



File: 50340 – 40/PHARM/PLAN

March 29, 2007

Ginette Vanasse  
Executive Director  
Post-Consumer Pharmaceutical Stewardship Association  
406 – 1111 Prince of Wales Drive  
Ottawa, ON K2C 3T2

Dear Ms. Vanasse:

Thank you for submitting on October 6<sup>th</sup>, 2006, the Post-Consumer Pharmaceutical Stewardship Association's Product Stewardship Plan, as required by section 4 of the Recycling Regulation and the supplementary letter of March 9<sup>th</sup>, 2007.

I have completed my review of the plan and the supplementary information and am satisfied that the plan meets the requirements of the Recycling Regulation and hereby approve the plan, with the exception of the residual container management requirement (section 5(1)(c)(ii) of the Recycling Regulation). Please be advised that this approval does not extend to any materials or content contained in the plan that are extraneous to the requirements of section 5 of the Recycling Regulation. Ministry staff will follow up on the residual container management issue and an amendment to October 2006 PCPSA plan and/or March 2007 supplementary letter may be required.

My approval comes with my understanding that your plan contemplates new targets, performance measures and strategies for which you must first establish a base from which to continuously improve. My expectation is that as you move from the planning stage to implementation, and reach key milestones, you will report these to the ministry in your Annual Report as required under section 8 of the Recycling Regulation.

I look forward to working with you to ensure the success of this program.

Sincerely,

Hu Wallis  
Director



## Post-consumer Pharmaceutical Stewardship Association

Provincial Program to assist in the collection, transportation and disposal  
of unused or expired medications from the public

# Post-consumer Pharmaceutical Stewardship Association

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# 1. INTRODUCTION

## 1.1 Background

In the fall of 1999, in response to a request from the British Columbia Minister of Environment (MOE), pharmaceutical industry associations created an association to act on behalf of the pharmaceutical industry and administer an approved Program Plan called the *Medications Return Program*. The Canadian Generic Pharmaceutical Association (CGPA), Canada's Research-Based Pharmaceutical Companies (Rx&D) and NDMAC-*Advancing Canadian self-care* representing the majority of the brand-owners of pharmaceuticals and self-care health products, created an association; the Post-consumer Pharmaceutical Stewardship Association (PCPSA).

The *Post-Consumer Residual Stewardship Program Regulation* passed on March 27, 1997, was expanded to include pharmaceutical products and ensure a level playing field for all brand-owners selling prescription drugs, nonprescription drugs and natural health products. The *Environmental Management Act* was brought into force on July 8, 2004. This legislation combined the *Waste Management Act* and *Environment Management Act* to create a single statute governing environmental protection and management in British Columbia. PCPSA is British Columbia's Industry Product Steward (IPS) and has Extended Producer Responsibility (EPR).

The concept of EPR is that those who produce, use or sell a product are responsible for the impacts of the product throughout the stages of its life cycle, including the end-of-life, waste management stage. EPR is based on the principle of user pay, whereby responsibility for managing materials and products in the waste stream is borne by producers and consumers rather than the general taxpayer.

The pharmaceutical product category is defined under the Residual Product Categories in Schedule 2 of the Recycling Regulation. This category consists of all unused or expired medications, including nonprescription drugs and natural health products as defined under the Food and Drugs Act (Canada). The regulation requires all brand-owners of pharmaceutical products sold in British Columbia to take responsibility for the management of their products by providing a way for the public to dispose of their unused or expired products in an environmentally responsible manner.

PCPSA is the appointed agency for pharmaceutical products to administer on their behalf, an approved Program Plan, under the Recycling Regulation for pharmaceutical Products called the *Medications Return Program*. Since 2000 it has fulfilled the obligations of participating brand owners.

## 1.2 Plan Summary

- ❖ *to provide a plan for collecting products within the pharmaceutical product category*
- ❖ *to achieve, or is capable of achieving within a reasonable time, any performance requirements or targets established in the plan*
- ❖ *to ensure that the brand-owners who sell, offer for sale or distribute pharmaceutical products in British Columbia under their own brand name, sponsor their portion of the costs of the Medications Return Program*
- ❖ *to ensure environmentally sound disposal of expired and unused medications and containers collected at collection sites*
- ❖ *to ensure that the public is able to return expired and unused medications for disposal throughout the province*
- ❖ *to provide access to collection sites*
- ❖ *to provide the public with information on the location of collection sites*
- ❖ *to undertake satisfactory consultation with stakeholders prior to submitting the plan for approval*
- ❖ *to provide an opportunity for stakeholders input in the program*
- ❖ *to provide a course of actions for assessing the performance of the plan*
- ❖ *to ensure that industry benchmarks for both acceptable costs and effective and sound environmental management are developed*
- ❖ *to provide ways for reducing the environmental impacts of the product collected*
- ❖ *to provide a mechanism for dispute resolution*

## 1.3 Program Terminology

The following terminology is used throughout the recycling regulation and this document

<b>Brand-owner:</b>	(i) a person who manufactures a pharmaceutical product and sells, offers for sale or distributes a pharmaceutical product in British Columbia under its own brand, or; (ii) a person who is not the manufacturer of a pharmaceutical product but is the owner or licensee of a trademark under which the pharmaceutical product is sold or distributed in British Columbia, whether or not they own the Drug Identification Number.
<b>Collection Sites:</b>	Community pharmacies who are registered in the program to collect unused and expired medications from the public.
<b>Consumable product</b>	Means a product that is intended to be consumed during use.
<b>Duty of a producer:</b>	The brand-owner is required to have an approved product stewardship plan in place or appoint an agency to undertake its duties.

