Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act: SOR/2018-133

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TOBACCO AND VAPING PRODUCTS ACT

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Her Excellency the Governor General in Council, on the recommendation of the Minister of Health, pursuant to subsection 42.2(1) [a] of the *Tobacco and Vaping Products Act* [b], makes the annexed *Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act*.

Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act

Interpretation

Definitions

1 (1) The following definitions apply in these Regulations.

Act means the *Tobacco and Vaping Products Act*. (*Loi*)

medical device has the same meaning as in section 1 of the *Medical Devices Regulations*. (*instrument médical*)

natural health product has the same meaning as in section 1 of the *Natural Health Products Regulations*. (*produit de santé naturel*)

non-prescription drug means a drug for human use that meets all of the following criteria:

(a) it is neither set out in the prescription drug list, as amended from time to time, established under subsection 29.1(1) of the *Food and Drugs Act*, nor is part of a class of drugs that is set out in it;
(b) it does not contain a *controlled substance*, as defined in subsection 2(1) of the *Controlled Drugs and Substances Act*, the sale or provision of which is authorized under that Act; and
(c) it has been assigned a drug identification number under subsection C.01.014.2(1) of the *Food and Drug Regulations*. (*drogue vendue sans ordonnance*)

Interpretation

(2) For the purposes of these Regulations, the expressions *drug*, *label*, *package* and *sell* have the same meanings as in section 2 of the *Food and Drugs Act*.

Non-application

Tobacco and Vaping Products Act

2 The Act does not apply in respect of the following that are vaping products:

(a) the following products that do not contain nicotine:
(i) a non-prescription drug, or a natural health product in respect of which a product licence has been issued under section 7 of the *Natural Health Products Regulations*, that is administered by a facial steamer or mask,
(ii) a non-prescription drug that is authorized to be sold for the treatment of respiratory illness or its symptoms, and
(iii) a natural health product in respect of which a product licence has been issued under section 7 of the *Natural Health Products Regulations* and that is authorized to be sold for the treatment of respiratory illness or its symptoms;
(b) a natural health product that is authorized for sale under Part 4 of the *Natural Health Products Regulations*;
(c) a drug that is authorized for sale under Division 5 or 7 of Part C of the *Food and Drug Regulations*;
(d) a drug that is authorized for importation under subsection C.10.001(2) of the *Food and Drug Regulations* or whose sale is exempt, under subsection C.10.002(1) of those Regulations, from the provisions of those Regulations;
(e) a drug that was sold under subsection C.08.011(1) of the *Food and Drug Regulations*;
(f) a medical device that was sold under section 43.5 of the *Medical Devices Regulations*;
(g) a medical device in respect of which an authorization has been issued under subsection 72(1) or 83(1) of the *Medical Devices Regulations*; and
(h) cannabis and marihuana referred to in sections 2 and 3, respectively, of the *Cannabis Exemption (Food and Drugs Act) Regulations*.

Non-prescription drugs and natural health products

3 The provisions of the Act — other than section 30.71 — do not apply in respect of a vaping product that is a non-prescription drug, or a natural health product in respect of which a product licence has been issued under section 7 of the *Natural Health Products Regulations*, that meets all of the following criteria:

(a) it is administered to the body by means of a medical device other than an *active device*, as defined in section 1 of the *Medical Devices Regulations*;
(b) its administration to the body does not depend on a source of energy other than energy generated by the human body or gravity, such as heat, pressure, chemical reaction, magnetism or elastic energy;

(c) no reasonable grounds exist to believe that its appearance, shape or other sensory attribute or function could make the product appealing to young persons; and
(d) its package and labels do not display an indication or illustration, including a brand element, for which there are reasonable grounds to believe that the indication or illustration could be appealing to young persons.

Licensed medical devices

4 (1) The provisions of the Act — other than those provided for in subsection 13(1) of the Act — do not apply in respect of a vaping product that is a licensed medical device.

