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New requirements in Canada relating to drug and medical device recalls

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Amendments to the *Food and Drug Regulations* (FDR) and the *Medical Devices Regulations* (MDR) that come into force on December 17, 2024 will establish new reporting requirements and other obligations regarding drug and device recalls in Canada.

What you need to know

- These amendments will introduce new reporting obligations for both voluntary (company-initiated) and mandatory recalls ordered by Health Canada for drugs and medical devices.
  - For voluntary drug and medical device recalls, manufacturers and importers are required to report the recall to Health Canada within 24 hours after making the decision to conduct a recall. However, to align with international standards, manufacturers and importers no longer need to report Type III voluntary medical device recalls to Health Canada.
  - For drug recalls, manufacturers and importers have 72 hours after reporting the commencement of a recall to provide Health Canada with the recall strategy in writing.
- Before customers are notified of the recall, manufacturers and importers will need to provide Health Canada with proposed recall communication materials for review. For recalls ordered by Health Canada, copies of new communications used after the recall may be requested by Health Canada.
- The amendments will come into force on December 17, 2024. It is expected that Health Canada will update its guidance documents on recall management to provide more clarity to industry on the new framework.

Amendments to the *Food and Drug Regulations* relating to recalls

Voluntary recalls

Once the amendments to the FDR are in force, manufacturers and importers of drugs will be required to report the commencement of a voluntary recall to Health Canada within 24 hours after making the decision to recall a product. This report must be made in writing. Health Canada's Recall policy for health products (POL-0016) and the Drug and natural health products recall guide (GUI-0039) included this expectation, which has now been formalized in legislation.

The required information that must be reported to Health Canada includes:

- product-specific information about the affected lots;
- quantity and distribution information of the drug;
- reason for the recall and how the issue was discovered;
- anticipated commencement and conclusion of recall activities; and
- an assessment of whether there is an anticipated disruption in the drug's supply.

Within 72 hours after making the decision to recall a drug, the manufacturer and importer will also have to provide Health Canada with a written report detailing: (1) the recall strategy and (2) the corrective and preventive actions intended to be taken to prevent a recurrence of the issue that led to the recall.

Recalls ordered by Health Canada

Most recalls in Canada are voluntary; however, Health Canada has the authority to order a recall under the *Food and Drugs Act*. Amendments to the FDR create specific requirements for recalls ordered by Health Canada, and include the obligation that the recalling party must notify Health Canada in writing within 24 hours of the start and completion of the recall. The amendments give Health Canada the authority to compel additional information at a time determined by Health Canada, similar to the list of information for voluntary drug recalls described above, including the recall strategy and description of proposed corrective action.

Guidance for both voluntary recalls and recalls ordered by Health Canada

The amended FDR creates a new requirement for the recalling party to provide Health Canada with proposed communication materials that would be distributed to impacted customers before the recall is initiated. The recalling party must provide copies subsequent communications (such as reasonable follow-up efforts) used throughout the recall upon Health Canada's request. There continues to be ambiguity in the amendments regarding when these obligations are triggered. Health Canada has stated that Guide GUI-0039 will be updated to provide more clarity to the "start" and "completion" dates of recalls.

Within 30 days of completion of the recall, the recalling party must provide Health Canada with the results of the recall, and the action(s) taken to prevent a reoccurrence of the issue that led to the recall. Enforcement actions are monitored by Health Canada's Regulatory Operations and Regions Branch, which has a number of enforcement powers under the *Act* to compel or induce recall compliance.

Amendments to the *Medical Devices Regulations* relating to recalls

Reportable voluntary recalls

Amendments to the MDR update the definition of "recall" to encompass both voluntary recalls and recalls ordered by Health Canada. For voluntary medical device recalls, the manufacturer and importer must report to Health Canada in writing within 24 hours of making the decision to commence the recall. Notably, the amendments use the same wording—"decision" to commence—for both devices and drugs recalls. The report must include: (1) the name and identifier of the device, (2) the name and address of the manufacturer, (3) the reason for the recall, and (4) a preliminary assessment of the risk associated with the defectiveness or potential defectiveness of the device.

On or before the day the manufacturer and importer notifies affected customers of the voluntary recall of a medical device, it must provide additional information to Health Canada, including:

- the number of affected units of the device manufactured, imported and sold in Canada;
- a copy of any communications issued regarding the recall;
- the proposed strategy for conducting the recall (including the time and manner in which Health Canada will be informed of the progress of the recall, and the proposed date of the recall completion);
- the proposed action to prevent reoccurrence; and
- the manufacturer's representative and contact information about the recall.

Exceptions for Type III (low risk) recalls

The definition of "recall" in Canada is broader than for ex-Canada jurisdictions. To align with international standards and maintain consistency around the public's perception of safety concerns involving medical devices, the amended MDR will not require manufacturers and importers to report Type III recalls to Health Canada.

Type III recalls occur when the recalled device is unlikely to cause any adverse health consequences, in contrast to Type I (recalls where the device has a reasonable probability of serious adverse health consequences or death) and Type II (recalls where the device may cause temporary adverse health consequences, but where there is not a significant probability of serious adverse health consequences) recalls.

Although low-risk recalls will no longer be required to be reported to Health Canada, record keeping requirements continue to apply to all recalls. This allows Health Canada to verify that the recalling party has properly classified the safety risk and is not under-reporting recall activities.

Recalls ordered by Health Canada

Amendments to the MDR introduce similar requirements for recalls ordered by Health Canada. The recalling party must notify Health Canada in writing within 24 hours of the beginning and completion of the recall. At a time decided by Health Canada, the recalling party must provide Health Canada with additional information, similar to the list of information for voluntary medical device recalls described above.

Unlike for voluntary device recalls, a recalling party ordered by Health Canada must provide Health Canada with a copy of any communications it intends to use *before* beginning the recall, and all additional communications used through the recall period upon request.

Guidance for both voluntary recalls and recalls ordered by Health Canada

For Type I and Type II device recalls, the results of the recall and the action taken to prevent a reoccurrence of the problem must be submitted to Health Canada within 30 days of completing the recall. Amendments to the MDR require recalling parties to keep records of completing the recall so that Health Canada may verify and assess the activities at a later date. The records must detail the rationale for the decision to conduct the recall, the actions taken to recall the device, and the results and completion of the recall. This requirement applies to all three risk recall types. Records must be retained for at least as long as the device is being sold in Canada or the projected useful life of the device plus two years, whichever is longer.

What's next?

The recall amendments to the FDR and MDR will come into force on December 17, 2024. Health Canada has announced that they are expected to update Guide GUI-0039 and GUI-0054 to provide more guidance and clarity on the "start" and "completion" dates of the new reporting requirements.

To discuss these issues, please contact the author(s).