes to the National Drug Schedules, visit the Drug Schedules Notice Board at www.napra.ca

NAPRA National Drug Schedules Notice Board

National Drug Schedule Advisory Committee Meeting
September 11-12, 2011
July 14, 2011

The next meeting of the National Drug Scheduling Advisory Committee (NDSAC) is scheduled for September 11-12, 2011. The main purpose of the meeting is to consider the following matter:

- A drug scheduling review initiated at the request of NAPRA, for the nonprescription nonsteroidal anti-inflammatory drugs (NSAIDs), excluding ASA and acetaminophen, currently available on the Canadian market. The primary intent of the drug scheduling review of these NSAIDs will be to determine if the current NDS scheduling remains appropriate.

Interested Party Status

Individuals, companies or organizations seeking Interested Party status for the drug scheduling review of nonprescription NSAIDs are invited to contact NAPRA as soon as possible. All requests for Interested Party status for this agenda item must be submitted in writing to the NDSAC Secretariat via regular mail or E-mail no later than 4:00 p.m. (EST) on Wednesday, July 27, 2011. If Interested Party status is granted to a party for this agenda item, the interrogatory period will begin July 28, 2011.

Alternate method of participation

Individuals, companies or organizations that choose not to pursue Interested Party status or have been denied such status, can provide comments, in writing, related to this agenda item outlined above. The comments must be received by the NDSAC Secretariat via regular mail or E-mail no later than 4:00 p.m. (EST) on Friday, September 2, 2011. Please note: only an acknowledgement of receipt for the comments received will be provided. All comments or information provided by this alternate method of participation shall be provided to NAPRA and any person, association or other entity that has realized Interested Party status.

For more information, please contact Kathy Vesterfelt, Manager, Professional and Regulatory Affairs, NAPRA at 613-569-9658, ext. 225.

July 2011

For a complete listing of the most recent changes to the National Drug Schedules, visit the Drug Schedules Notice Board at www.napra.ca
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://wwwhc-sc-gca/dhp-mps/medeff/index_e.html

At this site, pharmacists should subscribe directly to MedEffect e-Notice to receive the latest advisories, warning 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

**August**

- Certain Sandoz Products for Injection - Possible Fading of the Expiry Date and Lot Number on Labels of Vials of 10 mL or Less - Sandoz Canada Inc.
  - [For Health Professionals](2011-08-10)
- Multaq (dronedarone) - Information on Increase in Heart-Related Events in Patients with Permanent Atrial Fibrillation - Sanofi-aventis Canada Inc.
  - [For Health Professionals](2011-08-04)
  - [For the Public](2011-08-04)
- Finasteride (Propecia, Proscar): Potential rare risk of breast cancer in men [2011-08-04]

**July**

- Calcium Gluconate Injection 10% - Important Information Concerning the Presence of Aluminum
  - [For Health Professionals](2011-07-28)
- Multaq: Health Canada reviewing heart-related risk [2011-07-21]
- Level 1 Normothermic I.V. Fluid Administration Sets equipped with F-50 Gas Vent Filter Assembly - Market Withdrawal - Smiths Medical Canada Ltd.
  - [Notice to Hospitals](2011-07-21)
- Metoclopramide: Stronger warnings on risk of abnormal muscle movements [2011-07-20]

**June**

Supplement to *The Manitoba Pharmaceutical Association Newsletter* August, 2011
Retain a copy for reference.
Health Canada reviewing diabetes drug pioglitazone (Actos) and potential risk of bladder cancer [2011-06-17]

Antipsychotic drugs: Labelling update regarding the risk of abnormal muscle movements and withdrawal symptoms in newborns exposed during pregnancy [2011-06-15]

Health Canada reviewing safety of drospirenone-containing oral contraceptives (Yasmin and Yaz) and risk of venous thromboembolism [2011-06-07]

RITUXAN (rituximab) - Fatal Infusion Related Reactions in Patients with Rheumatoid Arthritis - Hoffmann-La Roche Limited

For Health Professionals [2011-06-07]

For the Public [2011-06-07]

May

Boston Scientific Urgent Device Notification - Non-Sterile Devices Stolen and Risk of Infection

Notice to Hospitals [2011-05-25]

Recent Advisories Warnings and Recalls

Certain Sandoz Products for Injection - Possible Fading of the Expiry Date and Lot Number on Labels of Vials of 10 mL or Less - Sandoz Canada Inc.

For Health Professionals [2011-08-10]

Multaq (dronedarone) - Information on Increase in Heart-Related Events in Patients with Permanent Atrial Fibrillation - Sanofi-aventis Canada Inc.

For Health Professionals [2011-08-04]

For the Public [2011-08-04]

Finasteride (Propecia, Proscar): Potential rare risk of breast cancer in men [2011-08-04]

Foreign Product Alert - Fifteen products promoted for weight loss [2011-08-03]

Foreign Product Alert - Pink Lady for Women Capsules - St Nirvana Herbal Slimming Capsules [2011-08-03]

Foreign Product Alert - Celerite Slimming Tea [2011-08-03]

Calcium Gluconate Injection 10% - Important Information Concerning the Presence of Aluminum

For Health Professionals [2011-07-28]

UPDATE: 1 Additional Unauthorized Health Product Tested: May Pose Serious Health Risks [2011-07-25]

Centrum Materna Prenatal Multivitamins: One bottle found to contain unidentified capsules instead of pink tablets [2011-07-25]

Multaq: Health Canada reviewing heart-related risk [2011-07-21]

Level 1 Normothermic I.V. Fluid Administration Sets equipped with F-50 Gas Vent Filter Assembly - Market Withdrawal - Smiths Medical Canada Ltd.

