

## **INDUSTRY STEWARDSHIP PROGRAM PLAN**



**MEDICATIONS PROGRAM PLAN**

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# Medications Program Plan

## Executive Summary

Manitoba Conservation has introduced a new Regulation under the Waste Reduction and Prevention Act to create a Medications Return Program in the province. The Household Hazardous Material and Prescribed Material Stewardship Regulation established requirements for a stewardship program for Pharmaceutical and Natural Health Products. The Manitoba Medications Return Program will consist of all types of prescriptions drugs and solid oral dosage of over-the-counter medications and natural health products sold for use in the province of Manitoba but limited to household quantities. The program will be designed to ensure that collection service is available to all regions of the province and products returned are prepared for environmentally responsible disposal. Collection of pharmaceutical waste is expected to happen at over 210 pharmacies across the province, as well as those sites currently offering HHW collection under Green Manitoba.

The Manitoba Medications Return Program Plan is being developed by the Post-Consumer Pharmaceutical Stewardship Association, a not-for-profit Industry Funding Organization, formed in 1999 to provide the pharmaceutical and consumer health products industries with a collective means for adhering to provincial regulations. PCPSA will consult with stewards, government staff, Manitoba Society of Pharmacists, Manitoba Pharmaceutical Association, Canadian Association of Chain Drug Stores, Research-Based Pharmaceutical Companies, Canadian Generic Pharmaceutical Association, Consumer Health Products Canada and other interested associations such as the Food & Consumer Products of Canada and Canadian Consumer Specialty Product Association (see appendix 1).

Once a draft program plan is available, PCPSA will be conducting consultations with affected business and members of the public in accordance with the Ministry guidelines to answer any questions they may have on the proposed program plan.

## 1. Introduction

The purpose of this document is to apply for approval of a Stewardship Program under the Government of Manitoba's Household Hazardous Material and Prescribed Material Stewardship Regulation.

### 1.1. Definition of Stewards

The Regulation defines "steward of designated material" as:

*“(a) the first person who, in the course of business or a prescribed activity in Manitoba, supplies a designated material to another person; or*

*(b) a person who, in the course of business or a prescribed activity in Manitoba, uses a designated material obtained in a supply transaction outside of Manitoba.”*

***For the purpose of this Plan, a steward will be deemed to be the brand-owner.***

In compliance with the Household Hazardous Material and Prescribed Material Stewardship Regulation, stewards must demonstrate participation in an approved program in order to do business in Manitoba. PCPSA will develop compliance protocols to ensure a level playing field among brand-owners selling medications in Manitoba. Stewards deemed to be in non-compliance with program requirements will be subject to enforcement of the Regulation which is the responsibility of the Government of Manitoba.

#### 1.2. Designated material category and sub-categories:

Pharmaceuticals are regulated in Canada under the *Food and Drugs Act and Regulations* and the *Natural Health Products Regulations*. For the purposes of the Manitoba Household Hazardous Material and Prescribed Material Stewardship Regulation the pharmaceuticals product category will be limited to three sub-categories:

- |                                 |                                |
|---------------------------------|--------------------------------|
| A. All prescriptions drugs      | All dosage forms               |
| B. Over-the-Counter Medications | Units sold in oral dosage form |
| C. Natural Health Products      | Units sold in oral dosage form |
- excluding food and beverage products,
  - including medicated patches,
  - is limited to household quantities.

Examples of dosage forms are:

- solids, semi-solids and powders
  - caplets, capsules, tablets, granules, mixtures, powders for injection, creams, lotions, gels, suppositories, etc.
- liquids
  - solutions, suspensions, syrups, ampoules, etc.
- aerosol canisters
  - sprays and inhalers
- Novel dosage forms
  - Strips, gums, patches, etc

## 2. Post-Consumer Pharmaceutical Stewardship Association

The Post-Consumer Pharmaceuticals Stewardship Association is the Industry Funding Organization (IFO) created to manage safe disposal of unused or expired medications returned from the public in regulated provincial programs. Its members represents the majority of brand-owners selling prescription drugs and consumer health products in Canada.

### 2.1 Vision

To be the Steward for environmental waste management programs of post-consumer pharmaceutical and consumer health products.

### 2.2 Mandate

To manage unused or expired medications in a cost efficient and environmentally acceptable manner that meets government policy or legislation for our members.

