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:** 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 Point Technical Barriers and Regulations Division  Global Affairs Canada 111 Sussex Drive Ottawa, Ontario, K1A 0G2 Canada Telephone: (343)203-4273 Fax: (613)943-0346 Email: [enquirypoint@international.gc.ca](mailto:enquirypoint@international.gc.ca) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****X],** **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):** Drugs; Pharmaceutics (ICS 11.120) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Regulations Amending the Food and Drug Regulations (Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19), 51 pages, (available in English and French) |
| **6.** | **Description of content:** In order to address the immediate COVID-19 public health emergency the Minister of Health made the *Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19* (Interim Order) on 16 September 2020. The Interim Order creates flexibilities in the authorization process, import and distribution of COVID-19 drugs and is valid for 12 months. Upon expiry, all authorizations and licences issued under the IO also expire, unless regulations are brought into place beforehand to ensure Canadians continue to have uninterrupted access to COVID-19 drugs.  The *Regulations Amending the Food and Drug Regulations (Interim Order Respecting the Importation, Sale and Advertising of Drugs for Use in Relation to COVID-19)*,introduce amendments to the *Food and Drug Regulations* (FDR) to incorporate optional flexibilities, related to market authorization, drug establishment licensing, and pre-positioning for COVID-19 drugs, that were available under the Interim Order. Furthermore, they allow for the continued sale of COVID-19 drugs authorized under the Interim Order.  These amendments to the FDR:   * Allow continued and timely access to safe and effective COVID-19 drugs for Canadians by normalizing the review, authorization and oversight of COVID-19 drugs under the FDR; * Enable the sale and advertising of COVID-19 drugs that were authorized under the Interim Order, not including those generic drugs authorized to alleviate shortages, to continue without interruption after the Interim Order ceases to have effect; * Enable new COVID-19 drugs that had not been authorized under the Interim Order, to seek authorization under the FDR with similar flexibilities as had been provided under the Interim Order; * Permit continuity of the post-market regulatory obligations placed on authorization holders, manufacturers and importers after expiration of the Interim Order; * Provide a legal pathway that allows the early importation of a promising COVID-19 drug for placement in Canadian facilities (pre-positioning), for which a Government of Canada contract for its procurement is in place, prior to that drug receiving market authorization in Canada; and * Enable continuity of a flexible approach for Drug Establishment Licenses (DELs) that authorize regulated activities in respect of COVID-19 drugs. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** These amendments to the *Food and Drug Regulations* are necessary to maintain a mechanism by which COVID-19 drugs are accessible to Canadians throughout the ongoing pandemic, while also providing adequate oversight. Furthermore, the regulatory agilities introduced in these amendments minimize burden to industry and reduce trade barriers, facilitating trade.; Protection of human health or safety |
| **8.** | **Relevant documents:**  Health Canada website:  <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/food-drug-regulations-amendments-covid-19.html> (English)  <https://www.canada.ca/fr/sante-canada/services/medicaments-produits-sante/medicaments/demandes-presentations/lignes-directrices/reglement-aliments-drogues-modifications-covid-19.html> (French)  *Canada Gazette*, Part II, Volume 155, 31 March 2021, pages 723 to 773 (available in English and French):  <https://canadagazette.gc.ca/rp-pr/p2/2021/2021-03-31/pdf/g2-15507.pdf> |
| **9.** | **Proposed date of adoption:** 31 March 2021; On the date of publication  **Proposed date of entry into force:** Some of the amendments to the FDR and transitional provisions will come into force upon registration to make the flexibilities accorded to COVID-19 drugs available as soon as possible. The remainder of the amendments and transitional provisions will come into force on the day that the Interim Order ceases to have effect (16 September 2021). |
| **10.** | **Final date for comments:** Non applicable (These regulations have been granted an exemption from publication in Canada Gazette, Part I, and therefore a pre-consultation was not conducted.) |
| **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 found at:  <https://canadagazette.gc.ca/rp-pr/p2/2021/2021-03-31/html/sor-dors45-eng.html>  <https://canadagazette.gc.ca/rp-pr/p2/2021/2021-03-31/html/sor-dors45-fra.html> |