HEALTH PRODUCTS STEWARDSHIP ASSOCIATION

MEDICATION RETURN PROGRAM PLAN FOR THE PRINCE EDWARD ISLAND PHARMACEUTICAL PRODUCT STEWARDSHIP PROGRAM

DECEMBER 2014

EXECUTIVE SUMMARY

On June 10, 2014 Prince Edward Island approved the *Environmental Protection Act* Materials Stewardship and Recycling Regulations (Regulation), pursuant to Section 25 of the Environmental Protection Act (EPA). Under the Regulation, Division 6 "Pharmaceutical Products" designates pharmaceutical products as a regulated material and defines pharmaceutical products and Brand Owners (Producers). Division 6 also makes Producers of pharmaceutical products responsible for establishing a Pharmaceutical Product Stewardship Program and states the program requirements that Producers must meet. The Regulation allows the Heath Products Stewardship Association (HPSA) to act as an agent on behalf of Producers to operate a pharmaceutical product stewardship program and fulfill compliance obligations under the Regulation.

For the purposes of this program plan document and program operation the Pharmaceutical Product Stewardship Program (PPSP) required under the Regulation is referred to as the Island Medication Return Program (IMRP). The IMRP addresses EPR for all types of pharmaceutical products, over the counter, and natural health products sold for use in the province of Prince Edward Island but are limited to the "Consumer" waste stream. The program is designed to ensure that collection service is available to all regions of the province and all returned pharmaceutical products are collected, handled, stored, packaged, transported and disposed of in a safe, compliant and environmentally responsible manner.

The IMRP is administered by the Health Products Stewardship Association (HPSA), a not-for-profit industry stewardship organization (ISO), established in 1999. HPSA was formed to provide the health product industries with a collective means for managing their extended producer responsibilities including the associated product liability and regulatory compliance requirements that vary from province to province.

The IMRP covers a five year period as stated in the Regulation beginning June 1, 2015 through to May 31, 2020 after which the program plan will undergo a review.

TABLE OF CONTENTS

1 GLOSSARY OF KEY DEFINITIONS AND ACRONYMS

1.1 Acronyms

CAP: Canada-Wide Action Plan for EPR
CAPDM: Canadian Association for Pharmacy Distribution Management
CCME: Canadian Council for Ministers of the Environment
EPA: Prince Edward Island Environmental Protection Act
EPR: Extended Producer Responsibility
HPSA: Health Products Stewardship Association
IMRP: Island Medication Return Program
ISO: Industry Stewardship Organization
IWMC: Island Waste Management Corporation
MOELJ: Prince Edward Island Department of Environment, Labour and Justice
PPSP: Pharmaceutical Product Stewardship Program
NPAC: Neighbourhood Pharmacies Association of Canada
OECD: Organization for Economic Co-operation and Development
PEICP: Prince Edward Island College of Pharmacists
PEIPA: Prince Edward Island Pharmacists Association
RCC: Retail Council of Canada

1.2 Terms and Definitions

a) Agent

Health Products Stewardship Association acts as an agent of Brand Owners (Producers) designated under section 104 of the *Environmental Protection Act* Materials Stewardship and Recycling Regulations.

b) Brand Owner:

For the purposes of the industry stewardship plan, the Brand Owner for a pharmaceutical product sold, offered for sale, or otherwise distributed in or into the province of Prince Edward Island is:

i) a person who manufactures a pharmaceutical product and sells, offers for sale or distributes a pharmaceutical product in Prince Edward Island 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 Prince Edward Island, whether or not they own the Drug Identification Number.

iii) if subparagraphs (i) and (ii) do not apply, a person who imports the product in the province for sale or distribution

c) Collection Location(s):

A location, typically a retail pharmacy, at which the collection of pharmaceutical products are provided for.

d) Consumer:

Means an individual acting for personal, family or household purposes.

e) Pharmaceutical Product (Designated Material):

