1 ***Section 2 of New Brunswick Regulation 2008-54 under the Clean Environment Act is amended***

(a) in the definition "brand owner"

(i) in subparagraph a)(ii) of the French version by striking out "la propriétaire ou une licenciée" and substituting "le propriétaire ou un licencié"***;***

(ii) in subparagraph b)(ii) of the French version by striking out "la propriétaire ou une licenciée" and substituting "le propriétaire ou un licencié"***;***

(iii) in subparagraph b.1)(iii) of the French version by striking out "la propriétaire ou une licenciée" and substituting "le propriétaire ou un licencié"***;***

(iv) in paragraph (b.2)

(A) in subparagraph (iii) of the French version by striking out "la propriétaire ou une licenciée" and substituting "le propriétaire ou un licencié"***;***

(B) in subparagraph (iv) of the English version by striking out "and" at the end of the subparagraph;

(v) by adding after paragraph (b.2) the following:

(b.3) in Part 5.4, with respect to pharmaceutical products and medical sharps sold, offered for sale or distributed in or into the Province, a person who

(i) is a manufacturer of pharmaceutical products or medical sharps,

(ii) is a distributor of pharmaceutical products or medical sharps,

(iii) is an owner or licensee of a registered or unregistered trademark under which pharmaceutical products or medical sharps are sold, offered for sale or distributed, or

(iv) if a pharmaceutical product or medical sharp is imported into the Province, is the first person to sell the pharmaceutical product or medical sharp; and

(vi) in paragraph (c) by striking out "(a), (b), (b.1) or (b.2)" and substituting "(a), (b), (b.1), (b.2) or (b.3)"***;***

(b) by adding the following definitions in alphabetical order:

"medical sharp" means a needle, safety engineered needle, lancet or other similar instrument that is designed, for medical purposes, to puncture the skin of a consumer or their companion animal and includes anything affixed to the medical sharp, including a syringe. (*objet médical pointu ou tranchant*)

"pharmaceutical product" means a drug as defined in section 2 of the *Food and Drugs Act* (Canada) and a natural health product as defined in subsection 1(1) of the *Natural Health Products Regulations* made under that Act, but does not include

(a) a food as defined in section 2 of the *Food and Drugs Act* (Canada),

(b) a cosmetic as defined in section 2 of the *Food and Drugs Act* (Canada),

(c) a drug that is a radiopharmaceutical as defined in Part C of the *Food and Drug Regulations* made under the *Food and Drugs Act* (Canada),

(d) a drug for veterinary use except a drug for veterinary use in a consumer's companion animal,

(e) a topical substance that does not contain an antibiotic, antifungal or analgesic, or

(f) a drug that is represented as being solely for use as a disinfectant on hard non-porous surfaces. (*produit pharmaceutique*)

2 ***Subsection 7(4) of the Regulation is amended by striking out "section 31, 48, 50.26, 50.45 or 50.67" and substituting*** "section 31, 48, 50.26, 50.45, 50.67 or 50.85"**.**

3 ***Subsection 11(1) of the Regulation is amended***

(a) in paragraph a) of the French version by striking out "d'un plan" and substituting "d'un programme"***;***

(b) in paragraph b) of the French version by striking out "du plan" and substituting "du programme"***;***

(c) in paragraph b.2) of the French version by striking out "du plan" and substituting "du programme"***;***

(d) in paragraph b.3) of the French version by striking out "du plan" and substituting "du programme"***;***

(e) by adding after paragraph (b.3) the following:

(b.4) with respect to the pharmaceutical products and medical sharps stewardship program, the following information:

(i) the amount of fees, interest on outstanding fees and penalties remitted to the Board;

(ii) the results of any inspections conducted under this Regulation;

(iii) a description of all enforcement activities; and

(iv) a description of other related activities of the Board;

4 ***Paragraph 20(2)(b) of the Regulation is amended by striking out "section 48, 50.26, 50.45 or 50.67" and substituting*** "section 48, 50.26, 50.45, 50.67 or 50.85"**.**

5 ***Subsection 21(2) of the Regulation is amended***

(a) in paragraph (d) of the English version by striking out "and" at the end of the paragraph;

(b) in paragraph (e) by striking out the period at the end of the paragraph and substituting a comma followed by "and"***;***

(c) by adding after paragraph (e) the following:

(f) the management of pharmaceutical products and medical sharps, if the money is recovered from a brand owner under Part 5.4.