<b>Medications:</b>	Prescription drugs, nonprescription drugs and natural health products.
<b>Member</b>	Brand-owner who is a member of the association
<b>Program Administrator:</b>	The individual or business who is contracted to manage the <i>Medications Return Program</i> in British Columbia.
<b>Regulation</b>	Recycling Regulation, B.C. 449/2004
<b>Stakeholders:</b>	Person or organization whose interests will be or are affected by the provisions of a proposed plan.

## 2. PRODUCT STEWARDSHIP PLAN

### 2.1 Overview

Brand-owners must either have an approved Product Stewardship Plan and comply with the plan or appoint an agency to carry out its duties under a Product Stewardship Plan. The plan defines the elements of the brand-owners' program for managing the product category listed in the regulation. Elements of a plan may include, program objectives and targets, governance, and operational systems for product collection and processing. Section 5 of Part 2 sets out the plan approval conditions and requirements, which include, among other things, program performance requirements, satisfactory consultation during plan development, and provisions for consumer access and awareness.

### 2.2 Plan Summary

- ❖ *Establish a province-wide, industry-administered pharmaceutical product Stewardship Program in compliance with the Regulation.*

The Post-Consumer Pharmaceutical Stewardship Association (PCPSA) is formed under the Society Act (B.C.) and registered nationally as a non-profit organization. The association's role is to perform on behalf of each Member certain duties required under the Regulation. This stewardship program called the *Medications Return Program* complies with the Regulation.

This program provides the pharmaceutical industry with a collective means of adhering to the requirements of the British Columbia *Recycling Regulation*. The program is funded by the pharmaceutical and self-care health product industries. Fees are collected by the association from brand-owners selling pharmaceuticals in British Columbia. A yearly review of brand-owners is compiled identifying companies that have set up business in the province through peers and directories of manufacturers, importers and distributors of drugs and natural health products.

Since 2000, the program has grown from 575 to 850 collection sites across the whole province and the public has returned for environmentally responsible disposal approximately 94,500 kg of unused or expired medications over the years. Please refer to section 2.4 for additional information on collection services and to our website for a full list of participating pharmacies.

### 2.3 Pharmaceutical product category

The pharmaceutical product category consists of all unused or expired drugs, as defined in the Food and Drugs Act (Canada), except veterinary drugs and:

- ✓ unused or expired drugs from a hospital, as defined in section 1 of the *Hospital Act*, or the office of a medical practitioner
- ✓ contact lens disinfectants
- ✓ antidandruff shampoo or products
- ✓ antiperspirants
- ✓ antiseptic or medicated skin care products
- ✓ sunburn protectants
- ✓ mouthwashes and
- ✓ fluoride toothpastes

### 2.4 Collection Services

- ❖ *to provide a convenient system for the collection and disposal of expired and unused medications*
- ❖ *to provide options for the collection of unused or expired medications in urban centers, small or isolated communities*
- ❖ *to provide the public with information on the location of collection sites*
- ❖ *to ensure that collection sites accept products from the public free of charge*
- ❖ *to ensure all registered community pharmacies in British Columbia are informed of their role in the Medications Return Program*
- ❖ *to provide the public with information on the safe disposal of unused or expired medications*

The collection sites for the *Medications Return Program* are community pharmacies. Since the participation of a pharmacist is central to the success of this program, we work closely with the licensing authority, the British Columbia College of Pharmacists. They provide us with lists of openings and closures on a regular basis. This ensures that all new locations are contacted and can receive information on this program in a timely fashion.

Pharmacists interested in offering the *Medications Return Program* in their store must contact the program administrator for an application form to register. Specific information is provided to ensure that pharmacists and staff are knowledgeable on the program and the way the program operates. All participating community pharmacies

receive a kit containing instructions on the program, posters and brochures for the public and a container (20 litres). All containers have a set of instructions for replacement and a screw top cap through which the pharmacist puts the unused or expired medications. PCPSA will review the size of the opening of their current containers to address some concerns for proper disposal of larger size gels containers and liquid products.

Once the registration form is completed and fax to our office, the pharmacist is contacted by phone to discuss the following points:

- a) The program is for returns from the public and not from hospitals, institutions, doctor's offices or their own practice.
- b) This program does not accept sharps, needles and syringes, since this is a medical device and is not considered a pharmaceutical product under the Food and Drug Act (Canada).
- c) Large quantities from individuals are acceptable.
- d) All liquid products are accepted, they are not to be poured into the container. When the original consumer container does not fit through the opening of the medications return container, it must be put into another properly sealed vial that will fit in the container. It is then inserted or dropped through the opening provided for this purpose.
- e) All dry medications can be dropped directly into the plastic container, including blister packs and inhalers in their original package.
- f) All pills should be pored into the container or the original container can be inserted or dropped through the opening.

Once the container is full, the pharmacist must complete documentation and follow the shipping instructions attached to the container. Within five working days, a replacement empty container will be delivered and the full container will be picked up by courier

All containers returned from a pharmacy are tracked by weight, pickup date, location and stored in a secure location until a shipment is accumulated for safe destruction through a licensed incineration facility. Medications returned under this program do not meet the criteria for toxicity as defined under the Transportation of Dangerous Goods Regulations. The medications collected are not considered hazardous material and do not require special consideration.

## **2.5 Responsibilities of the Pharmacy**

- a) The pharmacy is legally responsible for the safekeeping of the B.C. *Medications Return Program* container and its contents while on their premises. The containers must be handled and stored properly to ensure that they are not subject to spilling, lost or stolen.
- b) All liquids must be in their original container or other suitable container which fits in the *Medications Return Program* container opening.

- c) All employees involved in the program must read the instructions and sign as indicated at the end of the pharmacy manual.
- d) To recycle the outer container (except liquid medications) when a packaging recycling program is available in their region.