Under the *Environmental Protection Act* Materials Stewardship and Recycling Regulations, a pharmaceutical product means a drug within the meaning of section 2 of the *Food and Drugs Act* (Canada) and includes a natural health product within the meaning of the *Natural Health Products Regulations* made under that Act, but does not include:

i) A substance or mixture of substances manufactured, sold or represented for use in disinfection in premises in which food within the meaning of section 2 of the *Food and Drugs Act* (Canada) is manufactured, prepared or kept;
ii) A food within the meaning of section 2 of the *Food and Drugs Act* (Canada);
iii) A cosmetic within the meaning of section 2 of the *Food and Drugs Act* (Canada); or,
iv) Items in any of the following classes
    a. Contact lens disinfectants,
    b. Anti-dandruff products, including shampoos,
    c. Anti-perpirants,
    d. Sunburn protectants,
    e. Mouthwash,
    f. Fluoridated toothpaste,
    g. Topical substances not containing antibiotics or anti-fungal agents,
    h. Radio pharmaceuticals,
    i. Antiseptic or medicated skin-care products,
    j. Veterinary medications and products.

f) Program Plan:

A document that provides producers with a strategy for individually or collectively managing the extended producer responsibility of their products including any safety, environmental and regulatory requirements.

g) Retailer:

Under Regulation EC349/14 a retailer means a person who sells or offers for sale pharmaceutical products directly to consumers.

h) Waste Watch Drop-Off Centres:

Permanent locations (six) operated by Island Waste Management Corporation in Prince Edward Island where consumers can drop off pharmaceutical products and other hazardous waste from households for transfer and end-of life processing.

2 INTRODUCTION

The Organization for Economic Co-operation and Development (OECD) has defined EPR as "a policy approach in which a producer's responsibility, physical or financial, for a product is extended to the post-consumer stage of a product's lifecycle".

The purpose of this document is to provide a plan for the management of EPR for post-consumer pharmaceutical products in Prince Edward Island. The primary objective of this document is to ensure, through a detailed program plan, that HPSA members with pharmaceutical products are in compliance with the Prince Edward Island *Environmental Protection Act* Materials Stewardship and Recycling Regulations.

2.1 Regulatory Review

The IMRP is a regulatory driven EPR initiative. The following regulatory review examines the acts, regulations, guidelines and standards that are relevant to the IMRP.

2.1.1 Environmental Protection Act Materials Stewardship and Recycling Regulations

The compliance requirements of the IMRP are dictated primarily by the *Environmental Protection Act* Materials Stewardship and Recycling Regulations . This regulation requires Brand Owners of pharmaceutical products to provide for the collection and safe environmental management of their leftover products from consumers. Brand Owners must also provide consumers with access to free and convenient collection locations, such as retail pharmacies, to return their pharmaceutical products.

The Regulation defines “Pharmaceutical Products” as:

> A drug within the meaning of section 2 of the *Food and Drugs Act* (Canada) and includes a natural health product within the meaning of the *Natural Health Products Regulations* made under that Act, but does not include:
>
> i) A substance or mixture of substances manufactured, sold or represented for use in disinfection in premises in which food within the meaning of section 2 of the *Food and Drugs Act* (Canada) is manufactured, prepared or kept;
> ii) A food within the meaning of section 2 of the *Food and Drugs Act* (Canada);
> iii) A cosmetic within the meaning of section 2 of the *Food and Drugs Act* (Canada); or,
> iv) Items in any of the following classes
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> a. Contact lens disinfectants,
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> f. Fluoridated toothpaste,
> g. Topical substances not containing antibiotics or anti-fungal agents,
> h. Radio pharmaceuticals,

i. Antiseptic or medicated skin-care products,
j. Veterinary medications and products.

The Regulation defines “Brand Owners” as:

> In respect of pharmaceutical products sold, offered for sale or otherwise distributed in or into the province:
> a) a manufacturer of the pharmaceutical product;
> b) a distributor of the pharmaceutical product in or into the province; or
> c) where the pharmaceutical product is imported into the province, the first person to sell the pharmaceutical product in or into the province.

HPSA is the industry designated ISO that has developed compliance protocols to ensure a level playing field among Brand Owners selling pharmaceutical products in Prince Edward Island. Brand Owners not compliant with the *Environmental Protection Act* Materials Stewardship and Recycling Regulations are subject to enforcement under the EPA which is the responsibility of the government of Prince Edward Island.