Notice to Hospitals [2011-07-21]
Metoclopramide: Stronger warnings on risk of abnormal muscle movements [2011-07-20]

Health Canada reviewing safety of drospirenone-containing oral contraceptives (Yasmin and Yaz) and risk of venous thromboembolism [2011-07-15]

Tanta Pharmaceuticals Inc. Recalls Junior and Children's Strength Acetaminophen Tablets [2011-07-15]

Procter & Gamble Recalls Mouthwash [2011-07-14]

Foreign Product Alert - X-Hero and Male Enhancer [2011-07-12]

Foreign Product Alert - Slim Xtreme Herbal Slimming Capsules [2011-07-12]

Foreign Product Alert - Natural Vigra VIAGRA Tablets and Satibo Capsules [2011-07-12]


Foreign Product Alert - Black Ant [2011-07-12]

Foreign Product Alert - Beline Capsules [2011-07-12]

Advisories, Warnings and Recalls for the Public - 2011

August

Multaq (dronedarone) - Information on Increase in Heart-Related Events in Patients with Permanent Atrial Fibrillation - Sanofi-aventis Canada Inc.

For Health Professionals [2011-08-04]

For the Public [2011-08-04]

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July

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Foreign Product Alert - Slim Xtreme Herbal Slimming Capsules [2011-07-12]

Foreign Product Alert - Natural Vigra VIAGRA Tablets and Satibo Capsules [2011-07-12]
Proton pump inhibitors: hypomagnesemia accompanied by hypocalcemia and hypokalemia

Key points

• Prolonged treatment (≥ 1 year) with proton pump inhibitors (PPIs) is suspected of being associated with hypomagnesemia.
• In published cases, some patients presented with symptoms of potentially life-threatening cardiac arrhythmias and neurologic manifestations.
• The effects of PPIs on magnesium serum levels seem to be reversible.

Proton pump inhibitors (PPIs) are widely used for the treatment of conditions related to gastric acid secretion (e.g., duodenal and gastric ulcers, reflux esophagitis and gastroesophageal reflux disease). In Canada, 6 marketed PPIs are available as prescription medications: omeprazole (first marketed in 1989), lansoprazole (1995), pantoprazole (1997), esomeprazole (2001), rabeprazole (2001) and dexlansoprazole (2010).

The potential association between PPI treatment and hypomagnesemia has been suggested in the literature and communicated by other regulatory authorities. Hypomagnesemia is unclear. It may involve defects in magnesium absorption in the small intestine by affecting the function of the transient receptor potential melastin 6 (TRPM6) channel. Effects on magnesium absorption have not been reported with short-term use of PPIs. Published case reports suggest that PPI-induced hypomagnesemia occurs after prolonged use (≥ 1 year). Magnesium is involved in bone metabolism. Its deficiency may induce parathyroid dysfunction and hypoparathyroidism, thereby affecting the regulation of calcium levels. Hypomagnesemia may also trigger hypokalemia via activation of the potassium channel of the thick ascending limb of the loop of Henle, resulting in urinary potassium wasting.

The effects of PPIs on serum magnesium levels seem to be reversible. In all published cases, electrolyte levels returned to normal following cessation of PPI treatment (positive dechallenge). Recurrence of hypomagnesemia following reintroduction of the PPI (positive rechallenge) was documented in

*Response to withdrawal of the drug. Abatement of reaction after the drug is stopped or the dose is reduced is considered a positive dechallenge.
†Response to reintroduction of the drug. Reappearance of the AR after reintroduction of the drug is considered a positive rechallenge.
Adverse reaction and incident reporting — 2010

Canada Vigilance Program

The Canada Vigilance Program collects reports of suspected adverse reactions (ARs) to health products (pharmaceuticals, biotechnology products, blood products and biologics, natural health products, radiopharmaceuticals, and cells, tissues and organs). Further information about the program and its database can be found at www.health.gc.ca/medeffect.

Domestic and foreign AR reports

In 2010, Health Canada received 32,921 domestic AR reports,* of which 77% were considered to be serious.†

Domestic AR reports received by product type are provided in Table 1. The 32,921 reports represent 22,241 AR cases. A case consists of all information describing the AR(s) experienced by one patient at one time and suspected of being related to the use of one or more health products; thus, an AR case will include an initial AR report as well as any subsequent additional information received as follow-up report(s).

In Canada, Market Authorization Holders (MAHs) are required to

| Table 1: Number of domestic reports* of adverse reactions by product type in 2010 |
|------------------------------------------|------------------|
| Product type                            | No. (%) of reports |
| Pharmaceuticals                         | 22,104 (67.1)    |
| Biotechnology products                  | 8,860 (26.9)     |
| Blood products and biologics            | 903 (2.7)        |
| Natural health products                 | 677 (2.1)        |
| Radiopharmaceuticals                    | 348 (1.1)        |
| Cells, tissues and organs               | 29 (0.1)         |
| Total                                   | 32,921 (100.0)   |

*Candidates Vigilance receives reports for both initial and follow-up information concerning suspected adverse reactions.

ARs to health products are considered to be suspicions, as a definite causal association often cannot be determined.

Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.

Rania Mouchantaf, PhD, Health Canada

References


*This excludes 1035 AR reports received for product types that do not fall under the review of the Canada Vigilance Program, as outlined above. These reports were redirected to the appropriate AR reporting program.

†In the Food and Drugs Act and Regulations, a serious AR is defined as “a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.”

3 cases. In most cases, secondary hypokalemia or hypocalcemia, or both, accompanied the hypomagnesemia, with some patients presenting with symptoms of potentially life-threatening cardiac arrhythmias and neurologic manifestations (e.g., seizures, loss of consciousness and tetany).

As of Jan. 31, 2011, Health Canada received 5 reports of hypomagnesemia suspected of being associated with the following PPIs: omeprazole (n = 2), lansoprazole (n = 1), pantoprazole (n = 1) and esomeprazole (n = 1). One case was life threatening, and 4 patients required hospital care. Secondary hypokalemia was reported in 3 of the cases. One report described a positive dechallenge‡ and a positive rechallenge.†

Health professionals are reminded that, in some patients, hypomagnesemia may occur after prolonged treatment with PPIs, and it may be accompanied by hypocalcemia and hypokalemia. This adverse reaction may be underdiagnosed and underreported because of the low frequency of magnesium measurement in routine clinical practice. Health care professionals are encouraged to report any cases of hypomagnesemia suspected of being associated with the use of PPIs.