Community pharmacies are a natural, logical and safe site for the public to return unused or expired medications. They also offer easy access to those with special needs and varying degrees of personal mobility. In situations where an individual can't travel, health care providers, caregivers, mail out or other systems are in place to deliver medications and return products to a pharmacy. Pharmacists are the most knowledgeable of all health care professionals when it comes to medications. Many of these pharmacies are open extended hours, offering a convenient place for consumer disposal year-round. There is no charge to a consumer to return products. Community pharmacies currently participating in the program can be easily located by the public on the association's website at [www.medicationsreturn.ca](http://www.medicationsreturn.ca) or by phoning RCBC hotline services.

Since 2000, we increased the number of registered pharmacies from 575 to 850 representing 87% of licensed community pharmacies in the province. The remaining 13 % are either located in a hospital setting, offering the same service to their patients, or a return program is also offered through a chain drug store. PCPSA will increase the frequency of exchanges with its pharmacy managers to improve understanding of the program, develop adequate communication of the program's goals with staff working in the store; and provide promotional items (poster and brochures) for display.

The following lists provide an example of materials that would be acceptable. Note that this list is not exhaustive.

Accepted

- ✓ All prescription drugs
- ✓ Nonprescription medications
- ✓ Natural health products
- ✓ Vitamin and mineral supplements

Not accepted

- ✓ Sharps, needles or syringes
- ✓ Contact lens disinfectants
- ✓ Antidandruff products, shampoos
- ✓ Cosmetics, antiperspirants, antiseptic skin cleansers, medicated skin care products
- ✓ Sunburn protectants
- ✓ Mouthwashes
- ✓ Hard surface and toilet disinfectant cleaners
- ✓ Expired samples direct from physicians' offices
- ✓ Unused or expired drugs from a hospital and institutions
- ✓ Pharmaceuticals from farms and veterinary products

## 2.6 Program administrator

The Post-Consumer Pharmaceutical Stewardship Association contracts an administrator for the program and will ensure the following.

- Maintain and update database on participating community pharmacies
- Communications of program requirements to enrolled pharmacies.
- Collection of expired and unused medications from pharmacies.
- Storage of collected containers.
- Shipment and disposal of containers.
- Ensuring all necessary environmental permits and insurances are current.

The program administrator contracted by PCPSA is Residuals Management Group Ltd. of Vancouver, British Columbia.

## 2.7 Funding

Funding from the industry covers expenses incurred in the collection, transportation, storage, promotional activities and disposal in connection with the program. There is not user fees directed to the consumer at time of purchase or at the point of collection.

The cost of operating the British Columbia *Medications Return Program* is shared between pharmaceutical (brand name and generic) and self-care health products industries (Appendix A). Members will remit to the association an amount based on prescriptions dispensed in British Columbia during the previous year and/or at a per unit rate on the sale of self-care health products in the province. Updated list of participating brand-owners are also published on the association website.

Yearly reviews are taken to identify new brand-owners selling medications in British Columbia and advise them of their duties under the law. Health Canada has a directory for all drugs (prescription and nonprescription) sold in Canada, making it easier to identify company doing business in the province. Unfortunately there is no listing identifying brand-owners selling natural health products. A Natural Health Product Regulation was put in place on January 2004 with a transition phase to December 2009. When completed the new federal Natural Health Products Directorate (NHPD) will allow us to identify brand-owners operating in Canada. While many responsible brand-owners have funded the program since inception however getting full compliance from all brand-owners is not easy.

PCPSA is registered nationally as a non-profit organization and operates in accordance with provisions set out in its by-law. AGM are held annual, notices are sent to members and provisions are made for a reasonable contingency fund for this program.

### 3. EDUCATIONAL MATERIALS AND STRATEGIES

- ❖ *to ensure citizens of British Columbia are informed of the Program and are provided with current information regarding the availability of a system for the collection of unused and expired medications.*

Pharmaceuticals are generally dispensed at community pharmacies and a large number of self-care health products are also purchased in such locations. PCPSA will work together with community pharmacists and chain drug stores to provide signage and brochures promoting the *Medications Return Program*.

The program administrator has posters and brochures that can quickly be supplied to participating pharmacies, special events or other partners such as Regional District Environmental Service offices and municipalities. The brochure provides directions on what is accepted and not accepted; how to return the unused or expired medications and where to go in an easy fashion. Posters and brochures will help develop and promote awareness of the *Medications Return Program*.

Consumer awareness and attitude toward returning unused medications will be measure in 2007. PCPSA will commission a study on attitude and behavior in order to assess awareness and household behaviors with safe disposal of medications.

PCPSA will take advantage of health awareness events, environmental trade shows and similar activities to communicate the availability of the *Medications Return Program* to the public.

#### 3.1 Printed Materials:

Brochure/poster distribution: Program information brochures and point of purchase signage is distributed to pharmacy and other locations such as clinics, doctor's offices through a reorder system by, fax, email or through the website. Brochures are presently available in English; PCPSA will examine the options and possibilities of expanding the languages on our promotional material (Chinese and Punjabi).

Municipal Garbage and Recycling calendars: PCPSA will seek to promote the *Medications Return Program* in the annual calendar published by many regional districts and municipalities informing residents about municipal services.

Mailouts: PCPSA will extend distribution of brochures and posters to Regional Districts and Municipalities. PCPSA will contact ethnic groups such as SUCCESS and ethnic media for their assistance in promoting the program.

News bulletin is currently available on a quarterly basis to our members. We are also planning to develop another e-bulletin for the community pharmacists introducing

tips for the program and any special initiative promoting the *Medications Return Program* taking place in the province.

Local Newspapers: PCPSA has produced articles for community newspapers promoting the *Medications Return Program*. Other initiatives with associations promoting health or safety are planned such as Pharmacist Awareness Week or Health month.