2.1.2 Other Applicable Acts, Regulations, Guidelines and Standards

The list of additional acts, regulations, guidelines and standards that have been considered in the creation of the Pharmaceutical Product Stewardship Program plan is as follows:

a) Canadian Council for Ministers of the Environment (CCME) Canada-Wide Action Plan on EPR (CAP)

The CCME CAP for EPR is a guideline for regulatory and EPR program clarity for government, producers and ISOs like HPSA. It is used as the guideline on key elements common to all EPR programs in Canada.

b) Chapter D-3 “Dangerous Goods (Transportation) Act”

Chapter D-3 prescribes the handling and containment requirements for Dangerous Goods including infectious substances in the Province of Prince Edward Island.

c) Waste Resource Management Regulations

The Waste Resource Management Regulations set forth the requirements for waste carriers, generators and receivers in the Province of Prince Edward Island. The regulation defines special waste and requires generators/transporters of special waste to obtain a Special Waste Permit. Transporters of Hazardous Waste must be registered and issued a provincial registration number.

d) Pharmacy Act

The Pharmacy Act of Prince Edward Island defines what a pharmacy is and how it is accredited. Public-facing retail pharmacies act as the primary collection locations for the MSSP.

e) Prince Edward Island Environmental Protection Act

The Act is Prince Edward Island's key legislation for Environmental Protection. The act grants the Department of Environment, Labour and Justice (DELJ) and specifically the Minister broad powers to deal with the discharge of contaminants which cause negative effects.

3 THE HEALTH PRODUCTS STEWARDSHIP ASSOCIATION

The HPSA is the ISO created to manage safe disposal of unused or expired health products returned from the public in regulated provincial programs. HPSA's predecessor PCPSA began in 1999 by managing the BC Medication Return Program on behalf of producers as required under British Columbia regulation. HPSA's producer members represent the majority of brand-owners selling health products in Canada.

3.1 Vision

The vision of the HPSA is to be the recognized ISO provincially and nationally for environmental waste management programs of health products.

3.2 Mandate

The mandate of the HPSA is to collect and dispose of pharmaceutical products and medical sharps returned by the public in a cost-efficient and environmentally acceptable manner that meets government policy and/or regulatory requirements for its producer members.

3.3 Guiding Principles

1. Level Playing Field: Provide a level playing field (fair competition), achieve a high level of compliance, and reduce the potential for having Brand Owners fail to meet their financial obligations.
2. Environmental Standards: Ensure materials are disposed of in a responsible manner that safeguards the environment and worker health and safety in accordance with regulatory requirements.
3. No Cross-Subsidization: Ensure the collection of revenue from the program is in balance with the expenses for the program with fees closely reflecting the costs of managing each obligated product.
4. Operational Efficiencies: Ensure the program is delivered effectively and efficiently at the lowest possible cost.
5. Business Sustainability: Ensure sustainable management of the association by maintaining an appropriate operating contingency reserve, but not accumulating a surplus.
6. Continuous Improvement: Adhere to provisions for best practices to strive for continuous improvement in environmental and economic performance.
7. Harmonization: To the greatest extent possible, harmonize with other programs to achieve economies of scale.

4 DESIGNATED MATERIAL (PHARMACEUTICAL PRODUCTS)

A fundamental component of the IMRP plan is the definition of pharmaceutical products that consumers can return.

For the purposes of the IMRP, pharmaceutical products as a designated material are defined into categories as:

- All Prescription Drugs
- Over-the-Counter Medications (units sold in oral dosage form)
- Natural Health Products (units sold in oral dosage form)

4.1 Pharmaceutical Products Category and the Prince Edward Island Marketplace:

The definition of a Brand Owner under the *Environmental Protection Act* Materials Stewardship and Recycling Regulations is referenced in section 1.2 (b) of the program plan. In the province of Prince Edward Island the following pharmaceutical product Brand Owner distribution scenarios exist:

- Manufacturers selling their brand to wholesalers and retail pharmacies;
- Retail pharmacies selling their private label brand to consumers;
- First importers selling pharmaceutical products to wholesalers and retail pharmacies.

4.2 Collectors of Pharmaceutical Products Waste

Under the IMRP, unused or expired pharmaceutical products are brought to collection locations. Collection locations will consist of retail pharmacies located across Prince Edward Island.