#### **Guiding Principle**

1. Governments must be prepared to put into place sufficient enforcement mechanisms so that all affected companies will be required to participate.
2. Costs of running a provincial program is shared between pharmaceutical (brand name and generic) and consumer health products industries.
3. The focus of this program is to manage and dispose of products in the consumer (i.e., household) waste stream as opposed to commercial products.
4. The lowest overall costs must be the goal of the program and we must ensure that industry benchmarks for both acceptable costs and effective and safe environmental management are developed.
5. Disposal of products must only be managed in locations that have environmental and health protection standards for handling household special waste.

## 3. Medications Return Program

In compliance with the Regulation, the Manitoba Medications Return Program (MMRP) will provide all Manitoba residents with reasonable access to collection sites on a province-wide basis. PCPSA will be responsible for strategic planning, overseeing program and financial operations including hiring a local program administrator under contract to managing day-to-day operations of the program. An approved plan under the Hazardous Material and Prescribed Material Stewardship Regulation **must** provide for the following:

- a. the establishment and administration of a waste reduction and prevention program for prescribed household material;

- b. the appropriate management of waste material according to this guideline established by the Minister;
- c. a province-wide, convenient collection system for waste material without user fees at the point of collection;
- d. a system for the payment of expenses incurred in the collection, transportation, storage, processing and disposal of waste material in connection with the waste reduction and prevention program;
- e. the orderly collection of revenue from program subscribers in balance with expenses for the program;
- f. the establishment and administration of education activities for the program;
- g. the establishment and administration of a point-of-sale information for the program;
- h. payment of salaries and other costs for the administration and enforcement of the regulation and the Act as it relates to prescribed household material; and
- i. ongoing consultations with people the program may affect, including members of the public, in accordance with any consultation guidelines the Minister may establish.

### 3.1. Program Goals:

Medications and consumer health products are dispensed at community pharmacies. However some products can also be purchased in natural health stores and at other retailers. Municipalities (HHW events) and some pharmacies already offer medications disposal services. While this offers some service to parts of the province, one of the goals of the *Medications Return Program* is to provide convenient, regular and easy access province wide for responsible disposal of unused or expired medications.

- a) *Establish a province-wide, industry stewardship program for medications in compliance with the Regulation.*
- b) *To provide a plan for collecting products within the pharmaceutical and consumer health product categories.*
- c) *To ensure that the brand-owners who sell, offer for sale or distribute medications in Manitoba under their own brand name, sponsor their portion of the costs of a Medications Return Program.*
- d) *To ensure environmentally responsible disposal of expired and unused medications.*
- e) *To ensure that the public is able to return expired and unused medications for disposal throughout the province.*
- f) *To provide the public with information on the location of collection site.*
- g) *To provide a course of actions for assessing the performance of the plan.*
- h) *To harmonized the plan with other provinces*
- i) *To undertake satisfactory consultation with stakeholders prior to submitting the plan for approval.*

### 3.2. Rate Setting Fee:

Funding from the industry covers expenses incurred in the collection, transportation, storage, disposal, promotion activities and education in connection with the Manitoba *Medications Return Program* (MMRP).

There are no user fees directed to the consumer/patient at time of purchase or at the point of collection.

The cost of operating the MMRP is shared between pharmaceutical (brand name and generic) and consumer health products industries. Fees are collected by the association from brand-owners selling medications in Manitoba. To provide sufficient revenue for the successful operation of the MMRP, PCPSA members will remit to the association an amount based on prescriptions/units dispensed and/or sale of products in Manitoba during the previous calendar year (January/December).

## 4. Collection System:

- ❖ *to provide a convenient system for the collection and disposal of expired and unused medications;*
- ❖ *to ensure that pharmacies accept products from the public free of charge; and*
- ❖ *to ensure all community pharmacies in Manitoba are informed of their role in the Medications Return Program*

The collection sites for a *Medications Return Program* are community pharmacies. Registered pharmacy locations are easily identified through a web-based search engine on the PCPSA website. Pharmacies are a logical and safe system for the public to return unused or expired medications. Pharmacists are the most knowledgeable of all health care professionals when it comes to medications. They offer easy access to those with special needs and varying degrees of personal mobility. Many are open extended hours, offering a convenient place for consumer disposal year-round. In situations where an individual can't travel, health care providers, caregivers, courier or other systems can provide return of unused products to a pharmacy.

The pharmacy is responsible for the safekeeping of the *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, loss or theft.