### 3.2 Other resources

**Web Site:** The *Medications Return Program* website was launched in 2004. It provides the public with information and location of collection sites for the disposal of medications. Within the site is a searchable database of pharmacy and explanation of products accepted by the program.

As we continue to build our membership base, we will contact members with a patient/consumer website and ask for their assistance in advertising the *Medications Return Program* by providing a link to our website.

**RCBC Toll-Free Recycling Information Hotline:** PCPSA has contracted with the Recycling Council of British Columbia “recycling hotline” service. The RCBC Hotline is open during normal business hours, accessible to the public by a toll free telephone number (1-800-667-4321). RCBC hotline operators provide the public with a convenient “one stop” contact to obtain information on environmentally sound disposal of medications and any other recycling questions.

**Consumer information:** Due to the nature of the product, information on the safe use and storage is provided to the consumer at time of purchase.

PCPSA will send regular updates to regional districts and municipalities including key messages that can be used.

## 4. PROGRAM PERFORMANCE

### 4.1 Environmental impact throughout product lifecycle

The Recycling Regulation requires producers to disclose the efforts taken to measure and reduce environmental impacts throughout the lifecycle of a product. In regards to measuring the environmental impacts of pharmaceutical products (i.e. both prescription drugs and self-care health products) entering the environment, it is felt that such matters are already being dealt with effectively at the federal level under the *Canadian Environmental Protection Act*. Environment and Health Canada already assess the environmental and human safety impact of pharmaceuticals entering the environment through the *New Substances Notification Regulations*. Health Canada is responsible for the assessment of potential risks to human health posed by existing

substances in Canada. The Existing Substances Division conducts works jointly with Environment Canada, the department responsible for assessing risk of existing substances to the environment. The Domestic Substances List (DLS) is a compilation of about 23,000 substances used, imported or manufactured in Canada. They have begun to investigate and determine whether a substance is toxic as defined in the Act and reviewing options for controlling risks to human health and/or the environment.

Manufacturers are extremely limited in their ability to reduce the environmental impact of these products without affecting their legislative and regulatory obligations under the *Food & Drugs Act*.

Given the existing federal legislation, it is therefore recommended that this section of the recycling regulation be excluded from the program plan.

During public consultation, the incidence of pharmaceutical found in the waste water flowing from a treatment plant was brought up. A clear understanding of the relationship between the presence of certain substances in the environment and its effects on human health is far from having been established. Research suggests that risk of acute effects from exposure to the drugs levels present in the drinking water is very low. As we improve our testing methods/technologies we will be able to detect minuscule concentrations ranging from micrograms per litre down to nanograms per litre range.

The majority of people takes their medications as prescribed by a health professional however between 50 % to 90% of the active substances in drugs is not absorbed and is excreted by human.

## **4.2 Dispute resolution procedure**

The Recycling Regulation requires that a plan provides for a dispute resolution procedure. Any person or organization believing that the responsibilities of parties participating in the Medications Return Program do not meet the program plan should immediately provide a detailed description of the complaint to PCPSA:

By e-mail to [ginette.vanasse@medicationsreturn.ca](mailto:ginette.vanasse@medicationsreturn.ca)

By fax to 613-723-0779

By phone to 613-723-7282

PCPSA will within 5 days seek to resolve the dispute through a co-operative approach and voluntary resolution. In the absence of a successful resolution, PCPSA will convene a three party adjudication panel within 2 weeks. One individual will be chosen by PCPSA, one individual chosen by the pharmacy and one individual chosen by the complainant (not the complainant). The panel will consider the dispute and offer a binding decision on all parties involved. Should the decision not be accepted, legal recourse is available to the complainant.

### **4.3 Pollution prevention hierarchy**

This category of products is referred as a consumable product. Medications are taken for specific conditions or symptoms and should be fully consumed unless otherwise indicated by a health professional. Prescription drugs are prescribed by a physician and in most cases given in small quantity. Patients are directed by their physician and health professional to use the medication until finished.

Medications cannot be reused or recycled, as other products covered under this regulation. Some manufacturers/producers have been able to give excess medications with adequate shelf life (usually 6 months), for humanitarian use. This unique situation eliminates or reduces a product that is consumable; however it does not apply to products that have been purchased by a consumer.

The pollution prevention hierarchy requirements outlined in the Recycling Regulation to reduce the environmental impact of pharmaceutical products are not feasible without affecting pharmaceutical product safety, efficacy, and quality. Consequently, PCPSA disposes of the waste through incineration.

Pharmacists are instructed to recycle the outer container returned with the medications, (except liquids), where a plastic bottles recycling program is available in their area. Municipalities should be contacted directly for specific information on individual programs or information on private recycling program for businesses when a program is not yet offered. The current regulation under which PCPSA operate covers pharmaceutical products and not packaging.

## **5. EVALUATION AND ACCOUNTABILITY**

### **5.1 Performance Measures**

While we agree that recovery rate provides a way to measure program success; this method is not accurate or suitable for pharmaceuticals and its implications in determining the effectiveness of a producer's stewardship plan. Consequently, PCPSA will evaluate the success of the program through the following criteria:

- a) Composition studies: The presence of pharmaceuticals products in the garbage is predictable. Recommendations from separate studies done for the CRD and GVRD provided different interpretation of results when the standard deviation was larger than the volume of pharmaceuticals detected. Comparison of tonnage sold vs. tonnage collected and returned is not an acceptable measure of success with consumable products such as pharmaceuticals. PCPSA will investigate the benefit of participating in a composition study with selected regional districts.
- b) Number of Collection points: PCPSA has the most extensive network of the entire EPR program in British Columbia. The dedication from community

pharmacies demonstrates an extensive commitment to providing a convenient collection system in urban, rural and isolated communities. PCPSA will maintain a participation rate of 85 %, and continue to contact any locations with a significant change in collection pattern. In addition PCPSA will contact all new pharmacies or existing locations under new management for enrollment in the *Medications Return Program*. PCPSA would prefer 100 % participation; however the current turnover rate in pharmacy locations, ownership and management makes it unattainable.

