NOTIFICATION

Addendum

The following communication, dated 10 June 2022, is being circulated at the request of the delegation of Canada.

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**Title:** Regulations Amending the Food and Drug Regulations (Exports and Transhipments of Drugs)

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| **Reason for Addendum:** | |
| [ ] | Comment period changed - date: |
| [X] | Notified measure adopted - date: 16 May 2022 |
| [X] | Notified measure published - date: 8 June 2022 |
| [X] | Notified measure enters into force - date: 8 December 2022; These regulations come into force six months after the day they are published in the Canada Gazette, Part II. An additional transition period of three months is also included to allow a person who conducts a licensable activity with a drug solely for export to submit an application for a drug establishment licence and come into compliance with the regulations. |
| [X] | Text of final measure available from[[1]](#footnote-1):  <https://www.gazette.gc.ca/rp-pr/p2/2022/2022-06-08/html/sor-dors100-eng.html> (English)  <https://www.gazette.gc.ca/rp-pr/p2/2022/2022-06-08/html/sor-dors100-fra.html> (French) |
| [ ] | Notified measure withdrawn or revoked - date:  Relevant symbol if measure re-notified: |
| [ ] | Content or scope of notified measure changed and text available from1:  New deadline for comments (if applicable): |
| [ ] | Interpretive guidance issued and text available from1: |
| [ ] | Other: |

**Description:** The Proposed Regulations were notified to the WTO under G/TBT/N/CAN/644 (dated 17 June 2021).

The objectives of amendments to the *Food and Drug Regulations* are to improve oversight of drugs manufactured, packaged/labelled, tested, distributed or wholesaled in Canada solely for export and align Canadian regulation of exported drugs with that of international partners. The amendments also aim to clarify requirements respecting drugs transhipped through Canada.

The amendments to the *Food and Drug Regulations* require a person who fabricates, packages/labels, tests, distributes or wholesales a drug solely for export to hold a drug establishment licence and comply with good manufacturing practices. The amendments also clarify that drugs transhipped through Canada must be in bond.

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1. This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained. [↑](#footnote-ref-1)