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:** 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](mailto: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 (ICS: 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulations amending the Food and Drug Regulations (Improving Access to Generics) (24 pages, available in English and French). |
| **6.** | **Description of content:** The regulatory proposal seeks to address cases where generic drug products sometimes differ from their Canadian Reference Product (CRP) (e.g., a different salt, hydrate, or solvate of the medicinal ingredient), leading to difficulties in determining whether drugs could or could not be approved via the Abbreviated New Drug Submission (ANDS) pathway. In certain cases, in both generic and brand name drugs, it is possible that there is a change in the form of a medicinal ingredient during manufacturing of a drug. This type of change is referred to as an “in-situ change.” In such cases, the form of the medicinal ingredient in the dosage form is different from the form of the “input ingredient” used in the manufacturing process (the active pharmaceutical ingredient). The regulatory proposal also suggests consequential changes to ensure the definition of  ‘new active substance’ remains aligned with the definition of ‘innovative drug’; and, the definition of ”new active substance” in the Fees in Respect of Drugs and Medical Devices Regulations remains aligned with the definition of “innovative drug” in the Food and Drug Regulations (FDR). |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** The objectives of the proposed regulations include the following:   * to improve the access to safe, effective and high quality generic medicines by ensuring that the FDR reflect evolving science and regulatory decision making with respect to what Health Canada considers may be acceptable as an ANDS and for which a declaration of equivalence may be issued by clarifying regulatory requirements under the ANDS pathway for generic drug products that contain different forms (e.g., different salt forms) of the medicinal ingredient in comparison to the CRP, and * to create greater consistency and transparency with respect to the labelling and the identification of the medicinal ingredient for drugs approved under Part C, Division 8 of the FDR by codifying Health Canada’s position that the labelling should declare the medicinal ingredient in the dosage form. |
| **8.** | **Relevant documents:**  *Food and Drug Regulations:*  <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)  *Canada Gazette*, Part I, 30 March 2019, Pages 1283-1306 (available in English and French) |
| **9.** | **Proposed date of adoption:** On the date the amendments are registered, notification of registration will occur through publication in Canada Gazette, Part II, which is anticipated to be 18 months following publication in Canada Gazette, Part I.  **Proposed date of entry into force:** It is proposed these Regulations would come into force 90 days after the day on which they are published in the Canada Gazette, Part II. As a transitional provision, the proposed amended definition of "innovative drug" will not apply to a drug where the New Drug Submission (NDS) or Extraordinary Use New Drug Submission (EUNDS) was filed before the coming into force. Instead, the version of the "innovative drug" definition that was in effect at the time a NDS or EUNDS was filed by the innovator is the version that applies for an "innovative drug". |
| **10.** | **Final date for comments:** 7 June 2019 |
| **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://gazette.gc.ca/rp-pr/p1/2019/2019-03-30/html/reg2-eng.html>  <http://gazette.gc.ca/rp-pr/p1/2019/2019-03-30/html/reg2-fra.html> |