- c) Promotion of the program: PCPSA will contact regional/municipal districts and other organizations to explore the possibilities to promote the *Medications Return Program* in their annual campaign or other appropriate events. We will also inquire as to the type of pharmaceutical questions received by RCBC and assess if it can influence the program performance. Plans for year 1 are to contact all 28 regional districts and health authorities with promotional material and key messages for their website. Year 2 is to contact municipalities and advertise the program in the garbage and municipal calendars. In year 3 would evaluate the outcome of our promotional program through a public survey.
- d) Public awareness and attitude: PCPSA will review methods and performance targets used with similar programs and propose program targets and performance measures after a establishing a baseline with a consumer survey in year 1. The following year PCPSA will concentrate its efforts on promoting the program through a larger network and develop strategies to enhance public awareness. Recent studies have demonstrated that it takes several years to influence attitude and changes in behaviors. PCPSA plans to survey public opinion every 3 to 5 years to measure changes in awareness and use of the collection system.
- e) Quantity of pharmaceutical products collected: PCPSA is able to chart for each regional district the quantity of medications collected over the calendar year. PCPSA will document the collection and disposal of pharmaceutical waste by region and provide a comparison with prior years. The goal is to ensure that all participating community pharmacies take advantage of the program and dispose of medications regularly. PCPSA has seen an increase in medications returned following special events, such as *Pharmacy Awareness Week*. This trend is expected following events promoting the program. However we don't anticipate a steady increase in medications collected since individuals are directed by their physician and health professional to use medications until finished. A trend for our industry is to prescribe in smaller quantity and fewer refills.

## 5.2 Consultation on Product Stewardship Plan

PCPSA did undertake public consultation with stakeholders on the development of the plan. Four meetings were scheduled throughout the province; stakeholders (appendix B) were informed in early August and were asked to pre-register for

meetings taking place during the last week of August. Meetings were planned in Prince George, Kelowna, Victoria and Vancouver, however only Victoria and Vancouver had a reasonable number of participants (5 +). A Webinar session was available prior to these meetings for any participant unable to travel. In addition PCPSA develop a consultation questionnaire and used it to survey its members (85), participating community pharmacies (915), interested groups (38) and individuals. List of attendees with summary of meetings and consultation questionnaire results with responses are in appendix C. When required, calls and e-mails were made to participants to present additional explanations to comments raised.

### **5.3 Annual Report**

On or before July 1 each year the association shall submit to the Director a report of the association's activities for the preceding calendar year. The report will document the performance in relation to the plan. The report will also be available on the association's web site.

## **6. WASTE DISPOSAL SITES**

Some regional districts have collected pharmaceuticals at their regular and special waste disposal sites. PCPSA prefers that medications are returned to a pharmacy location. Pharmacies are more knowledgeable in handling medications and offer a secure environment for safe disposal. It is not appropriate for medications to be returned with other household hazardous waste and handled by individuals not used to handling medications. With the number of collection sites available throughout the province, PCPSA believe that specific information, to ensure that medications are not part of special waste collection sites, is essential.

PCPSA only contracts with licensed service providers with a proven record of using established, approved and verifiable procedures for the final treatment and processing of residuals in compliance with all applicable environmental regulations.

## APPENDICES

### APPENDIX A:

#### **List of Participating Brand Owners in 2006**

3M Pharmaceutical  
Abbott Laboratories, Limited  
Actelion Pharmaceuticals Canada Inc.  
Alberto-Culver Canada Inc.  
Alcon Canada Inc.  
ALTANA Pharma Inn.  
AmgenCanada Inc.  
Apotex Inc.  
Ashbury Biologicals Inc.  
Astellas Pharma Canada Inc  
Astra Zeneca Canada Inc.  
Avon Canada Inc.  
Axcan Pharma Inc.  
Baxter Canada  
Bayer Inc.  
Berlex Canada Inc.  
Biovail Pharmaceuticals Canada  
Blistex Canada Inc.  
Boeringer Ingelheim Canada  
Bristol-Myers Squibb Pharmaceutical  
Chattem (Canada) Inc.  
Church & Dwight  
Cobalt Pharmaceuticals Inc.  
Combe Incorporation  
Contract Pharmaceutical Ltd.  
Crombie Kennedy Nasmark  
Dr. J. O Lambert Ltd.  
Dormer Laboratoires Inc.  
E-Z-EM Canada Inc.  
Eli Lilly Canada Inc.  
Ferring Inc.  
Galderma  
Génome Canada  
GenPharm  
GlaxoSmithKline Consumer Healthcare  
GlaxoSmithKline Inc.  
Hemosol Inc.  
Herbalife of Canada Limited