Rania Mouchantaf, PhD, Health Canada

References


This excludes 1035 AR reports received for product types that do not fall under the review of the Canada Vigilance Program, as outlined above. These reports were redirected to the appropriate AR reporting program.

†In the Food and Drugs Act and Regulations, a serious AR is defined as “a noxious and unintended response to a drug that occurs at any dose and that requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.”

Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.
submit AR reports received in accordance with the requirements of the Food and Drugs Act and Regulations. MAHs are required to send, within 15 days, all reports of serious ARs that have occurred in Canada (domestic) and all reports of serious unexpected ARs‡ that have occurred outside Canada (foreign) to the Canada Vigilance Program. In 2010, MAHs submitted 78.9% of all the domestic reports received. The remaining reports were received directly from the community and hospitals (Table 2).

The number of domestic AR reports was 19.7% higher in 2010 than in 2009 (Fig. 1). Most of the domestic reports received by both MAHs and Health Canada originated from health care professionals (Table 3).

In 2010, the number of foreign AR reports received from MAHs was 363,961 (Fig. 2). At this time, foreign reports are not included in the Canada Vigilance database.

Sex and age

The distribution for the 22,241 cases by sex was 57% female, 38% male and 5% sex unknown. The distribution by age group is 7% pediatric (<19 years), 47% adult (19–64 years), 25% elderly (≥65 years) and 21% age unknown.

Suspect products

The top 10 groups of suspect products most commonly identified in AR reports are listed in Table 4. Anatomical Therapeutic Chemical (ATC) groups are classified according to the World Health Organization’s ATC classification system (www.whocc.no/atc_ddd_index). Several factors may influence the number of ARs reported for a specific health product or product type, such as length of time a product is on the market, volume of use, publicity of an AR, regulatory actions, method of data collection (reports submitted voluntarily vs. organized data-collection systems). For example, ARs may be reported more frequently in organized data-collection systems (e.g., patient registries, surveys, patient support and disease management programs) and may affect the pattern of reporting. It is not possible to compare the risk of health products based solely on numbers of AR reports. In addition, rare and serious reactions may not necessarily represent a large number of reported ARs.

Adverse reactions

Table 5 displays the top 10 ARs reported to the Canada Vigilance Program, based on System Organ Class.§ The most commonly reported ARs were general disorders and administration site conditions, which include disorders that affect several body systems or sites (e.g., drug ineffective, fatigue, fever, edema, pain, reactions at the administration site).

Table 3: Number of domestic reports* of adverse reactions by type of originating reporter in 2010

<table>
<thead>
<tr>
<th>Reporter type</th>
<th>No. (%) of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consumer/patient</td>
<td>8 733 (26.5)</td>
</tr>
<tr>
<td>Physician</td>
<td>8 102 (24.6)</td>
</tr>
<tr>
<td>Health professional†</td>
<td>5 782 (17.6)</td>
</tr>
<tr>
<td>Nurse</td>
<td>5 100 (15.5)</td>
</tr>
<tr>
<td>Pharmacist</td>
<td>4 615 (14.0)</td>
</tr>
<tr>
<td>Dentist</td>
<td>12 (0.04)</td>
</tr>
<tr>
<td>Naturopath</td>
<td>5 (0.02)</td>
</tr>
<tr>
<td>Other</td>
<td>572 (1.7)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>32 921 (100.0)</strong></td>
</tr>
</tbody>
</table>

*Canada Vigilance receives reports for both initial and follow-up information concerning suspected adverse reactions.
†Type not specified in report.

### Table 2: Number of domestic reports* of adverse reactions by source in 2010

<table>
<thead>
<tr>
<th>Source</th>
<th>No. (%) of reports</th>
</tr>
</thead>
<tbody>
<tr>
<td>MAH</td>
<td>25 967 (78.9)</td>
</tr>
<tr>
<td>Community†</td>
<td>5 727 (17.4)</td>
</tr>
<tr>
<td>Hospital</td>
<td>1 120 (3.4)</td>
</tr>
<tr>
<td>Other</td>
<td>107 (0.3)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>32 921 (100.0)</strong></td>
</tr>
</tbody>
</table>

Note: MAH = Market Authorization Holder.
*Canada Vigilance receives reports for both initial and follow-up information concerning suspected adverse reactions.
†Consumer, patient and non-hospital–based health care professionals.

In the Food and Drugs Act and Regulations, a serious unexpected AR is defined as “a serious adverse drug reaction that is not identified in nature, severity or frequency in the risk information set out on the label of the drug.”

Adverse reactions are coded using the Medical Dictionary for Regulatory Activities (MedDRA) Terminology. The terminology is organized in a hierarchical structure where the System Organ Class is the highest level of the hierarchy and represents the broadest concept of groupings. Further information about the MedDRA Terminology can be found at www.hc-sc.gc.ca/dhp-mps/medeff/databas-don/meddra-eng.php.

Adverse reactions (ARs) to health products are considered to be suspicions, as a definite causal association often cannot be determined. Spontaneous reports of ARs cannot be used to estimate the incidence of ARs because ARs remain underreported and patient exposure is unknown.
The next most common ARs were gastrointestinal disorders.

**Conclusion**

Health Canada would like to thank all who have contributed to the Canada Vigilance Program and encourages the continued support of postmarketing surveillance through AR reporting. The purpose of postmarket spontaneous reporting systems is the identification and analysis of new safety information for health products. Any ARs suspected of being associated with the use of health products can be reported to the Canada Vigilance Program (www.health.gc.ca/medeefect).

**Medical device incidents**

Medical device incidents are collected by the Health Products and Food Branch Inspectorate and are entered into the Medical Device System database. The Inspectorate is responsible for compliance monitoring activities for a broad spectrum of regulated health products, including medical devices which range from adhesive bandages to pacemakers. It is also responsible for the delivery of a national compliance and enforcement program in an effort to minimize health risks to Canadians while maximizing the safety of health products. A major component of this program involves the collection, review and follow-up of incidents related to medical devices, which are reported to the Inspectorate via the submission of mandatory and voluntary problem reports. Manufacturers and importers are required to submit mandatory reports as per sections 59 to 61 in the Medical Devices Regulations. Voluntary reports are submitted mostly by health care professionals and patients/users.