6 ***Paragraph 45(1)(k) of the Regulation is amended by striking out "stewardship program" and substituting*** "stewardship plan"**.**

7 ***Paragraph 50.23(1)(l) of the Regulation is amended by striking out "stewardship program" and substituting*** "stewardship plan"**.**

8 ***Paragraph 50.42(1)k) of the French version of the Regulation is amended by striking out "son plan" and substituting*** "le plan"**.**

9 ***The Regulation is amended by adding after section 50.69 the following:***

PART 5.4

DESIGNATED MATERIAL – PHARMACEUTICAL PRODUCTS AND MEDICAL SHARPS

Definitions

50.7 The following definitions apply in this Part.

"consumer" means a person who uses a pharmaceutical product or medical sharp for the person's own purpose or for that of their companion animal, and not for the purpose of re-sale. (*consommateur*)

"pharmaceutical product and medical sharp waste" means any pharmaceutical product or medical sharp that is no longer required or can no longer be used by a consumer. (*déchets de produits pharmaceutiques et déchets médicaux pointus ou tranchants*)

"retailer" means a person who sells or offers for sale pharmaceutical products or medical sharps in the Province to a consumer. (*détaillant*)

"return facility" means a collection facility that accepts pharmaceutical product and medical sharp waste from persons who wish to return it, and that is identified as a collection facility in an approved pharmaceutical products and medical sharps stewardship plan. (*point de récupération*)

Pharmaceutical products and medical sharps as designated materials

50.71 Pharmaceutical products and medical sharps are designated materials for the purposes of section 22.1 of the Act.

Restriction on supply of pharmaceutical products and medical sharps

50.72 No brand owner shall sell, offer for sale or distribute pharmaceutical products or medical sharps to a person in the Province unless the brand owner is registered with the Board.

Submission of pharmaceutical products and medical sharps stewardship plan

50.73(1) With its application for registration under this Regulation, a brand owner shall submit a pharmaceutical products and medical sharps stewardship plan for approval by the Board.

50.73(2) A stewardship plan shall apply to the manufacture, storage, collection, transportation, processing or other handling of pharmaceutical products and medical sharps that are sold, offered for sale or distributed within the Province.

Designation of agent

50.74 A brand owner may designate an agent to act on behalf of the brand owner with respect to the brand owner's obligations under this Regulation.

Transitional provisions respecting registration

50.75(1) A brand owner who is selling, offering for sale or distributing pharmaceutical products or medical sharps within the Province immediately before the commencement of

this section shall submit an application for registration within 120 days after the commencement of this section.

50.75(2) A brand owner referred to in subsection (1) is not required to submit a pharmaceutical products and medical sharps stewardship plan with the application for registration, but shall ensure that a stewardship plan is submitted no later than 180 days after the date of commencement of this section.

50.75(3) A brand owner shall implement the stewardship plan referred to in subsection (2) within 180 days after the stewardship plan is approved by the Board.

50.75(4) Despite section 50.72, a brand owner referred to in subsection (1) may continue selling, offering for sale or distributing pharmaceutical products and medical sharps within the Province until the Board renders its decision in respect of the brand owner's application for registration.

50.75(5) If the Board refuses to register a brand owner referred to in subsection (1), the brand owner shall cease selling, offering for sale or distributing pharmaceutical products and medical sharps immediately on receiving notice of the Board's decision to refuse the application.

Contents of pharmaceutical products and medical sharps stewardship plan

50.76 A pharmaceutical products and medical sharps stewardship plan shall contain the following:

(a) the plan for the collection, transportation, storage and processing of pharmaceutical product and medical sharp waste within the Province, including the pharmaceutical product and medical sharp waste of other brand owners;

(b) information on the expected quantity or weight of pharmaceutical products and medical sharps, by material type, to be distributed within the Province and the expected quantity or weight of pharmaceutical product and medical sharp waste, by material type, to be collected or processed;

(c) information on the province-wide collection system, including information with respect to return facilities, by material type, to be used by the consumer;

(d) a description of how existing collection and processing systems were considered to maximize waste diversion in the Province;

(e) the geographical areas that will be used for annual reporting purposes;

(f) the plan for the provision of services to remote or rural areas;

(g) the plan for the management of pharmaceutical product and medical sharp waste, by material type, in adherence to the following order of preference:

(i) recycling;

(ii) recovery of energy; and

(iii) disposal in compliance with the Act;

(h) information on current and future research and development activities in the Province related to the management of pharmaceutical products and medical sharps;

(i) the communications plan to inform consumers of the stewardship plan, including the consumer's reasonable and free access to collection methods;

(j) the location of any long-term storage, containment or final treatment and processing facilities for pharmaceutical products and medical sharps;

(k) a description of how pharmaceutical product and medical sharp waste will be managed, by material type, in a manner that employs environmental, human health and safety standards that meet or are more strict than applicable laws;

(l) the plan for the elimination or reduction of the environmental impacts of pharmaceutical product and medical sharp waste, by material type;

(m) a description of greenhouse gas emission impacts that will result from the implementation of the stewardship plan and opportunities for reducing those impacts;

(n) a description of the material types that will be used for performance measures and targets and annual reporting purposes; and

(o) a dispute resolution procedure to deal with disputes arising between the brand owner and a service provider.