4.3 Retailers of Pharmaceutical Products

The *Environmental Protection Act* Materials Stewardship and Recycling Regulations define a retailer as a person who sells or offers for sale pharmaceutical products directly to consumers. Under the Regulation, retailers must display education and awareness program information that is supplied to it by the Brand Owner's agent. HPSA acting as the collective agent for member Brand Owners participating in the IMRP will make available education and awareness program information to pharmaceutical product retailers in Prince Edward Island.

5 PROGRAM DESIGN

The IMRP provides all Consumers with reasonable access to collection locations on a province-wide basis. HPSA is responsible for strategic planning, overseeing the program and financial operations. The goals of the program are to:

- Establish a province-wide industry run Pharmaceutical Product Stewardship Program in compliance with the *Environmental Protection Act* Materials Stewardship and Recycling Regulations.
- Provide a plan for collecting post-consumer pharmaceutical products.
- Ensure that the Brand Owners who sell, offer for sale or distribute pharmaceutical products in Prince Edward Island are members of HPSA and fund a Pharmaceutical Product Stewardship Program.
- Ensure environmentally responsible disposal of pharmaceutical products.
- Ensure that the public is able to return pharmaceutical products for disposal throughout the province.
- Provide the public and pharmaceutical product retailers with information about:
    - The IMRP and the products accepted for collection and disposal;
    - How and when products can be returned; and
    - The health and environmental benefits of using the IMRP.
- Harmonize the plan with other provincial programs.

According to the *Environmental Protection Act* Materials Stewardship and Recycling Regulations the program plan must provide for the following:

1. The management structure of the program (Section 3);
2. How discarded products will be collected (Section 5.1);
3. The plans for the receipt of discarded products at the return facilities that participate in the program and the policies and procedures to be followed by the return facilities (Section 5.1);
4. The quality control and assurance aspects of the program, including tracking and auditing mechanisms(Section 5.6); and
5. An education and awareness program for consumers (Section 5.4) that includes information about
    i. The IMRP, specifying products accepted by the program,
    ii. How and when consumers can access collection facilities, and
    iii. The health and environmental benefits of participating in the IMRP.

5.1 Program Requirements for Collection, Transportation and Processing of Pharmaceutical Products

5.1.1 Collection Location Requirements:

Retail pharmacies participating in the IMRP as collection locations must have a registered pharmacist or registered pharmacy technician that is trained on how to receive, handle and package products returned to the pharmacy by consumers.

Pharmacy managers interested in participating must complete a registration form. Details on the program are provided to ensure that pharmacy management and staff are knowledgeable on the program and its operation. All participating retail pharmacies receive information with instructions on the program, an order form and containers for the collection of unused or expired medication.

Collection locations must also meet the following requirements:

- Collection locations must provide the service to the public at no charge.
- The collection location must provide to the public the ability to drop off products during regular business hours.
- Collection locations must prominently display, and have, awareness, promotion and educational materials for the public.
- A licensed pharmacist or pharmacy technician must be present when a consumer drops off products.
- Collection locations must have a valid provincial registration number.
- There must be an agreement in place between the collection location and HPSA that addresses collection, handling and storage of unused and expired products.
- If the location is offering safe disposal of unused and expired medications under the IMRP and it is not a retail pharmacy then the location has to be approved by the HPSA and has to meet the full requirements of the Waste Management Resource Regulations of the EPA before participation in the program can begin.

5.1.2 Transportation Requirements:

- All applicable conditions of the Waste Resource Management Regulations must be adhered to by the waste management service provider(s) when transporting pharmaceutical waste.

5.1.3 Processing Requirements:

- Post-consumer pharmaceutical waste collected in the IMRP must be treated by high temperature incineration.
- To ensure safety, mitigate the risk of diversion and maximize the efficiency of the thermal treatment process pharmaceutical waste will be contained in leak-resistant and diversion-resistant secondary packaging (i.e.: plastic pharmaceutical waste pails and liners).

- Waste-to-Energy is the preferred treatment method for post-consumer pharmaceuticals.
- Processors must be registered with the government of PEI and have a provincial registration number.