Holista Healthcare Corporation  
Hudson's Bay Company  
Innovus Research Inc.  
Jamieson Laboratories  
Janssen-Ortho Inc.  
Johnson & Johnson Ltd.  
Katz Group Canada Inc.  
King Pharma Canada Inc.  
Laboratoires Aeterna Inc.  
Lander Co. Canada Ltd.  
Leo Pharma Inc.  
Loblaw Companies Ltd.  
Lorus Therapeutics Inc.  
Lundbeck Canada Inc.  
Mayne Pharma Inc.  
McNeil Consumer Healthcare  
Mead Johnson Nutritionals  
Methalotum Company of Canada Ltd.  
Merck Frosst Canada & Co.  
Neurochem Inc.  
Novartis Consumer Health Care  
Novartis Pharmaceuticals Canada Inc.  
Novo Nordisk  
Novopharm  
Nu-pharm Inc.  
Nucro-Technics  
Odan Laboratories  
Organon Canada Ltd.  
Paladin Labs Inc.  
Patheon Inc.  
Peoples Drug Mart (B.C.)  
Pfizer Canada Inc.  
Pfizer Consumer Healthcare  
Pharmaceutical Partners of Canada Inc.  
Pharmascience  
Platinum Naturals (Health Way Products)  
Procter & Gamble Inc.  
Procter & Gamble Pharmaceuticals  
Purdue Pharma  
Quixtar  
Ratiopharm  
Rivex Pharma Inc  
Roche Ltd.  
Ropack Inc.  
Sandoz Canada  
Sanofi-Aventis Canada Inc.  
Santé Naturelle (A.G. ) Ltée

Schering Canada Inc.  
Servier Canada Inc.  
Shaklee Canada  
Shire BioChem Inc.  
Solvay Pharma Inc.  
Stiefel Canada Inc.  
Swiss Herbal Remedies Ltd.  
Taro Pharmaceuticals Inc.  
Theramed Corporation  
Theratechnologies Inc.  
Trophic Canada  
Unipharm  
USANA Canada Co.  
Valeant Canada Ltd.  
Vita Health Products  
Wal-Mart Pharmacy  
WellSpring Pharmaceutical Canada  
WN Pharmaceuticals Ltd.  
Wyeth-Consumer Healthcare  
Wyeth-Pharmaceutical

## **APPENDIX C**

Comments from Webinar session  
Comments from Victoria  
Comments from Vancouver  
Summary of issues and responses to comments  
Consultation questionnaire results



March 9<sup>th</sup>, 2007

Mr. Hu Wallis  
Director  
Environmental Quality Branch  
Ministry of Environment  
PO Box 9339 Stn Prov Govt  
Victoria, BC V8W 9M1

Dear Mr Wallis:

Further to the conference call on December 7th on PCPSA plan review, you will find PCPSA clarifications on issues raised by our staff on the *Medications Return Program* plan.

## 1. Educational Materials and Strategies

### a) Community Pharmacies

- **Pharmacy managers:** We provide pharmacy managers with a pharmacy manual and promotional information such as posters and brochures upon registration. Starting in 2007, the program administrator will review on a quarterly basis, our list of participating pharmacies versus the BC College of Pharmacy list of licensed community pharmacies. We will then contact all recently opened pharmacies and pharmacies with a change in address and/or manager to discuss the program. PCPSA will communicate once or twice a year with pharmacy managers on program results and special initiatives taking place in the province. Whenever feasible, we will use the internet and e-mail addresses to exchange information with pharmacy managers. Information will also be provided with a change of container.
- **Pharmacy staff:** In 2007, PCPSA will send a promotional kit (poster, brochure and pharmacy manual on *Medications Return Program*) to all registered pharmacies for the staff.

\* Note: community pharmacists were changed to pharmacy managers in the document.

## b) Consumer Awareness Survey vs Public Survey

- A research firm will conduct research on behalf of PCPSA. A questionnaire will be developed to obtain information on public behavior and awareness of recovery programs. This survey will be conducted at the beginning of 2007.

\* Note: In the proposed plan, consumer awareness (page 10) is the same as consumer survey or public survey.

**2. Containers** - The ministry is reviewing the residual container requirement in the regulation and will follow up on this issue with PCPSA.

## 3. Recovery Rate, Performance Targets and Measures

### a. Composition studies:

For the Regional Districts that conduct waste composition studies, the waste composition studies should be statistically significant to establish the presence of pharmaceuticals within the HHW category, as more is collected through the MRP significantly less should appear in waste collection.

Target until 2011:	Decrease the presence of pharmaceuticals in RD's that conduct waste composition studies.
Performance measure:	Report amounts of pharmaceuticals estimated in statistically significant RD's waste composition studies.
Strategies: 2008	Review information collected from composition study to investigate the benefits of participating in a composition study with selected regional districts.

### b. Number of collection points: Community Pharmacies in the province

Target until 2011:	Maintain a pharmacy program participation rate of 90%.
Performance measure:	Report percentage of participating pharmacies yearly.
Strategies:	Contact new licensed community pharmacies from amended list purchased from the College of pharmacists in B.C. on a monthly basis.  Contact existing pharmacies with ownership and/or manager changes on a quarterly basis.  Contact pharmacies with a significant change in collection pattern.

**c. Public awareness:**

Target for 2011:	50% increase in public awareness of a Medications Return Program compared to 2007.
Performance measures:	Establish a public awareness level based on public survey in 2007.  Measure changes in awareness, behaviour through survey in 2010.
Strategies:  Year 1	Establish a level for public awareness of recovery programs.  Set performance targets for awareness and behaviour.  Work with RCBC to increase exposure through their website and other events.  Promote program by advertising in two RD's recycling calendars, RD's website and 4 special events.
Year 2 - 3	Increase publicity in another 2 RD annual calendar and continue to support special events (4).
Year 4	Measure awareness and usage of program with public survey.
Year 5	To be developed based on results in year 4.

**c. Quantity collected:**

Weight of medications returned by the public in pharmacies.

Target until 2011	Maintain a minimum quantity collected of 14,000 kg.
Performance measure:	Report total quantity collected on a yearly basis with quarterly results by regional districts.
Strategies: Year 1	Promote program at special events (e.g. Pharmacy Awareness week, stakeholders initiatives).
Year 2	Continue to work with members and participating pharmacies to organize special collection events and publicize program.  Promotion of program in different media.
Year 3 and 4	Continue to work with members and community pharmacies with special collection events and retailers publicity.
Year 5	To be developed based on public survey results in year 4.