In 2010, a total of 7588 reports were entered into the Medical Device System database. Of these reports, 5828 (76.8%) were domestic mandatory reports, 1354 (17.8%) were foreign mandatory reports, and 406 (5.4%) were domestic voluntary reports.


Completed Medical Devices Problem Report forms can be submitted by email as attachments to: mdpr@hc-sc.gc.ca. Please include the acronym MDPR in the subject line of the email in order to generate an automated confirmation of receipt by the Inspectorate.

Marielle McMorran, BSc, BSc(Pharm); Melanie Adams, PhD, Health Canada

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### Table 4: Top 10 groups of suspect health products most commonly reported in 2010, by Anatomical Therapeutic Chemical (ATC) group*

<table>
<thead>
<tr>
<th>Health product (ATC group)</th>
<th>No. (%) of times reported†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunosuppressants (L04)</td>
<td>5 208 (20.4)</td>
</tr>
<tr>
<td>Psychoaleptics‡ (N06)</td>
<td>1 563 (6.1)</td>
</tr>
<tr>
<td>Psycholeptics‡ (N05)</td>
<td>1 459 (5.7)</td>
</tr>
<tr>
<td>Drugs for treatment of bone diseases (M05)</td>
<td>1 340 (5.2)</td>
</tr>
<tr>
<td>Antineoplastic agents (L01)</td>
<td>1 295 (5.1)</td>
</tr>
<tr>
<td>Analgesics (N02)</td>
<td>1 110 (4.3)</td>
</tr>
<tr>
<td>Antibacterials for systemic use (J01)</td>
<td>907 (3.6)</td>
</tr>
<tr>
<td>Lipid-modifying agents (C10)</td>
<td>799 (3.1)</td>
</tr>
<tr>
<td>Agents acting on the renin–angiotensin system (C09)</td>
<td>653 (2.6)</td>
</tr>
<tr>
<td>Drugs for acid-related disorders (A02)</td>
<td>569 (2.2)</td>
</tr>
</tbody>
</table>

* Solicited reports or organized data-collection systems (e.g., patient registries, surveys, patient support and disease management programs) may affect the total number of ARs reported for specific products or product types.

† One case may contain one or more suspect product(s). The total number of suspect health products reported was 25 551 in a total of 22 241 cases.

‡N05 psycholeptics: antipsychotics, anxiolytics, hypnotics and sedatives; N06 psychoaleptics: antidepressants, psychostimulants, psycholeptics and psychoaleptics in combination, anti-dementia drugs.

### Table 5: Top 10 adverse reactions reported in 2010, by System Organ Class*

<table>
<thead>
<tr>
<th>System Organ Class</th>
<th>No. (%) of times reported†</th>
</tr>
</thead>
<tbody>
<tr>
<td>General disorders and administration-site conditions</td>
<td>15 540 (21.4)</td>
</tr>
<tr>
<td>Gastrointestinal disorders</td>
<td>8 395 (11.6)</td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>6 915 (9.5)</td>
</tr>
<tr>
<td>Investigations</td>
<td>6 080 (8.4)</td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>4 758 (6.6)</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>4 392 (6.0)</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td>4 095 (5.6)</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>3 807 (5.2)</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>2 859 (3.9)</td>
</tr>
<tr>
<td>Injury, poisoning and procedural complications</td>
<td>2 521 (3.5)</td>
</tr>
</tbody>
</table>


† One case may contain one or more reaction(s). The total number of ARs reported was 72 683 in a total of 22 241 cases.
Case presentation

Recent Canadian cases are selected based on their seriousness, frequency of occurrence or the fact that the reactions are unexpected. Case presentations are considered suspicions and are presented to stimulate reporting of similar suspected adverse reactions.

Floseal hemostatic matrix: suspected association with misinterpretation as recurrent malignant disease

Floseal is a granular hemostatic agent that consists of a bovine-derived gelatin matrix component and a human-derived thrombin component. Before application, these two components are combined to allow the mixing and reconstitution of the thrombin into the gelatin matrix. Floseal is indicated in surgical procedures (other than ophthalmic) as an adjunct to hemostasis when control of bleeding by ligature or conventional methods is ineffective or impractical. Floseal is expected to resorb in the tissues within 6 to 8 weeks. In Canada, the product is regulated as a class IV medical device (highest risk class).

In 2010, Health Canada received 2 reports of adverse incidents in which Floseal was suspected of persisting at surgical sites following partial nephrectomy for cancer. In both cases, follow-up radiographic imaging several months after surgery (6 and 9 months, respectively) revealed an asymptomatic mass (1 cm × 1.5 cm, and 3 cm × 4 cm, respectively) that was initially interpreted as recurrent malignant disease. The physician later reinterpreted the mass as a possible persistence of Floseal. In both cases, the report suggested that the mass could have been related to excess use of Floseal without adequate irrigation. Other cases have been reported in the medical literature in which Floseal persisted in the tissues after tumour resection and was misinterpreted as recurrent malignant disease during follow-up.

Health Canada encourages the reporting of similar adverse incidents suspected of being associated with Floseal to the Health Products and Food Branch Inspectorate through the toll-free hotline (1-800-267-9675).

References

Risk communication information

Health Canada considers many factors in the evaluation of an emerging health product safety concern (e.g., availability and reliability of data, seriousness of the event) and the urgency of the communication.

The chart below outlines the urgency level of each type of communication disseminated by Health Canada and industry for public and professional audiences.