Since the voluntary participation of a pharmacist is central to the success of this program, we would work closely with the licensing authority, the Manitoba College of Pharmacy (MSP) and the Manitoba Pharmacists Association (MPhA) with promoting participation and educating the public on returning unused medications to the pharmacy. PCPSA will also track changes in pharmacy openings/closures/managers with the assistance of MPhA and MSP.

Pharmacy managers interested in offering the *Medications Return Program* in their store must complete a registration form. Specific information is provided to ensure that pharmacy managers and staff are knowledgeable on the program objective and the way the program operates. All participating community pharmacies receive a kit containing instructions on the program, posters, brochure and flyers with a container. Once the registration form is completed and faxed to our office, the pharmacist is contacted by phone to discuss the following points:

- ✓ The program is for returns from the public and not from hospitals, institutions, doctor's offices or their own operations.
- ✓ This program does not accept sharps, needles and syringes, since this is a medical device and is not considered a drug.
- ✓ All liquid products are accepted, they are not to be poured into the container. The package is inserted or dropped through the opening provided for this purpose.
- ✓ All employees working at the site must be knowledgeable about the program offered to the public.
- ✓ All pills should be deposited into the container or the original package can be inserted or dropped through the opening.
- ✓ To recycle the outer container (except liquid medications) where facilities exist, a recycling facility is available in their region. Where recycling options are not available, the containers are disposed in the waste stream.

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

## **5. Program Administrator**

Through a Request for Proposal (RFP), invitations were requested for proposals from prospective companies to provide administrative services for a period of three (3) years, with a potential option of up to an additional two (2) years. Collection of pharmaceutical waste is expected to happen at over 210 pharmacies across the province, as well as those sites currently offering HHW collection under Green Manitoba. Priority was given to a local program administrator.

Services are to include: collection, transportation, consolidation, processing and permanent disposal of pharmaceutical waste (from consumer sources). All containers returned 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. Expired medications do not represent a serious threat to public health. Medications returned under this program do not meet the criteria for toxicity as defined under the Transportation of Dangerous Goods Regulations and do not require special handling conditions.

## 6. Performance Target

Medications are intended to be consumed entirely to treat specific condition or symptom. Ideally, none should be left over. Because of the practice of keeping medications for future use, there is typically a considerable lag time between its purchase and its eventual disposal.

Reduction: Ideally all medications purchased should be used by the consumer/patient.

Targets: Once the program has been in full operation (year 2) we will strive to increase collection over the remaining term of the plan at an estimated 10% per year.

### 6.1. Quantity Collected

Target until 2015	Develop program to collect 10,000Kg or .01 kg per capita.
Performance measure:	Report total quantity collected on a yearly basis with quarterly results by districts (8).
Strategies: Year 1	Promote program through pharmacies and municipalities (e.g. Pharmacy Awareness Week, waste collection calendar).
Year 2	Continue to work with members and participating pharmacies to promote and increase publicity on program.  Promotion of program in different media.
Year 3	Continue to work with members and community pharmacies with special collection events and retailers publicity.
Year 4	Conduct public survey and continue to work on communication and education.
Year 5	To be developed based on public survey results in year 4.

## 7. Performance Measure

- A year to year comparison analysis will be completed to monitor the overall progress.
- Once the program is established, some performance measures will be developed through a combination of methods, such as surveys and the number of collection sites.
- Data on actual quantities recovered with special events through current HHW events and depots could be used for comparison with the medications returned through our collection sites.
- The plan will provide for an audit procedure to ensure proper tracking mechanisms, such as certificates of destruction are in place for management of medications from point of collection to final destruction.

### 7.1. Number of Collection Points

Target until 2015:	Pharmacy program participation rate of 70%. Ensure that collection system is in place prior to promoting safe disposal to the public;
Performance measure:	Report percentage of participating pharmacies yearly.
Strategies:  Year 1	Promotion and education plan for pharmacists will be developed to solicit voluntary participation and registration;  Contact all licensed community pharmacies in Manitoba  Work with the Manitoba Pharmaceutical Association and the Manitoba Society of Pharmacies on promoting the program to members.
Year 2	Contact on a quarterly basis existing pharmacies with ownership and/or manager changes.  Contact pharmacies with a significant change in collection pattern.  Work with chain drug stores to increase registration
Year 3-5	Set up regular communications with participating pharmacies.  Educate and promote the program to pharmacy staff with bi-annual newsletter.