#### d) Promotion:

Target until 2011	Publicity on the MRP in 14 regional districts or municipalities' websites with recycling sections.  Indication of program with 13 annual recycling calendars.
Performance measure:	Increase in awareness of program to disposed to medications.
Strategies: Year 1	Contact all 28 regional districts with promotional material and key messages for their websites.  Contact 10 municipalities and 28 RD's to advertise the program in the garbage and municipal calendars.
Year 2 and 3	Follow up on advertising on RD/municipalities websites and annual calendars and contact another 5 municipalities.
Year 4	Follow up on advertising on RD/municipalities websites and annual calendars.  Evaluate the outcome of our promotional program through a public survey.
Year 5	TBD

#### 4. Consultation

a) Issues summary Is included in a separate document

b) Posting details for public consultation

A letter of introduction, webinar and conference registration forms, draft program plan and consultation questionnaire were posted on August 15<sup>th</sup> on our website at [www.medicationsreturn.ca](http://www.medicationsreturn.ca). and removed on October 31<sup>st</sup>, 2006. In addition, separate cover letters were sent to PCPSA's members and participating community pharmacies inviting them to participate in the public consultation through the questionnaire.

#### 5. Section 2 – Written notification requirement

- Membership forms signed by members were faxed to the MOE as records of appointment of agency.

#### 6. Compliance process:

Program Revenues Program is funded through fees remitted by producers / brand owners of pharmaceuticals and self-care health products.

Methods for enrolling obligated brand-owners and ensuring a level playing field:

Compliance process and enforcement measures are central to ensure full compliance of all obligated parties. For the purposes of initiating actions with the British Columbia

MOE; non-compliance is defined as a lack of responsiveness from a brand-owner after more than two notices on producers' responsibilities have been sent from PCPSA. Exceptions can be made if the Board determines that the producer/brand-owner is not covered by the regulations (excluded products) or fees are paid by a third party.

In the event that PCPSA does not receive a financial contribution from stewards within the prescribed timeframe(s), PCPSA management may utilize the following notifications to underscore the importance of timely submission:

- 1<sup>st</sup> contact (60 days prior): Letter is sent to brand-owner obligated under the Recycling Regulation informing them of their responsibilities. PCPSA role is to advise any potential brand-owner and offer the approved *Medications Return Program* as a way to fulfill their regulatory requirements.
- 2<sup>nd</sup> contact (30 days): A second letter is sent to a brand-owner for lack of reply from the previous correspondence. At this point in time, PCPSA will point out that they are liable if their company contravenes the Act.
- 3<sup>rd</sup> contact (30 days): A final letter with a deadline for submitting membership documents and payments toward the plan is sent by PCPSA. At this point, the Board will consider each brand-owner on a case-by-case basis to approve final step.
- 4<sup>th</sup> contact: A request for non-compliance actions is sent to the MOE with a copy to the brand-owner.

I trust this information provided the require details to complete the review of the *Medications Return Program*.

Sincerely,

A handwritten signature in cursive script that reads "Yvonne Conasse".

Executive Director

**Public consultation meetings Pharmaceutical category  
Issues Summary**

**Issues raised**

**PCPSA's responses**

Funding

How was the program funded?

The costs of operating the British Columbia *Medications Return Program* are shared between the brand name (45%) generic (35%) and self-care health products (20%) industries. Members will remit to the Association an amount based on prescriptions dispensed in British Columbia during the previous year and/or at a per unit rate on the sale of self-care health products. Retail stores with their own brand of products are covered under this regulation, and must join an organization with a program plan. Failure to belong to a recognized pharmaceutical stewardship program contravenes government regulations and could lead to fines being assessed.

Collection sites

Would the program expand its collection sites?

Number/percentage of participation from pharmacies?

The collection sites for the *Medications Return Program* are community pharmacies. Since the participation of a pharmacist is central to the success of this program, we work closely with the licensing authority, the *College of Pharmacists of British Columbia*. This ensures that all new locations are contacted and can receive information on this program in a timely fashion.

PCPSA has the most extensive network of the entire EPR program in B.C. This dedication from community pharmacies demonstrates an extensive commitment to providing a convenient collection system in both urban and rural communities.

In 2006, we had 856 pharmacies participating in the *Medications Return Program*. With 915 licensed community pharmacies and 70 hospital pharmacy locations, PCPSA had 87% of possible locations in the province. The remaining locations are mostly pharmacies in a hospital setting, offering this service to their patients, or a return program is offered through their retail chain stores. The turnover rate in pharmacies is approximately 15%, therefore we review our collection site list on a monthly basis. This involves contacting new pharmacy openings, those with changes in ownership and/or relocations of pharmacy stores ensuring that the program is maintained. PCPSA's goal is to have a 90% participation rate.

Unused or expired drugs from hospitals  
Are hospitals included in this program?

There are programs in place to dispose of biomedical waste and medications in all hospital setting. Medications provided to patients in a hospital setting is not part of household waste as defined under the regulation. The program does include pharmacies located in a hospital when pharmacists offer services to out-patients.

Office of a medical practitioner  
Why are they excluded from this program?

In the code of conduct from the Canada's Research-Based Pharmaceutical Companies (Rx&D), it is clearly stated that sales representatives leaving clinical evaluation packages (CEP) in a doctor's office, are responsible for ensuring that all excess and/or expired CEP are picked up and returned to the storehouse or head office.

Outer Container Recycling  
Concerns express with the outer containers not captured by the program!

Concerns were also expressed as to the personal information available on prescription drugs.