5.2 Program Efficiencies

HPSA will be working directly with industry associations, waste management service provider(s) and retail pharmacy collection sites to ensure adherence to program standards for the collection, transportation and disposal of pharmaceutical waste from the IMRP. Retail pharmacies registered as collection locations in the IMRP can accept unused or expired medication from the public under HPSA collection standards. Public facing retail pharmacy collection locations that also accept waste materials from healthcare professionals (i.e.: doctors, dentists, long term care facilities, etc.) or operate as a methadone clinic must manage these materials separately under their own commercial arrangements with service providers outside of the IMRP. Hospital pharmacies (non-outpatient pharmacies), long term care pharmacies exclusively serving institutions and commercial compounding pharmacies only serving hospitals are not eligible to participate in the IMRP.) HPSA will be monitoring program usage through collection location data analysis, vendor support, waste audits and random inspections at collection site locations.

5.3 Accessibility

As of October 14, 2014 a total of 49 pharmacies were registered by the Prince Edward Island College of Pharmacists (PEICP). HPSA will work to register public facing retail pharmacies in the IMRP.

5.4 Promotion and Education

HPSA will be launching a promotion and education strategy to consumers and collection locations about the IMRP. The strategy will have the following components:

5.4.1 Consumer Outreach Strategy

- A brochure will publicize that HPSA is setting up the IMRP on behalf of the health industries and provide information to the public on the program. A print version of the brochure will be available to consumers at all participating collection locations and will also be available in electronic format on the HPSA website.
- Consumers can find other IMRP details on the HPSA website (www.healthsteward.ca) as well as the nearest IMRP collection location.

5.4.2 Collection Location Outreach Strategy

- Outreach/education packages for collection locations will explain the HPSA industry-run program, timelines, the unused or expired medication products covered and expectations for their participation as collection locations.
- IMRP education material will be provided to collection locations upon registration and can be ordered year round by calling HPSA or going through the HPSA website.

- HPSA will engage the Retail Council of Canada (RCC), the Prince Edward Island Pharmacists Association (PEIPA), the Prince Edward Island College of Pharmacists (PEICP) and the Neighbourhood Pharmacy Association of Canada (NPAC) to promote the IMRP through their networks and outreach channels (i.e., industry newsletters, events and websites).

5.4.3 Retailer Outreach Strategy

HPSA will provide promotional and educational materials for consumers to be displayed by retailers free of charge. Materials can be ordered by retailers directly for distribution to their clients through an HPSA supplied order form available on the HPSA website.

5.5 Financial Resources Summary

HPSA is the ISO responsible for the IMRP. HPSA staff administer the program and its various components, including contracts with waste management service providers and vendors.

Funding from the industry covers all of the expenses incurred for the collection, transportation, storage, disposal, promotion activities and education in connection with the IMRP.

There is no visible user fee (eco fee) directed to the consumer at the point of purchase or at the point of collection.

5.6 Quality Control and Assurance

5.6.1 Collection Location

A Collection Standards Agreement will be developed for pharmacies to register as collection locations in the IMRP. This Agreement will apply to each participating pharmacy for the collection, handling, storage and generation of unused and expired pharmaceutical products returned by the public.

5.6.2 Service Providers

Approved service providers under an HPSA stewardship programs will have to sign a Transportation Standards Agreement and/or Disposal Standards Agreement. The Agreements are specific to the on-going collection of pharmaceutical products at pharmacies registered under the IMRP for the sole purpose of secure and compliant transportation and disposal. The Agreements are intended to prevent any potential for inappropriate possession at the point of collection and during transportation and transfer to approved end disposal facilities.

5.6.3 Annual Report

The reporting requirements that HPSA will provide on behalf of its members are clearly defined in the *Environmental Protection Act* Materials Stewardship and Recycling Regulations. HPSA will submit an annual report on the Pharmaceutical Product Stewardship Program on or before June 30th of each year to the Minister of the Department of Environment, Labour and Justice.

The annual report has to meet the following minimum requirements:

- The name of all Brand Owners on whose behalf the HPSA prepared the report must be listed;
- The total weight of all pharmaceutical products received at collection locations for the previous year;
- A description of how pharmaceutical products generated by collection locations were handled and disposed of during the previous calendar year;
- A description of the actions taken by HPSA to ensure compliance with the requirements for collection and disposal of pharmaceutical products returned by consumers to collection locations; and
- The annual report must be ready for release on or before June 30th each year.

