



21 December 2022

(22-9621)

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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 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
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], 3.2 [], 7.2 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Drugs and medical devices (ICS codes: 11.120, 11.040)
5. Title, number of pages and language(s) of the notified document: Regulations Amending Certain Regulations made under the Food and Drugs Act (Agile Licensing); (93 page(s), in English), (93 page(s), in French)
6. Description of content: Health Canada is proposing new targeted provisions and regulatory amendments to the <i>Food and Drug Regulations</i> and <i>Medical Devices Regulations</i> that would deliver on the Department's modernization commitments and leverage long-standing policies and practices. The proposal would take into account recent experience with regulatory agilities successfully piloted through the COVID-19 interim orders and their transition to regulations. This proposal is comprised of distinct components that would: <ul style="list-style-type: none">• Enable the use of terms and conditions on the drug identification number of any drug;• Broaden the scope of use of terms and conditions for Class II, III, and IV medical devices;• Require risk management plans for certain human drugs to manage risks and uncertainties;

- Allow for the option of a rolling review for certain drug submissions, including those for drugs intended to address a public health emergency;
- Extend modified requirements and prepositioning that apply to COVID-19 drugs to other drugs needed to address future public health emergencies;
- Clarify expectations that a drug be fabricated, packaged/labelled, tested and stored, including during transportation, in a manner that assures its quality;
- Modernize requirements for biologics by repealing outdated requirements and replacing them with those that reflect current practices;
- Clarify, in regulation, the authority to consider certain information obtained outside of a new drug submission to support Health Canada's examination of that submission for a new drug;
- Require manufacturers to submit human clinical trial data broken down by population sub-groups (disaggregated data) for new and supplemental human drug submissions, as submitted to the United States Food and Drug Administration or the European Medicines Agency; and
- Update requirements respecting standards for labelling and requirements for those that claim a manufacturer's standard for their drug.

7. Objective and rationale, including the nature of urgent problems where applicable: The objective of this proposal is to contribute to the modernization of the Canadian therapeutic product regulatory system.

The amendments would:

- enable the Minister of Health to better manage risks and uncertainties for a drug or medical device that is authorized for sale;
- facilitate earlier market access for certain drugs, including public health emergency drugs;
- provide clarity to industry and the regulator respecting quality control rules and expectations under good manufacturing processes as well as the types of information and material that may be considered by the Minister in support of the review of a drug submission;
- replace product-specific requirements for biologics with broader, more flexible regulations that would better address advancements in science and technology;
- provide Health Canada with disaggregated data to evaluate the safety and effectiveness of drugs within diverse subpopulations; and
- address long standing concerns from industry respecting labeling of the standard and requirements for certain drugs that claim a manufacturer's standard.

8. Relevant documents:

Canada Gazette, Part I, December 17, 2022, pages 6058-6150, <https://canadagazette.gc.ca/rp-pr/p1/2022/2022-12-17/pdf/g1-15651.pdf#page=38> (available in English and French)

Proposed Guidance Documents:

Consultation on proposed agile regulations and guidance for licensing drugs and medical devices: <https://www.canada.ca/en/health-canada/programs/consultation-proposed-agile-regulations-guidance-licensing-drugs-medical-devices.html> (English)

Consultation sur le projet de règlement agile et des lignes directrices pour l'homologation des médicaments et des instruments médicaux : <https://www.canada.ca/fr/sante-canada/programmes/consultation-projet-reglementation-souple-lignes-directrices-homologation-medicaments-instruments-medicaux.html> (French)

9. Proposed date of adoption: To be determined

Proposed date of entry into force: The proposed regulatory amendments would come into force in accordance with the following:

Immediate coming into force (upon registration, date of adoption):

- Amendments related to public health emergency drugs (including terms and conditions, rolling reviews and pre-positioning);
- Assuring drug quality during manufacturing;
- Modernizing requirements for biologic drugs;
- Information considered to support the examination of drug submissions;
- Disaggregated clinical trial data for new human drug submissions and supplemental new human drug submissions; and
- Standards.

Delayed coming into force (one year following registration):

- Terms and conditions (for all drugs and for Class II, III and IV medical devices);
- Risk management plans; and
- Rolling reviews (for drugs other than public health emergency drugs).

At a time set out in a future regulatory amendment once the Department determines that provisions specific to COVID-19 are no longer required:

- Amending the definition of public health emergency drug to no longer include a new drug for which the purpose or conditions of use recommended by the manufacturer relate to COVID-19; and
- Removing other COVID-19-specific provisions.

10. Final date for comments: 27 March 2023**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/p1/2022/2022-12-17/html/reg1-eng.html> (English)

<https://canadagazette.gc.ca/rp-pr/p1/2022/2022-12-17/html/reg1-fra.html> (French)