To provide health product risk information to Canadians as quickly as possible, Health Canada posts risk communications on the MedEffect™ Canada Web site at www.health.gc.ca/medeffect. This central hub of health product safety information offers the most comprehensive coverage and access to risk communications issued by both Health Canada and industry.
<table>
<thead>
<tr>
<th>Date</th>
<th>Product</th>
<th>Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 6</td>
<td>Cytarabine injection</td>
<td>Potential for crystallization in vials</td>
</tr>
<tr>
<td>May 4</td>
<td>Omega Alpha Kidney Flush</td>
<td>Recall</td>
</tr>
<tr>
<td>Apr 29</td>
<td>Triad Group manufactured health products</td>
<td>Updated list of recalled products</td>
</tr>
<tr>
<td>Apr 26 &amp; 28</td>
<td>Anzemet (dolasetron mesylate) intravenous injection</td>
<td>Product withdrawal</td>
</tr>
<tr>
<td>Apr 21</td>
<td>Triad Group manufactured health products</td>
<td>Recall: update</td>
</tr>
<tr>
<td>Apr 19</td>
<td>Topical benzocaine products</td>
<td>Reminder of health risks</td>
</tr>
<tr>
<td>Apr 18</td>
<td>Mary Ginseng House 100% Pure High Calibre Pow Sum Ontario Ginseng</td>
<td>Recall: microbial contamination</td>
</tr>
<tr>
<td>Apr 11</td>
<td>Vivaglobin</td>
<td>Risk of thrombotic events</td>
</tr>
<tr>
<td>Apr 7</td>
<td>U-Prostal</td>
<td>Recall: undeclared terazosin hydrochloride</td>
</tr>
<tr>
<td>Apr 6</td>
<td>RUSCH Irrigation Trays</td>
<td>Recall: potential contamination of co-packaged alcohol prep pads</td>
</tr>
<tr>
<td>Apr 5</td>
<td>Friendly Flora and Healthy Skin with Greens+</td>
<td>May pose serious health risks to Canadians with milk allergies</td>
</tr>
<tr>
<td>Mar 24</td>
<td>Salvia divinorum</td>
<td>It's Your Health: Salvia divinorum</td>
</tr>
<tr>
<td>Mar 21</td>
<td>Natural health products</td>
<td>It's Your Health: Adulteration of natural health products</td>
</tr>
<tr>
<td>Mar 17</td>
<td>Mylan-Minocycline and Mylan-Amlodipine</td>
<td>Recall: mislabeling of products</td>
</tr>
<tr>
<td>Mar 10 &amp; 15</td>
<td>Multaq (dronedarone)</td>
<td>Updated safety information in regards to hepatocellular injury</td>
</tr>
<tr>
<td>Mar 9</td>
<td>Bertec Medical Beds</td>
<td>Recall of medical bed model FLH668NDCM</td>
</tr>
<tr>
<td>Mar 8</td>
<td>Ixiaro Japanese encephalitis vaccine</td>
<td>Recall of lot JEV09L37C</td>
</tr>
<tr>
<td>Feb 14 &amp;</td>
<td>Plum A+ Infusion Pumps</td>
<td>Recall: audible alarm failure</td>
</tr>
<tr>
<td>Mar 7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb 19 to</td>
<td>Foreign products</td>
<td>8 Foreign Product Alerts (FPAs) were posted on the Health Canada Web site during this period; FPAs are available online (<a href="http://www.hc-sc.gc.ca/ahc-asc/media/index-eng.php">www.hc-sc.gc.ca/ahc-asc/media/index-eng.php</a>) or upon request</td>
</tr>
<tr>
<td>May 20</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Advisories are available at www.health.gc.ca/medeffect.

*Date of issuance. This date may differ from the posting date on Health Canada's Web site.
Foreign Product Alert - Black Ant [2011-07-12]
Foreign Product Alert - Beline Capsules [2011-07-12]
Valproate anti-epileptic drugs may pose risks to children when taken by mothers during pregnancy [2011-07-08]
14 Additional Unauthorized Health Products Tested: May Pose Serious Health Risks [2011-07-06]
"Man Up Now" Removed From Sale at Delta and Surrey Stores: May Pose Serious Health Risks to Canadians [2011-07-04]

June

Health Canada reviewing stop-smoking drug Champix (varenicline tartrate) and potential risk of heart problems in patients with heart disease [2011-06-27]
Counterfeit Cialis Seized in the Greater Toronto Area [2011-06-21]
Health Canada reviewing diabetes drug pioglitazone (Actos) and potential risk of bladder cancer [2011-06-17]
Antipsychotic drugs: Labelling update regarding the risk of abnormal muscle movements and withdrawal symptoms in newborns exposed during pregnancy [2011-06-15]
Unauthorized Health Products Removed From Sale at Burnaby and Richmond Stores: May Pose Serious Health Risks to Canadians [2011-06-15]
Tanta Pharmaceuticals Inc. Recalls Junior and Children's Strength Acetaminophen Tablets [2011-06-07]
Health Canada reviewing safety of drospirenone-containing oral contraceptives (Yasmin and Yaz) and risk of venous thromboembolism [2011-06-07]
RITUXAN (rituximab) - Fatal Infusion Related Reactions in Patients with Rheumatoid Arthritis - Hoffmann-La Roche Limited

For Health Professionals [2011-06-07]
For the Public [2011-06-07]
Taro Pharmaceuticals Canada Inc.’s Voluntary Recall of Docusate Sodium Capsules [2011-06-03]
Get your patients to Get Better Together!

What if there was a free, easy-to-use resource that helped your patients take positive steps to better cope with their own chronic conditions, prescriptions and comply with your advice?

Get Better Together! is a free Manitoba-wide program for anyone with an ongoing medical condition to learn how to manage their condition better. Get Better Together (GBT) is the name for the highly successful Chronic Disease Self-Management Program developed and licensed by Stanford University Patient Education Centre.

It has been offered by the Wellness Institute in Winnipeg at multiple locations for several years, and has been offered province-wide since 2008. The program is free of charge to participants and is offered in 2½ hour sessions once a week for 6 weeks.

Get Better Together! helps participants learn strategies to control pain, deal with fatigue and frustration, start a basic exercise program, handle stress, and eat well to live well. Personal goal setting and problem-solving help patients build confidence for successful self-management.