APPENDIX A: *Environmental Protection Act* Materials Stewardship and Recycling Regulations – Division 6

DIVISION 6

Pharmaceutical Products

85. In this Division, Definitions

(a) "administrator" means an administrator appointed under section 91; administrator

(b) "agent" means an agent of a brand owner designated under section 88; agent

(c) "brand owner" means, in respect of a pharmaceutical product sold, offered for sale or otherwise distributed in or into the province, brand owner

(i) a manufacturer of the pharmaceutical product,

(ii) a distributor of the pharmaceutical product in or into the province, or

(iii) where the pharmaceutical product is imported into the province, the first person to sell the pharmaceutical product in or into the province;

(d) "pharmaceutical product" means a drug within the meaning of section 2 of the *Food and Drugs Act* (Canada) and includes a natural health product within the meaning of the *Natural Health Products Regulations* made under that Act, but does not include pharmaceutical product

(i) a substance or mixture of substances manufactured, sold or represented for use in disinfection in premises in which food within the meaning of section 2 of the *Food and Drugs Act* (Canada) is manufactured, prepared or kept,

(ii) a food within the meaning of section 2 of the *Food and Drugs Act* (Canada),

(iii) a cosmetic within the meaning of section 2 of the *Food and Drugs Act* (Canada), or

(iv) items in any of the following classes:

(A) contact lens disinfectants,

(B) anti-dandruff products, including shampoos,

(C) anti-perspirants,

(D) sunburn protectants,

(E) mouthwash,

(F) fluoridated toothpaste,

(G) topical substances not containing antibiotics or anti-fungal agents,

(H) radio pharmaceuticals,

(I) antiseptic or medicated skin-care products,

(J) veterinary medications and products;

pharmaceutical product stewardship program

(e) "pharmaceutical product stewardship program" means a program approved by the Minister under section 89 that establishes a process for the collection, transportation and disposal of pharmaceutical products;

retailer

(f) "retailer" means a person who sells or offers for sale pharmaceutical products directly to consumers. (EC349/14)

Designation

86. (1) For the purposes of the Act and these regulations, pharmaceutical products are a designated material.

Discarding pharmaceutical products

(2) No person shall discard pharmaceutical products except

(a) at a facility approved to accept pharmaceutical products pursuant to these regulations; or

(b) in accordance with an approved pharmaceutical product stewardship program. (EC349/14)

Pharmaceutical Product Stewardship Program

Prohibition

87. (1) No brand owner of a pharmaceutical product shall sell, offer for sale or otherwise distribute a pharmaceutical product in or into the province unless the brand owner, or an agent of the brand owner of the pharmaceutical product, operates a pharmaceutical product stewardship program in respect of the pharmaceutical product.

Idem

(2) No retailer shall sell, offer for sale or otherwise distribute a pharmaceutical product in or into the province unless the brand owner of the pharmaceutical product, or an agent of the brand owner of the pharmaceutical product, operates a pharmaceutical product stewardship program in respect of the pharmaceutical product. (EC349/14)

Designation of agent

88. A brand owner may, by written agreement with any person, designate that person as the agent of the brand owner to operate a pharmaceutical product stewardship program on the brand owner's behalf. (EC349/14)

Proposal

Proposal for approval of pharmaceutical product stewardship program

89. (1) A brand owner who wishes to apply for approval of a pharmaceutical product stewardship program shall file with the Minister a completed proposal in a format approved by the Minister.

Idem

(2) An agent of a brand owner who wishes to operate a pharmaceutical product stewardship program on the brand owner's behalf and who

wishes to apply for approval of the program shall file with the Minister a completed proposal in a format approved by the Minister.

Material to be submitted

(3) An applicant shall submit with a proposal made under subsection (1) or (2) detailed information respecting

(a) the management structure of the program;

(b) how discarded pharmaceutical products will be collected;

(c) the plans for the receipt of discarded pharmaceutical products at the pharmaceutical product return facilities that participate in the program and the policies and procedures to be followed by the pharmaceutical product return facilities;

(d) the quality control and assurance aspects of the program, including tracking and auditing mechanisms; and

(e) an education and awareness program for consumers of pharmaceutical products that includes information about

(i) the pharmaceutical product stewardship program, specifying products accepted by the program,

(ii) how and when consumers can access pharmaceutical product return facilities, and

(iii) the environmental benefits of participating in the pharmaceutical product stewardship program.

