NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Canada **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Department of Health**Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:** Canada’s Notification Authority and Enquiry PointGlobal Affairs CanadaTechnical Barriers and Regulations Division 111 Sussex Drive, Ottawa, ON K1A 0G2Canada Telephone: (343)203-4273Fax: (613)943-0346E-mail: enquirypoint@international.gc.ca |
| **3.** | **Notified under Article 2.9.2 [X], 2.10.1 [****], 5.6.2 [****], 5.7.1 [****], other:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Prescription Drugs, Natural Health Products, Non-Prescription Drugs, Medical Devices (ICS: 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act Regulations Amending the Food and Drug Regulations and the Natural Health Products Regulations (Vaping Products) (22 pages, available in English and French)   |
| **6.** | **Description of content:** Health Canada has put forward new regulations to exclude certain health products from the application of all or parts of the *Tobacco and Vaping Products Act* (TVPA) when they are not associated with TVPA risks, such as inducement to smoking and nicotine addiction. The new regulations seek to ensure that the application of the TVPA and the *Food and Drugs Act* (FDA) and their regulations on vaping products regulated under the FDA is representative of their associated harms while achieving the purposes of the TVPA. The new regulations also extend existing requirements for child-resistant packaging under the *Food and Drug Regulations* to any drug or natural health product (NHP) that contains nicotine and to which the TVPA applies. The new regulations also require warning statements on the labels that the drug should be kept out of the reach of children and that there is enough nicotine in the package to seriously harm a child. These requirements do not extend to prescription drugs, NHPs or non-prescription drugs, or medical devices that are excluded from the TVPA under the new regulations. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objective of the *Regulations Excluding Certain Vaping Products Regulated Under the Food and Drugs Act from the Application of the Tobacco and Vaping Products Act* (the Regulations) and the *Regulations Amending the Food and Drug Regulations and the Natural Health Products Regulations (Vaping Products)*  is to ensure that the application of the TVPA and the FDA and their regulations on vaping products regulated under the FDA is representative of their associated harms while achieving the purposes of the TVPA. |
| **8.** | **Relevant documents:** * *Canada Gazette*, Part II, 11 July 2018, pages 2433-2454 (available in English and French)
 |
| **9.** | **Proposed date of adoption:** Not stated **Proposed date of entry into force:** The Regulations come into force upon registration, with the exception of the new child-resistant packaging and labelling requirements for nicotine-containing vaping products. Those requirements will come into force six months after registration. |
| **10.** | **Final date for comments:** Not applicable (Published in Canada Gazette Part II on 11 July 2018 with exemption from Pre-publication in Canada Gazette Part I)  |
| **11.** | **Texts available from: National enquiry point [****X] or address, telephone and fax numbers and email and website addresses, if available, of other body:** The electronic version of the regulatory text can be downloaded at: <http://www.gazette.gc.ca/rp-pr/p2/2018/2018-07-11/html/sor-dors133-eng.html><http://www.gazette.gc.ca/rp-pr/p2/2018/2018-07-11/html/sor-dors133-fra.html><http://www.gazette.gc.ca/rp-pr/p2/2018/2018-07-11/html/sor-dors132-eng.html><http://www.gazette.gc.ca/rp-pr/p2/2018/2018-07-11/html/sor-dors132-fra.html> |