A session on medication usage allows participants to brainstorm ways to remember to take medications as well as offers them guidelines on making treatment decisions to help them become better partners with all members of the health care team. A session on medication responsibilities gives tips such as:

- Inform all your health care providers of all medications you’re taking
- Use the same pharmacy consistently for all medications
- Inform all health care providers if you are not taking your medications as prescribed

The program has been well studied and shown to improve compliance with medications and lifestyle change prescriptions, reduce hospitalization and ER visits, and improved communication with healthcare professionals.

Many patients report being inspired to improve their health through the program:

*This program has helped me out of a depressed slump I was in. Everyone is shocked to see how well I’m doing now.*

The program is led by a combination of health care staff and trained peer leaders. Research on the peer-led model demonstrates that when the program is led by peer leaders with health conditions, participants do even more to make positive changes to their health habits.

Programs are offered across Manitoba and in multiple locations in Winnipeg. To refer patients, simply direct them to call (204) 632-3927 or to www.getbettertogether.ca. If you would like brochures for your Pharmacy, or more information about the program, please contact us.

Get Better Together Manitoba Program
Phone: (204) 632-3927
Email: gbt@wellnessinstitute.ca
Website: www.getbettertogether.ca

Get Better Together! is supported by Manitoba Health, Regional Health Authorities across Manitoba, and the Wellness Institute at Seven Oaks General Hospital.
ANNUAL GOLF TOURNAMENT

KINGSWOOD GOLF & COUNTRY CLUB LTD.
LASALLE, MANITOBA  (6 minutes from South Perimeter, South on Hwy. 330)
TUESDAY, SEPTEMBER 13, 2011

TOURNAMENT RESTRICTED TO THE FOLLOWING: Please check one:

PHARMACIST  ______
M.Ph.A./M.S.P. STAFF  ______
PHARMACEUTICAL REP  ______
WHOLESALERS  ______
SPOUSES OF ABOVE  ______
PHARMACY STAFF  ______*
M.Ph.A. SPECIAL GUESTS  ______
*new category

Prizes for best gross and net scores will be up for grabs, as well as many great prizes for not having the best gross and net scores. **SHOTGUN START AT 12:00 Noon** with dinner at 5:30 p.m. THE PUTTING CONTEST will be held to raise funds for the “Canadian Foundation for Pharmacy”.

Hole sponsorship is **$300.00 per hole** which includes a sign displayed on the course indicating your support.

~ LOTS OF PRIZES ~

If you wish to provide a donation or sponsor a hole for the event, please forward to the M.Ph.A. Office, 200 Tache Avenue, or call the office and we can arrange to have them picked up. Phone 233-1411 ask for Pamela or email pgordon@mpha.mb.ca. All sponsors will be provided with as much exposure and recognition at the event as possible.

-------------------------------------------------

M.Ph.A. GOLF TOURNAMENT REGISTRATION FORM

NAME ____________________________________________

ADDRESS ____________________________________________

PHONE NO. ____________________ (W) ____________________ (H)  E-mail:______________________________

I will golf with: ___________________________ I require placement in a foursome _____

FEE: $75.00 (Includes Golf, Dinner and applicable taxes) if you register before August 28th.
FEE: $85.00 (Includes Golf, Dinner and applicable taxes) if you register AFTER August 28th.

GOLF CART RESERVATIONS: TO BE MADE DIRECTLY WITH THE KINGSWOOD GOLF & COUNTRY CLUB AT (204)736-4079.

