



4 June 2019

(19-3829)

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Committee on Technical Barriers to Trade

Original: English/French

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>CANADA</u> 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 Point Global Affairs Canada Technical Barriers and Regulations Division 111 Sussex Drive, Ottawa, ON K1A 0G2 Canada Telephone: (343)203-4273 Fax: (613)943-0346 E-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): Drug Products – Prescription and Non-prescription; Medical devices products; Veterinary drugs (ICS: 11.120, 11.220)
5. Title, number of pages and language(s) of the notified document: Fees in Respect of Drugs and Medical Devices Order (90 pages, available in English and French) and Regulations Amending and Repealing Certain Regulations Made Under the Financial Administration Act (8 pages, available in English and French)
6. Description of content: Health Canada is embarking on a process to modernize its cost recovery regime for health products. The Budget Implementation Act, 2017 amended the Food and Drugs Act to provide Health Canada with new authorities to establish an agile cost recovery system capable of supporting regulatory system delivery and transformation, while maintaining transparency and accountability principles. Applicable fee regulations under the Financial Administration Act have been repealed and new fee regulations are established under the Food and Drugs Act. Health Canada has used these new authorities to update and revise existing fees for human drugs, veterinary drugs and medical devices to better reflect costs of program delivery.
7. Objective and rationale, including the nature of urgent problems where applicable: The regulations will revise the fee structure and cost recovery framework for drugs and medical devices to ensure that Health Canada has an agile modernized system that supports effective and responsive service delivery, a fair and consistent approach to

	program funding, while at the same time alleviating the costs of regulatory services on Canadian taxpayers.
8. Relevant documents: <ul style="list-style-type: none"> • <i>Food and Drug Regulations:</i> http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/index.html (English) http://laws-lois.justice.gc.ca/fra/reglements/C.R.C.%2C_ch._870/index.html (French) • <i>Medical Devices Regulations:</i> https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/ (English) https://laws-lois.justice.gc.ca/fra/reglements/DORS-98-282/ (French) • <i>Canada Gazette</i>, Part II, 29 May 2019, pages 1795-1884, 1987-1994 (available in English and French) 	
9. Proposed date of adoption: 29 May 2019 Proposed date of entry into force: 1 April 2020	
10. Final date for comments: Not applicable	
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 proposal can be found at: http://gazette.gc.ca/rp-pr/p2/2019/2019-05-29/html/sor-dors124-eng.html http://gazette.gc.ca/rp-pr/p2/2019/2019-05-29/html/sor-dors124-fra.html http://gazette.gc.ca/rp-pr/p2/2019/2019-05-29/html/sor-dors134-eng.html http://gazette.gc.ca/rp-pr/p2/2019/2019-05-29/html/sor-dors134-fra.html	