Approval or imposition of pharmaceutical products and medical sharps stewardship plan

50.77(1) As soon as after a pharmaceutical products and medical sharps stewardship plan has been submitted to the Board, the Board shall

(a) approve the stewardship plan for a period of time not to exceed five years, or

(b) reject the stewardship plan with written reasons.

50.77(2) If the Board rejects a pharmaceutical products and medical sharps stewardship plan, the Board may require the brand owner to

(a) comply with a stewardship plan prepared and approved by the Board, or

(b) resubmit a stewardship plan within the period of time specified by the Board.

50.77(3) The Board may refuse to register or may suspend the registration of a brand owner if the brand owner does not submit a stewardship plan within the period of time specified by the Board under paragraph (2)(b).

50.77(4) A stewardship plan referred to in paragraph (2)(a) expires on the date set by the Board, but the period of time for which the stewardship plan is to be effective shall not exceed five years.

50.77(5) If the Board rejects a stewardship plan submitted by a brand owner and does not act under subsection (2), the Board shall refuse to register the brand owner or shall suspend or cancel the registration of the brand owner.

Compliance with pharmaceutical products and medical sharps stewardship plan

50.78 A brand owner shall implement and comply with the pharmaceutical products and medical sharps stewardship plan as approved or imposed by the Board under section 50.77.

Renewal of pharmaceutical products and medical sharps stewardship plan

50.79(1) At least 90 days before the expiry date of a pharmaceutical products and medical sharps stewardship plan approved or imposed by the Board, a brand owner shall submit a stewardship plan to the Board for review and approval.

50.79(2) Sections 50.76 to 50.78 apply with the necessary modifications to a stewardship plan submitted under this section.

Amendment of pharmaceutical products and medical sharps stewardship plan

50.8(1) The Board may amend an approved or imposed pharmaceutical products and medical sharps stewardship plan

(a) to correct a clerical error,

(b) to reflect a change in the name or address of a brand owner, or

(c) on the request of the brand owner.

50.8(2) A brand owner may at any time apply to have its stewardship plan amended and sections 50.76 to 50.78 apply with the necessary modifications to the application.

Performance measures and targets

50.81(1) Within two years after the approval or imposition of the initial pharmaceutical products and medical sharps stewardship plan by the Board and in each subsequent stewardship plan, a brand owner shall submit for approval to the Board one or more performance measures, by material type, used to assess the goals and objectives of the brand owner's stewardship plan as well as the targets, by material type, set by the brand owner for each of the performance measures.

50.81(2) When the information with respect to performance measures and targets has been submitted to the Board under subsection (1), the Board shall, as soon as practicable,

(a) approve the performance measures and targets, by material type, or

(b) reject the performance measures and targets, by material type, with reasons.

50.81(3) If the Board rejects the performance measures and targets, the Board may require the brand owner to

(a) comply with performance measures and targets, by material type, prepared and approved by the Board, or

(b) resubmit performance measures and targets, by material type, within the period of time specified by the Board.

50.81(4) The Board may suspend the registration of a brand owner if the brand owner does not submit performance measures and targets, by material type, within the period of time specified under paragraph (3)(b).

50.81(5) If the Board rejects the performance measures and targets, by material type, submitted by a brand owner and does not act under subsection (3), the Board shall suspend or cancel the registration of the brand owner.

Annual report and other information

50.82(1) On or before April 30 in each year, a brand owner shall provide the Board with an annual report detailing the effectiveness of the pharmaceutical products and medical sharps stewardship plan during the previous calendar year including, but not limited to, the following:

(a) the total amount of pharmaceutical product and medical sharp waste, by material type,

(i) collected within the Province, and

(ii) collected within the geographical areas specified in the stewardship plan,

(b) the total amount of pharmaceutical product and medical sharp waste, by material type, processed or in storage;

(c) the amount and percentage of pharmaceutical product and medical sharp waste, by material type, collected that was recycled, recovered for energy, contained, or otherwise treated or disposed of;

(d) a description of the types of processes utilized to recycle, recover energy from, contain, or otherwise treat or dispose of, pharmaceutical product and medical sharp waste, by material type;

(e) a description of collection methods used and, if applicable, the location of return facilities;

(f) the location of any processing or containment facilities for pharmaceutical product and medical sharp waste;

(g) the types of consumer information, educational materials and strategies adopted by the brand owner;

(h) the annual financial statements, as prepared by an independent auditor, of the revenues received and the expenditures incurred by the stewardship plan;

(i) an assessment of the performance of the brand owner's stewardship plan that is prepared by an independent auditor; and

(j) any other information requested by the Board that relates to the stewardship plan.