Associated products

(2) Despite subsection (1), in the case where certain provisions of the Act do not apply to a vaping product that is a drug that has been assigned a drug identification number under subsection C.01.014.2 (1) of the *Food and Drug Regulations*, or that is a natural health product in respect of which a product licence has been issued under section 7 of the *Natural Health Products Regulations*, those same provisions of the Act do not apply in respect of a vaping product that is a licensed medical device whose license authorizes its sale for use with the drug or natural health product.

Exception

(3) Subsections (1) and (2) do not apply to a licensed medical device that meets either or both of the following criteria:

(a) reasonable grounds exist to believe that its appearance, shape or other sensory attribute or function could make the product appealing to young persons;
(b) its package or labels display an indication or illustration, including a brand element, for which there are reasonable grounds to believe that the indication or illustration could be appealing to young persons.

Definition of *licensed medical device*

(4) In this section, ***licensed medical device*** means a medical device in respect of which a licence has been issued under subsection 36(1) of the *Medical Devices Regulations*.

Prescription vaping products

5 The provisions of the Act — other than those provided for in subsection 13(1) of the Act — do not apply in respect of a prescription vaping product that has been assigned a drug identification number under subsection C.01.014.2(1) of the *Food and Drug Regulations*.

Non-prescription drugs and natural health products

6 (1) Sections 7.21, 7.22 and 30.47 and paragraph 30.5(a) of the Act do not apply in respect of a vaping product that is a non-prescription drug or a natural health product in respect of which a product licence has been issued under section 7 of the *Natural Health Products Regulations*.

Exception

(2) Subsection (1) does not apply to a non-prescription drug or natural health product referred to in, as the case may be, paragraph 2(a) or section 3.

Name of manufacturer

7 (1) Subsections 30.3(1) and (2) and section 30.4 of the Act do not apply in respect of, as the case may be, the promotion, use or display of the name of the manufacturer of a vaping product — in respect of which one of the following has been assigned or issued — in the case where the

manufacturer does not sell or advertise a vaping product that is manufactured, sold or represented for a purpose other than for use in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings:

(a) a drug identification number assigned for a drug under subsection C.01.014.2(1) of the *Food and Drug Regulations*;
(b) a licence issued in respect of a medical device under subsection 36(1) of the *Medical Devices Regulations*; or
(c) a product licence issued in respect of a natural health product under section 7 of the *Natural Health Products Regulations*.

Definition of *manufacturer*

(2) In subsection (1), ***manufacturer*** has the meaning assigned by the following provisions, as the case may be:

(a) in respect of a drug, by section A.01.010 of the *Food and Drug Regulations*;
(b) in respect of a medical device, by section 1 of the *Medical Devices Regulations*; or
(c) in respect of a natural health product, by subsection 1(1) of the *Natural Health Products Regulations*.

Coming Into Force

Registration

8 These Regulations come into force on the day on which they are registered.

N.B. The Regulatory Impact Analysis Statement for these Regulations appears following SOR/2018-132, Regulations Amending the Food and Drug Regulations and the Natural Health Products Regulations (Vaping Products). (sor-dors132-eng.html)

Footnotes

a S.C. 2018, c. 9, s. 53

b S.C. 1997, c. 13; S.C. 2018, c. 9, s. 2

Government of Canada activities and initiatives

#YourBudget2018 – Advancement

(https://www.budget.gc.ca/2018/docs/themes/advancement-advancement-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Advancement&utm_campaign=CAbdgt18)
Advancing our shared values

#YourBudget2018 – Reconciliation

(https://www.budget.gc.ca/2018/docs/themes/reconciliation-reconciliation-en.html?utm_source=CanCa&utm_medium=%20Activities_e&utm_content=Reconciliation&utm_campaign=CAbdgt18)
Advancing reconciliation with Indigenous Peoples

#YourBudget2018 – Progress

(https://www.budget.gc.ca/2018/docs/themes/progress-progres-en.html?utm_source=CanCa&utm_medium=Activities_e&utm_content=Progress&utm_campaign=CAbdgt18)
Supporting Canada's researchers to build a more innovative economy