

Medications Return Program

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 require 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

- Brand-owner:** (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.
- Collection Sites:** Community pharmacies who are registered in the program to collect unused and expired medications from the public.
- Consumable product** Means a product that in intended to be consumed during use.
- Duty of a producer:** The brand-owner is required to have an approved product stewardship plan in place or appoint an agency to undertake its duties.

Medications:	Prescription drugs, nonprescription drugs and natural health products.
Member	Brand-owner who is a member of the association
Program Administrator:	The individual or business who is contracted to manage the <i>Medications Return Program</i> in British Columbia.
Regulation	Recycling Regulation, B.C. 449/2004
Stakeholders:	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) was formed under the Society Act (BC) 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:

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

2.4 Collection Services

- ❖ *to provide a convenient system for the collection and disposal of expired and unused medications.*
- ❖ *to provide the public with information on the location of collection sites*
- ❖ *to provide convenient options for the collection of unused or expired medications in urban centers, small, isolated communities*
- ❖ *to ensure that collection facilities are available without charge to any consumer who wishes to return acceptable products*
- ❖ *to ensure all registered pharmacies in British Columbia are informed of their role in the Medications Return Program.*

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 (at least one of which will have minimum dimensions of 56 cm by 43 cm) 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.

Once the registration form is completed and fax to our office, the pharmacist will be 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.
- c) All liquid products must be in suitable sealed containers and inserted or dropped through the opening provided for this purpose.
- d) All dry medications can be drop directly into the plastic container, including blister packs and inhalers.
- e) 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 until a shipment is accumulated for safe destruction through a licensed incineration facility.

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.

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.

Community pharmacies are a natural, logical and safe site for the public to return unused or expired medications. 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 or by phoning RCBC hotline services.

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 product
- ✓ 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

The costs 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. List of participating brand-owners are published on the association website.

Yearly reviews are taken to identify new brand-owners selling medications in British Columbia and advising them of their duties as a producer 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 others have been able to operate undetected.

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 brochures that can quickly be supplied to participating pharmacies or other partners such as Regional District Environmental Service offices. 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*.

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

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.

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 contact the Regional Districts and Municipalities regarding circulating the brochures with the annual household waste collection calendars or other possibilities to inform the public.

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.

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, while there are some published sources of information available, such matters are already being dealt with effectively at the federal level under the *Canadian Environmental Protection Act*. Since Environment and Health Canada assess the environmental and human safety impact of

pharmaceuticals entering the environment through the *New Substances Notification Regulations*, an additional assessment framework at the provincial level is not required. 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.

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

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. Medications cannot be reused or recycled, as other products covered under the same regulation. However, 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. We do however ask the pharmacists to recycle the outer container when a packaging recycling program is available in their community.

5. EVALUATION AND ACCOUNTABILITY

5.1 Performance Measures

Since traditional recovery rate is not applicable to consumable product such as pharmaceuticals, PCPSA will evaluate the success of the program through the following criteria:

a) The quantity of pharmaceutical products collected: PCPSA is able to chart for each region 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.

b) Number of collection points: At the end of each calendar year, PCPSA will contact any locations with a significant change in collection pattern. The circumstances will be evaluated and improvements made as warranted. In addition PCPSA will contact all new pharmacies or existing locations under new management for enrollment in the *Medications Return Program*.

c) Public awareness of the program: PCPSA will contact regional/ municipal districts offices and 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 questions received by RCBC on medications and assess if it can influence the program performance. Other partnerships will be explored within the province to increase public awareness.

d) Performance measures: PCPSA will analyze methods and performance targets used with similar programs to measure success and continuous improvement.

5.2 Consultation on Product Stewardship Plan

PCPSA will undertake consultation with stakeholders on the development of the plan. It will initially survey its members and participating community pharmacies (list available on our website).

And finally PCPSA will solicit comments from interested groups and individuals on the *Medications Return Program*. To assist in evaluating the program plan, PCPSA has developed a consultation questionnaire and will offer public consultation meetings or a webinar to discuss the draft plan and how it proposes to meet the Recycling Regulation.

Please refer to Appendix B for the list associations/organizations to be contacted.

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

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.

APPENDIX A:

List of Participating Brand Owners in 2006

3M Pharmaceutical	Janssen-Ortho Inc.
Abbott Laboratories, Limited	Johnson & Johnson Ltd.
Actelion Pharmaceuticals Canada Inc.	Katz Group Canada Inc.
Alberto-Culver Canada Inc.	King Pharma Canada Inc.
Alcon Canada Inc.	Lander Co. Canada Ltd.
ALTANA Pharma Inn.	Leo Pharma Inc.
AmgenCanada Inc.	Loblaw Companies Ltd.
Apotex Inc.	Lorus Therapeutics Inc.
Ashbury Biologicals Inc.	Lundbeck Canada Inc.
Astellas Pharma Canada Inc	Mayne Pharma Inc.
Astra Zeneca Canada Inc.	McNeil Consumer Healthcare
Avon Canada Inc.	Mead Johnson Nutritionals
Axcan Pharma Inc.	Methalotum Company of Canada Ltd.
Baxter Canada	Merck Frosst Canada & Co.
Bayer Inc.	Neurochem Inc.
Berlex Canada Inc.	Novartis Consumer Health Care
Biovail Pharmaceuticals Canada	Novartis Pharmaceuticals Canada Inc.
Blistex Canada Inc.	Novopharm
Boeringer Ingelheim Canada	Nupharm Inc.
Bristol-Myers Squibb Pharmaceutical	Odan Laboratories
Chattem (Canada) Inc.	Organon Canada Ltd.
Church & Dwight	Paladin Labs Inc.
Cobalt Pharmaceuticals Inc.	Patheon Inc.
Combe Incorporation	Peoples Drug Mart (B.C.)
Crombie Kennedy Nasmark	Pfizer Canada Inc.
Dr. J. O Lambert Ltd.	Pfizer Consumer Healthcare
E-Z-EM Canada Inc.	Pharmaceutical Partners of Canada Inc.
Eli Lilly Canada Inc.	Pharmascience
Ferring Inc.	Platinum Naturals (Health Way Products)
Fournier Pharma Inc.	Procter & Gamble Inc.
Galderma	Procter & Gamble Pharmaceuticals
Génome Canada	Purdue Pharma
GenPharm	Quixtar Canada Corporation
GlaxoSmithKline Consumer	Ratiopharm
Healthcare	Rivex Pharma Inc
GlaxoSmithKline Inc.	Roche Ltd.
Hemosol Inc.	Ropack Inc.
Herbalife of Canada Limited	Sandoz Canada
Holista Healthcare Corporation	Sanofi-Aventis Canada Inc.
Hudson's Bay Company	Santé Naturelle (A.G.) Ltée
Jamieson Laboratories	Schering Canada Inc.
	Servier Canada Inc.

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

APPENDIX B:

List of organizations/individuals invited to participate

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APPENDIX B:

List of organizations/individuals invited to participate

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