PAYMENT MUST ACCOMPANY ALL ENTRIES - NO EXCEPTIONS

DEADLINE FOR ENTRIES IS **SEPTEMBER 9, 2011**
# PROFESSIONAL DEVELOPMENT LOG

**Name:** J. Lerner  
**License #:** 12345  
**Year:** 2005-2006

<table>
<thead>
<tr>
<th>Date</th>
<th>Program Title, Provider, File No. (accredited) or Practice Issue (non-accredited)</th>
<th>Contact Hours</th>
<th>Key Ideas/ Thoughts/Learning Points</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>An accredited program</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nov. 21/05</td>
<td>Adherence to Asthma Therapy Provider: Novopharm CCCEP # 060-1103</td>
<td>1.0</td>
<td>Discussed preferred devices for treatment in children (MDI + spacer + facemask) and compared different devices and proper techniques</td>
</tr>
<tr>
<td>Jan 15/06</td>
<td>Treatment of Depression with New Antidepressants Article Provider: Organon CCCEP # 108-0304</td>
<td>1.75</td>
<td>Sertraline use vs. Fluoxetine and other “new” antidepressants. Discussed side effect profiles and gave cases when combination use were beneficial.</td>
</tr>
<tr>
<td>Jan 30/06</td>
<td>Pharmacist’s Letter January 2006, Vol. 22 no. 1 ACPE # 123-456</td>
<td>1.0</td>
<td>Antibiotics: rifampin, penicillin, tetracyclines etc. Combining AB’s and new treatment methods.</td>
</tr>
<tr>
<td><strong>A program that was accredited for 1.75 CEUs, but took 2.5 hours to complete</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Feb 12/06</td>
<td>Discussion with colleague, Dr. Sugar about brittle Type II Diabetics and patients with compliance issues. <strong>Practice Issue:</strong> Improving patient compliance</td>
<td>2.0</td>
<td>Discussed preferred combination therapy for various patients we’ve both encountered – what worked and what didn’t. Shared articles about increasing compliance with patients.</td>
</tr>
<tr>
<td>Feb 20/06</td>
<td>Apotex CE Essentials Online: Stroke CCCEP # 383-0206</td>
<td>2.0</td>
<td>Refresher on different types of strokes, and the various treatment methods. Stroke prevention was also discussed.</td>
</tr>
<tr>
<td>Mar 2/06</td>
<td>Diabetes and Heart Health Clinic Provider: Health Science Centre, presented by Dr. J. Smith, Dr. R. Jones and K. Lee. <strong>Practice Issue:</strong> To develop guidelines for the effective management of Type II Diabetes specific to my practice.</td>
<td>6.0</td>
<td>Review of current guidelines for testing and treatment. BP testing, and screening for blood sugars.</td>
</tr>
<tr>
<td>Mar 10/06</td>
<td>Video: Advancing Quality in the Name of Patient Safety MPhA File # 23340M</td>
<td>6.0</td>
<td>Discussed different methods of preventing medication errors and best practice approach for informing patients &amp; physicians and responding to the errors.</td>
</tr>
<tr>
<td>April 30/06</td>
<td>The Pharmacists Role in Helping Patients Achieve their Asthma Goals: Is Total Control Achievable? Provider: R- Briefcase CCCEP # 263-0405</td>
<td>2.0</td>
<td>Discussed guidelines to help patient gauge if their asthma is well controlled. Inhaled corticosteroids are mainstay in asthma therapy.</td>
</tr>
<tr>
<td><strong>How to record Learning Projects in PDL, if applicable</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar 2/06</td>
<td>Refer to Learning Project 1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mar 10/06</td>
<td>Medical Letters on Drugs and Therapeutics. Vol. 3, No. 5, 2006. <strong>Practice Issue:</strong> Drug knowledge</td>
<td>1.0</td>
<td>Treatment of menopausal vasomotor symptoms. Drugs for percutaneous coronary interventions – anticoagulation therapy is recommended for all PCI’s.</td>
</tr>
<tr>
<td>July 5/06</td>
<td>Optimizing Pharmacy Care for Individuals Living with Mental Illness Provider: MPhA MPhA File # 23065M</td>
<td>3.5</td>
<td>Schizophrenia: New dosing efficiency, side effects and controversies surrounding various treatments. Bipolar Disorder: medication updates</td>
</tr>
<tr>
<td>Date</td>
<td>Activity</td>
<td>CEUs</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>---------------------------------------------------------------------------</td>
<td>------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>July 26/06</td>
<td>Counselling Pediatric Patients Provider: Novopharm CE Compliance Centre</td>
<td>1.0</td>
<td>Dosage form and taste can play a significant role in compliance. Discussed different factors that can attribute to non-compliance and how to improve compliance.</td>
</tr>
<tr>
<td>August 19/06</td>
<td>CPHA Professional Advancement Online Learning Centre: Children’s Health: Resolving Pediatric infections. CCCEP # 906-1202</td>
<td>3.0</td>
<td>Guidelines for treatment of bacterial meningitis, chicken pox and otitus media. Treatment options include: rifampin for prophylaxis bacterial meningitis tx (vs. cipro)</td>
</tr>
<tr>
<td>Oct 10/06</td>
<td>Preceptorship - Third Year Pharmacy Student MPhA File No. 25076M Review of Canadian Diabetes Association Clinical Practice Guidelines for the management of Type II diabetes (<a href="http://www.diabetes.ca/cpg2003/chapters.aspx">http://www.diabetes.ca/cpg2003/chapters.aspx</a>)</td>
<td>1.5</td>
<td>If glycemic targets are not achieved using lifestyle management within 2 to 3 months, antihyperglycemic agents should be initiated. In the presence of marked hyperglycemia (A1C ≥9.0%), antihyperglycemic agents should be initiated concomitant with lifestyle counselling. Further recommendations included regarding oral antihyperglycemic agents, insulin and combination therapies.</td>
</tr>
</tbody>
</table>

**TOTAL CONTACT HOURS**

(minimum of 25 hours of learning activities each PD Year including a minimum of 15 CEUs)

(PD Year is November 1st to October 31st)

<table>
<thead>
<tr>
<th>CEUs</th>
<th>22.75</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.25</td>
<td></td>
</tr>
</tbody>
</table>
2011 Learning Portfolio Summary

Name: ________________________________  MPhA Licence No. __________

According to the Regulations to the Manitoba Pharmaceutical Act, participation in continuing professional development activities and maintenance of a Learning Portfolio documenting these learning activities as approved by MPhA Council, is a requirement of an annual practicing license for pharmacists. Pharmacists are required to participate in a minimum of 25 hours of professional development (PD) between November 1st and October 31st each year of which a minimum of 15 CEUs (equivalent to 15 hours) must be accredited learning activities and the remaining 10 hours may include either accredited or non-accredited learning activities.

The 2011 Learning Portfolio Summary is a statement declaring professional development activities for the period November 1st, 2010 to October 31st, 2011 and together with all Professional Development Log form(s) (PDLs) documenting these learning activities, must accompany the completed 2012 MPhA Practicing Licence Application. Licence applications submitted without a 2011 Learning Portfolio Summary and accompanying PDLs will not be processed.

The 2011 Learning Portfolio Summary and accompanying PDLs may be submitted online to kcobb@mpha.mb.ca If submitting these forms online, please indicate this in the MPhA Professional Development Requirement section of the 2012 MPhA Practicing Licence Application. An e-mail will be sent confirming receipt of Learning Portfolio Summaries and PDLs received online. In this case, licence applications received by mail will not be processed until the corresponding 2011 Learning Portfolio Summary and accompanying PDLs are received online. Editable forms are available for download on the MPhA website (www.mpha.ca under Quality Assurance; Professional Development; Learning Portfolio). A sample PDL is posted on the webpage to assist in documenting a variety of learning activities.

Indicate the number of Continuing Education Units (CEUs) claimed from involvement in accredited learning activities, the number of hours claimed from involvement in non-accredited learning activities and then the total number of hours involved in all PD activities for the period of November 1st, 2010 to October 31st, 2011.

Please Note: On average, the time required to complete an accredited learning activity equals the CEU value assigned, i.e. 1 CEU = 1 contact hour involved in the accredited learning activity. The CEU value assigned may not be increased however, if additional time is spent involved in the learning activity, it may be claimed as a non-accredited learning activity.