## 7.2. Public Awareness

Target for 2015:	50% increase in public awareness of a Medications Return Program compared to 2010.
Performance measures:	Establish a public awareness level based on public survey in 2010.
Strategies:	Conduct survey to measure awareness and behaviour.
Year 1	Analyze the data collected to acquire a sound understanding of the issues, barriers and opportunities;  Develop effective messaging and tactics.
Year 2	Set performance targets for awareness and behaviour.  Work with Association of Manitoba Municipalities to increase exposure through their website and other events.  Promote program by advertising in recycling calendars, municipality websites and special events.
Year 3-4	Develop communication material to promote the program and to support special events.
Year 5	Measure awareness and usage of program with public survey.

## 7.3. Promotion

Target until 2015	Publicity on the MMRP on municipalities' websites with recycling sections.
Performance measure:	Publicity in 30 % of municipalities, calendars and Green Manitoba website.
Strategies: Year 1	Municipalities that currently provide events for safe disposal of medications will be encouraged to promote returns to pharmacies,  Contact Municipalities and Council with promotional material and key messages for their websites..
Year 2 and 3	Posters, brochures and hand-outs will be developed to promote the program in pharmacies,  Advertise the <i>Medications Return Program</i> through websites, flyers, poster and other advertisement, and.
Year 4	Evaluate results and adjust strategies, as needed
Year 5	Evaluate the outcome of our promotional program through a public survey.

## 8. Dispute resolution

The 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 decision on all parties involved. Should the decision not be accepted, legal recourse is available to the complainant.

## 9. Annual Report

Section 16 (1) calls for the submission an annual report within 90 days after the fiscal year end, and posting the report on the association's website.

PCPSA will prepare an Annual Report for the one-year period ending December 31 of the previous year. The report will document the performance in relation to the plan and steps to reduce any gap between actual and projected performance.

### 8.1 Financial Statement

- ✓ PCPSA will submit an independently audited financial statement, including a section for the Manitoba Medications Return Program expenses.

### 8.2 Educational Materials and Strategies

- ✓ Posters, brochures and hand-outs will be developed to promote the program in pharmacies,
- ✓ Advertise the *Medications Return Program* through websites, flyers, poster and other advertisement, and
- ✓ Evaluate results and adjust strategies, as needed.

### 8.3 Collection Sites

- ✓ The location and number of community pharmacies registered; and
- ✓ quantity of medications collected at each location and their contribution to achieving program goals;

### 8.4 Reducing environmental impacts throughout product life cycle

The *Waste Reduction and Prevention Act* (WRAP) 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 medications; (i.e. both prescription drugs and consumer health products), the Government of Canada's new Chemicals Management Plan is conducting analysis on the risk assessment of substances entering the environment through the categorization process. Given the existing federal legislation, it is therefore recommended that this section be excluded in the annual report.

#### 8.5 Pollution Prevention and 4Rs Hierarchy

Since reuse and recycling options are not available for the medications collected, the best environmental option for medication destruction is high temperature incineration in environmentally certified facilities.

#### 8.6 Recovery Rate

A variety of municipal and non-municipal systems are currently employed for collecting and managing medications.

##### a) Municipal Infrastructure

The Manitoba Government contracts Miller Environmental Corporation to collect and dispose of pharmaceutical waste from households. Collection events are currently held periodically at rural locations and in Winnipeg. Information on material collected and quantity generated will be used to establish benchmark for this program.

##### b) Non-Municipal Infrastructure

In addition to the municipal collection and handling system, Manitoba residents have limited access to retailer collection systems.

##### c) The amount of product sold and collected and recovered

The quantity of medications available for collection is difficult to estimate since 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 relatively small quantity. Patients are directed by their physician and health professional to use the medication until finished. In humans, data has shown up to 90% of the active substances excreted into our sewage systems.

## 10. Pollution Prevention and Best Management

Medications cannot be reused or recycled, as other products covered under this regulation.

Products collected under this program will be disposed through incineration at government approved facilities. A certificate of destruction, as well as 3<sup>rd</sup> party verification will be obtained.

## **11. Conclusion**

PCPSA has organized and operated *Medications Return Programs*, a program that allows consumers to return (at no charge) their residual medications to pharmacies in the province of British Columbia since 2000. As a result, PCPSA has been able to divert approximately 236,292 kg of unused or expired medications from landfills or waterways.

PCPSA is prepared to implement a similar program in Manitoba.