50.82(2) Subject to subsection (3), at the same time a brand owner submits its annual report, it shall provide to the Board a statement in writing as to the total amount of pharma-

ceutical products and medical sharps, by material type, distributed by it during the previous calendar year or during a period of time approved by the Board.

50.82(3) If a report referred to in subsection (1) or a statement referred to in subsection (2) is submitted by an agent referred to in section 50.74, the report or statement and distribution information shall include only the aggregate information of all of the brand owners represented by the agent.

50.82(4) The information provided under subsection (2) to the Board by a brand owner who is not represented by an agent referred to in section 50.74 shall be treated as confidential.

Consumer information

50.83(1) On request, a brand owner shall provide to each retailer of its pharmaceutical products and medical sharps, educational and consumer material that informs consumers with respect to

(a) the brand owner's pharmaceutical products and medical sharps stewardship plan,

(b) access to return facilities, and

(c) the environmental, economic, health and safety benefits of participating in the pharmaceutical products and medical sharps stewardship program.

50.83(2) A brand owner shall not release any educational and consumer material referred to in subsection (1) unless the material has been submitted to the Board at least one month before its intended release.

50.83(3) Subsection (2) applies with the necessary modifications to any changes proposed to be made to the information supplied in the material referred to in subsection (1).

Passing on of costs

50.84(1) Subject to subsection (2), a brand owner or a retailer, on behalf of a brand owner, may recover from the consumer costs associated with implementing or operating a pharmaceutical products and medical sharps stewardship plan, or costs associated with supplying material under section 50.83.

50.84(2) A brand owner or a retailer who recovers costs under subsection (1) shall integrate those costs

(a) into a total advertised sales price of a pharmaceutical product or medical sharp, and

(b) into the sales price of the pharmaceutical product or medical sharp on the receipt of sale.

50.84(3) A brand owner or a retailer is not prohibited from informing the public that the price of a pharmaceutical product or medical sharp includes costs recovered under subsection (1) and communicating those costs to the public.

Fees

50.85(1) The Board may charge a brand owner a fee established by the Board to cover the Board's annual administrative costs in carrying out its duties under the Act and this Regulation in relation to pharmaceutical products and medical sharps.

50.85(2) The annual administrative costs include office, operational and inspection expenses and the cost of salaries, benefits and expenses of members and employees of the Board that are attributable to the Board's duties referred to in subsection (1).

50.85(3) The annual administrative costs of the Board incurred or to be incurred by it, together with any sum needed to make up any deficiency in the assessment for the preceding year, shall be borne equally by each brand owner.

50.85(4) The Board shall assess up to one-half of the amount established in subsection (1) on or before April 1 of the fiscal year in respect of which the costs are incurred, and assess the remaining amount after December 1 of that fiscal year.

Remittance of fees, imposition of interest and penalties

50.86(1) A brand owner shall remit the fees provided for in section 50.85 at the times and in the manner directed by the Board.

50.86(2) If the Board is satisfied that a brand owner has not remitted fees fully in accordance with subsection (1), the Board may serve written notice on the brand owner requiring payment of the following amounts:

(a) the full amount of the fees that are outstanding;

(b) interest on the amount of the outstanding fees calculated monthly at a rate not exceeding 2% per month; and

(c) a penalty in an amount established by the Board, which shall not exceed the amount of the outstanding fees.

50.86(3) A written notice under subsection (2) shall include the time and manner in which the payments required under that subsection are to be made.

50.86(4) A brand owner served with a written notice under subsection (2) shall pay the amounts set out in the notice in accordance with the notice.

50.86(5) All fees, interest and penalties that are not paid to the Board in accordance with a written notice constitute a debt due to the Board.

50.86(6) The Board may, under the signature of the proper officer, issue a certificate setting out the name of a brand owner who has not paid fees, interest or penalties in accordance with a written notice and certifying the total amounts of the fees, interest or penalties remaining unpaid, and the certificate, without proof of the appointment, authority or signature of the person purporting to have signed it, is admissible in evidence and is, in the absence of evidence to the contrary, proof of the amount of the fees, interest and penalties remaining unpaid.

Use of fees, interest and penalties

50.87 The Board shall use the fees, interest and penalties remitted to it or paid to it under this Part solely to meet its purposes in relation to pharmaceutical products and medical sharps as established under the Act and this Regulation and for no other purpose.