1. Accredited Learning Activities - ________ CEUs (min. = 15 CEUs)
2. Non-accredited Learning Activities - ________ hours
3. Total Time Involved in PD Activities - ________ hours (add 1. and 2.)(min. = 25 hours)

4. Place a check mark in front of the competencies listed below that were addressed by the learning activities (accredited and non-accredited) involved in from Nov. 1st, 2010 to Oct. 31st, 2011.
   ___Communication skills  ___Disease conditions  ___Documentation
   ___Jurisprudence  ___Pharmaceutical care process
   ___Technical competencies  ___Drug therapy

5. Place a check mark in front of the competencies that you planned to address during Nov. 1st, 2010 to Oct. 31st, 2011 but were unable to find appropriate programs or other learning resources.
   ___Communication skills  ___Disease conditions  ___Documentation
   ___Jurisprudence  ___Pharmaceutical care process
   ___Technical competencies  ___Drug therapy

Please ensure PDLs are attached or submitted online.
Retain a copy of this Learning Portfolio Summary in your Learning Portfolio.
New and Revised Immunization Schedules on the Manitoba Health Website & Discontinuation of School-Based Grade 4 Varicella Catch-Up Program

NEW: Recommended Immunization Schedule for Infants, children and Adults

- A new one page summary of Manitoba’s Recommended Immunization Schedule for Infants, Children and Adults is now available at the following link: http://www.gov.mb.ca/health/publichealth/cdc/div/schedules.html
- This document was created primarily for public use, however it may be useful to both you and your clients as it also contains links to the relevant vaccine fact sheets for publicly-funded vaccines.

REVISED: Manitoba Immunization Schedules – Reference Guide for Health Professionals

- A revised version of this document is now available at the following link: http://www.gov.mb.ca/health/publichealth/cdc/fs/irg.pdf
- In 2008, print copies of the document were distributed to health care providers throughout the province. Please note that Manitoba Health will NOT be producing print copies of this revised document or any subsequent revisions.
- Printer-friendly PDF versions of both of the documents noted above, are available on the Manitoba Health website should you wish to keep hard copies. We recommend that you check the website frequently for updates.

Discontinuation of School-Based Grade 4 Varicella Catch-Up Program

- Manitoba Health recommends the discontinuation of the school-based grade 4 varicella catch-up program. The catch-up program is no longer required as all children currently in grade 4 have been offered varicella vaccine at one or more occasions (at 12 months of age and at 4-6 years of age) since the inception of the program in 2004.

Manitoba Health recommends all health care providers offer any missed vaccines, as per the Recommended Immunization Schedule for Infants and Children, at every opportunity.

Pneumococcal Polysaccharide (Pneu-P-23) Vaccine Program

Recently, Manitoba Health updated the eligibility criteria for the Pneumococcal Polysaccharide Vaccine (Pneu-P-23). Homeless individuals and illicit drug users have now been added to the eligibility criteria. As with previous years, this vaccine is available at no charge to all Manitobans who are 65 or older and those at most risk for invasive pneumococcal disease.

The revised version of the Pneumococcal Polysaccharide (Pneu-P-23) Fact Sheet is available on the Manitoba Health website at http://www.gov.mb.ca/health/publichealth/cdc/fs/ppv23.pdf. For specific Manitoba Health eligibility criteria, please visit http://www.gov.mb.ca/health/publichealth/cdc/vaccineeligibility.html

Routine re-immunization is NOT recommended. Please refer to the product monograph and/or the Canadian Immunization Guide (2006) for detailed information.
Volunteer Opportunity for Pharmacist
If interested please contact Vicki Olatundun at vicki.olatundun@siloam.ca or 204.956.4344

What is the Saul Sair Health Centre at Siloam Mission?

Saul Sair Health Centre at Siloam Mission provides holistic healthcare in Winnipeg’s inner city. Patrons include the chronically addicted, the mentally ill, street workers, and those who are homeless or in danger of becoming homeless. Services are provided with dignity and without discrimination based on race, gender, religion or identification.

A ministry of Siloam Mission, Saul Sair Health Centre operates as a connecting point between the compassionate and Winnipeg’s less fortunate. Health professionals offer their skills to help alleviate the hardships of homelessness and assist individuals in achieving better health.

Thanks to the generous $1,000,000 gift from the estate of the late Winnipeg Pharmacist Mr. Saul Sair, our health centre opened on August 8, 2007. Since then, we have been addressing the complex health needs of Winnipeg’s inner city. Staff and volunteer health-care professionals of many fields provide care for those experiencing poverty and homelessness. Services include primary care, dentistry, physiotherapy, counselling services, chiropractic care, foot care, and health education. No one is refused treatment and care is offered free of charge.

What qualifications are required?

- Fill out an application form including reviewing and agreeing with or agreeing not to take away from the policies and statement of beliefs
- Attend an orientation
- A heart for those who are experiencing poverty and homelessness
- Desire to develop genuine relationships with those who use Siloam Mission services
- Willingness to serve and work as a team with the other volunteers and staff, but work without direct supervision
- Current registration and license with the Manitoba Pharmaceutical Association
- Current CPR/First Aid certification
- Current liability insurance

Tasks and/or duties:

The Volunteer Pharmacist will:
- Complete medication reviews with patrons
- Provide medication education to patrons
- Ensure medication storage room is stocked and up-to-date
- Ensure vaccinations and drug guidelines are up to date
- Carry out and review the Medication Education Delivery System (M.E.D.S.) program at Saul Sair Health Centre
- Consult with interprofessional volunteer team members

What type of challenges might you experience?

- Working with people with addictions, behavioral and social issues (i.e. low literacy skills)
- Emotional stress of working with those who are experiencing homelessness and poverty
- Challenge of maintaining appropriate boundaries
When and where will any training/orientation occur?

- Orientations are held twice a month at Siloam Mission – contact Volunteer Services for the next date!
- There will be on the job training and orientation provided by the director of the Saul Sair Health Centre upon arrival.

Possible Times to Volunteer: (days/times)

- Monday to Friday 9:00am-4:00pm

Site Supervisor: Vicki Olatundun
Phone: 956-4344
Fax: 956-0956
Email: vicki.olatundun@siloam.ca