Additional information

(4) The Minister may require an applicant to provide any additional information that the Minister requires to consider the proposal.

Requirements for approval of pharmaceutical product stewardship program

(5) The Minister shall approve a pharmaceutical product stewardship program if the Minister is satisfied that

(a) the proposal has been made in accordance with the requirements of these regulations;

(b) the proposal

(i) includes the information referred to in clauses (3)(a) to (e) and is otherwise acceptable to the Minister, and

(ii) adequately provides for the operation of the pharmaceutical product stewardship program in compliance with the Act and these regulations; and

(c) approval of the program is in the public interest having regard to the matters referred to in clauses (3)(a) to (e).

Reasons for refusal

(6) Where the Minister refuses to approve a pharmaceutical product stewardship program, the Minister shall provide written reasons for the refusal to the applicant.

Approval of pharmaceutical product stewardship program

(7) Where the Minister approves a pharmaceutical product stewardship program, the applicant shall, not later than the commencement date of the program, pay the fee prescribed by subsection (8).

Approval fee

(8) The fee for an approval of a pharmaceutical product stewardship program is $5,000, payable to the Minister of Finance, Energy and Municipal Affairs. (EC349/14)

Payment of annual fee

90. (1) A brand owner or an agent who operates a pharmaceutical product stewardship program shall, on or before June 30 of each year, pay the annual fee prescribed by subsection (2).

Annual fee

(2) The annual fee for a pharmaceutical product stewardship program is $5,000, payable to the Minister of Finance, Energy and Municipal Affairs. (EC349/14)

Appointment of administrator

91. The Minister may

(a) appoint any person as the administrator of a pharmaceutical product stewardship program; and

(b) specify the duties and responsibilities of an administrator appointed under clause (a). (EC349/14)

Information

Request for information by Minister

92. A brand owner or an agent who operates a pharmaceutical product stewardship program shall, upon request in writing from the Minister, provide the Minister with any information about the pharmaceutical product stewardship program, including any of the following:

(a) the types of processes used to dispose of discarded pharmaceutical products;

(b) the location of the pharmaceutical product return facilities for discarded pharmaceutical products;

(c) the location of any long-term destruction or final treatment and processing facilities for discarded pharmaceutical products;

(d) records showing that the program adheres to established industry vendor qualification standards, or information demonstrating that the discarded pharmaceutical products collected are managed in a manner that employs environmental and human health and safety standards meeting or exceeding applicable federal, provincial and local regulations. (EC349/14)

Internalization of fees

93. No retailer shall charge a consumer any separate fee with respect to the costs associated with implementing or operating a pharmaceutical product stewardship plan. (EC349/14)

Display of education and awareness program information

94. A retailer shall prominently display, at the point of display or the point of sale of a pharmaceutical product, the education and awareness program information referred to in clause 89(3)(e) that is supplied to it by the brand owner or the brand owner's agent. (EC349/14)

Review of pharmaceutical product stewardship program

95. A brand owner or an agent who operates a pharmaceutical product stewardship program shall review the pharmaceutical product stewardship program and

(a) submit to the Minister all proposed amendments to the pharmaceutical product stewardship program; or

(b) advise the Minister in writing that in its opinion no amendments to the pharmaceutical product stewardship program are necessary,

not later than the date that is 5 years after the date the pharmaceutical product stewardship program was first approved under subsection 89(5) and every 5 years thereafter. (EC349/14)

Reporting quantity of pharmaceutical products collected

96. A brand owner or an agent who operates a pharmaceutical product stewardship program shall, on or before June 30 of each year, or on or before the date set by the Minister, inform the Minister in writing of the total quantity of discarded pharmaceutical products collected during the previous calendar year. (EC349/14)

Operation of pharmaceutical product stewardship program

97. (1) No brand owner who operates a pharmaceutical product stewardship program shall fail to operate the pharmaceutical product stewardship program in accordance with the program as approved under subsection 89(5).

Idem

(2) No agent who has been designated to operate a pharmaceutical product stewardship program on a brand owner's behalf shall fail to operate the pharmaceutical product stewardship program in accordance with the program as approved under subsection 89(5). (EC349/14)