The current regulation under which we operate covers pharmaceutical products and not packaging. However, the program does address the recycling of containers. Pharmacy managers are instructed to recycle the outer containers (except for liquid medications) when a plastic bottles recycling program is available in their area. Municipalities should be contacted directly for specific information on individual programs or information on private recycling programs for businesses. Post-consumer packaging from the pharmaceutical industry represents a very small percentage of the total packaging waste generated across the province. MOE should investigate the benefits of regulating packaging similar to other provincial programs.

PCPSA directs pharmacy managers to remove personal information or cover it with a black marker when the original containers are inserted in the *Medications Return Program* containers making it impossible to identify the patient.

Pharmaceutical category

What products are accepted in this program?

Clarifications were provided for acceptable products and those products not covered under this program. The pharmaceutical products category consists of all prescription medications, nonprescription drugs and over-the-counter medications such as herbal products, vitamins and mineral supplements. Liquid medications are covered and instructions to pharmacists provided at time of registration clearly states that liquid medications must remain in their original consumer containers. When the original consumer container does not fit through the opening of the medications return container, it must be put into another properly sealed vial that will fit in the container. Unused medications do not have to be returned to the store where they were purchased. These points will be clarified with pharmacy managers.

Sharps, needles and syringes are not included in this program since they are not considered pharmaceutical products under the *Food and Drug Act (Canada)* and this regulation.

The program covers the collection and disposal of post-consumer medications. Pharmacy waste products such as stale dated medications and other unused pre-consumer medications are not covered under this program. These items must be disposed with commercial disposal companies or the manufacturer.

Program performance

How do you measure recovery rates in comparison to the other products captured in the regulation?

Medications are taken for specific conditions or symptoms and should be fully consumed unless otherwise indicated. Research shows that the majority of people take their medications as prescribed by a health professional. However, there are unused medications that require proper disposal. Public awareness surveys could be used to measure program performance, since quantity collected is not an accurate performance measure for a consumable product.

Quantity of medications dispensed by the pharmacist in hospitals was raised.

The questions of quantities of products sold and dispensed versus the dosage prescribed per treatment to a patient should be referred back to the pharmacist and health professional. PCPSA has no influence on the size of the vials and quantities of medications prescribed or sold. It was noted that the pharmaceutical industry has seen a decrease in the number of refills available with a prescription and the quantities of medications available as well.

State of the environment

Recent studies have shown the presence of pharmaceuticals in our water, how do you intend to address that problem?

Research has indicated that 50% to 90% of the active substances in drugs are not absorbed and are excreted. A number of pharmaceutical substances are present in our water, although it must be emphasized that concentrations found are very low, ranging from micrograms per litre down to nanograms per litre. A clear understanding of the relationship between the presence of certain substances in the environment and its effects on human health is far from having been established. Environment Canada and Health Canada already assess the environmental and human safety impact of pharmaceuticals entering the environment through the *New Substances Notification Regulations*. Health Canada is responsible for the assessment of potential risks to human health posed by existing substances in Canada. Substances Division of Environment Canada is responsible for assessing risk of existing substances to the environment.

Special Waste and Household Hazardous Waste events

How they dealt with pharmaceutical products returned by consumers.

PCPSA recommended that pharmaceuticals are returned to a pharmacy for proper handling and safe disposal.

Capital Regional District (CRD) has been collecting pharmaceuticals at their special waste site and would like to receive a *Medications Return Program* container for safe disposal. The request will be taken under consideration. A site visit will be scheduled in order to assess security and access to the *Medications Return Program* container.

Waste composition study

In the fall of 2005, CRD funded a waste composition survey in their region.

The results showed the presence of pharmaceuticals in the household garbage, but the level was deemed insignificant. Recommendations from the CRD representatives were to focus in promoting the program and changing behavior rather than using volumes as a performance measure. It was clearly stated that tonnage is not an appropriate measure to assess program performance.

Similar findings with the Greater Vancouver Regional District studies.

PCPSA had no prior information on these studies conducted in 2004 and 2005 and was unable to assess the validity of the quantity of medications detected in samples at GVRD solid waste facilities. One must take into account the standard deviation, margin of errors, collection of samples and methodology (empty container and packaging) used before making assumptions and conclusions. PCPSA would investigate the benefit of participating in composition waste studies with regional districts.

Household focus  
group study

Consumer awareness, attitude and behavior are separate indicators to measure success and influence changes.

CRD shared with the group some impressive statistics on current disposal methods of pharmaceuticals by residents in their district. PCPSA will continue to work with CRD in promoting safe disposal methods for pharmaceuticals with the *Medications Return Program*. PCPSA will develop resources to be used in educating the public.

Regional statistics

Is the data available?

PCPSA will be tracking containers information on a regional basis and will provide this information on request.

Education Material  
and Strategies

Will the program be expanding?

Although the *Medications Return Program* has an extensive network for collection sites, some feel the promotion of the program in pharmacies has had inadequate results. Several participants express their willingness to work with PCPSA in promoting this service to their members and clients. PCPSA has revised its plan to include a public survey and to identify and contact other associations in the health, municipal and regional districts to circulate information on the program. Other initiatives were mentioned and advertising will be carefully considered with professionals in this area.

Consumer awareness

The lack of public awareness in comparison to other stewardship programs is a key concern for many participants.

The draft plan outlines several mediums and strategies for enhancing public awareness of the program's existence. Recommendations are; "take back days" at community pharmacies; stickers on medication containers or tear-off sheets indicating that a program is available for unused or expired medications; distribution of brochures through a larger network such as hospitals, doctor's offices, clinics and pharmacies; involvement of local governments or regional health authorities; information on the *Medications Return Program* included with instructions that are given in many pharmacies to patients; multi-lingual promotions (Chinese and Punjabi); supply key messages for recycling calendars and recycling information distributed by municipalities or regional districts; continue to participate in the annual "*Pharmacy Awareness Week*" and newspaper advertising could include some ethnic groups.