NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

|  |  |
| --- | --- |
| **1.** | **Notifying Member:** Canada **If applicable, name of local government involved (Article 3.2 and 7.2):**  |
| **2.** | **Agency responsible:** Health Canada**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 Division111 Sussex DriveOttawa, ON K1A 0G2CanadaTelephone: (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):** Drug products, biologics, and veterinary drugs (ICS:11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulations Amending Certain Regulations Made Under the Food and Drugs Act (Sale of a New Drug for Emergency Treatment) and Regulations Amending Certain Regulations Concerning the Sale of Drugs (Public or Canadian Armed Forces Health Emergencies) (43 pages, available in English and French) |
| **6.** | **Description of content:** The Food and Drug Regulations (FDR) contains emergency provisions, which can be used in certain circumstances to provide Canadians with access to human and veterinary drugs in medical emergencies when the drug is not authorized in Canada.  These provisions are administered through the Special Access Program (SAP), for human drugs and through the Emergency Drug Release Program (EDR) for veterinary drugs.There is a need for the FDR to clearly address the stockpiling of drugs by public health officials and requests for immediate use in a public or military health context. The proposed regulations would provide clarity on the application requirements for public health officials, as well as reporting, record keeping and drug labelling requirements.  Sale of a New Drug for Emergency TreatmentThis regulatory proposal seeks to make amendments to the "Sale of New Drug for Emergency Treatment" provisions in Division 8 of the FDR. The proposed amendments would better reflect current operations and provide enhancements to the current processes administered by Health Canada's SAP and EDR program. Public or Canadian Armed Forces Health Emergencies — Drugs for Immediate Use or StockpilingA proposed new regulatory framework in Division 11 (Public or Canadian Armed Forces Health Emergencies — Drugs for Immediate Use or Stockpiling) would allow public health officials at all levels of government to request a specific quantity of an unauthorized drug in the following two scenarios:1. for immediate use in a military or public health emergency or event or incident; 2. for the purposes of stockpiling in anticipation of a public or military health emergency or event or incident.   |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objective of this proposal is to facilitate access to drugs for Canadians by modernizing the emergency provisions in the FDR to arrive at less burdensome processes for drugs accessed through the SAP or EDR program; and facilitating access to unauthorized drugs to address public or military health emergencies through an appropriate regulatory mechanism. |
| **8.** | **Relevant documents:** * *Canada Gazette*, Part I, 11 May 2019, pages 1806-1849 (available in English and French)
 |
| **9.** | **Proposed date of adoption:** It is anticipated that these regulations would be adopted 12 months after publication in the Canada Gazette, Part I. **Proposed date of entry into force:** The proposed regulatory amendments would come into force on the day on which the regulations are registered, which is anticipated to be 12 months after Canada Gazette, Part I. |
| **10.** | **Final date for comments:** 19 July 2019 |
| **11.** | **Texts available from: National enquiry point [** **]** **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/p1/2019/2019-05-11/html/reg1-eng.html> <http://www.gazette.gc.ca/rp-pr/p1/2019/2019-05-11/html/reg1-fra.html><http://www.gazette.gc.ca/rp-pr/p1/2019/2019-05-11/html/reg2-eng.html><http://www.gazette.gc.ca/rp-pr/p1/2019/2019-05-11/html/reg2-fra.html> |