Enhancing oversight: Health Canada's regulatory reform for drug and medical device recalls

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On July 3, 2024, Health Canada published SOR/2024-136 – Regulations Amending the Food and Drug Regulations and the Medical Devices Regulations (Recalls, Establishment Licences and Finished Product Testing) in the *Canada Gazette*. This new regulation amends the *Food and Drug Regulations* (FDR) and the *Medical Device Regulations* (MDR) to update the regulatory framework for recalls and establishment licences of drugs and medical devices, and address innovations in medical technology and emerging challenges such as COVID-19.

The amended regulations will come into force on Dec. 14, 2024, bringing new reporting obligations with respect to drug and medical device recalls in Canada.

What you need to know

The amendments generally increase Health Canada's post-market oversight of drugs and medical devices. Briefly, some of the key changes include:

1. **Updating the definition of "recall" in the MDR:** "Recall" has been expanded beyond voluntary recalls and now includes those ordered by the Minister of Health, thus introducing specific reporting obligations for recalls initiated by Health Canada.
2. **Type III low-risk medical device recalls no longer need to be reported** : Recalls involving medical devices unlikely to cause any adverse health consequences (low-risk) no longer require reporting to Health Canada. Amendments to the MDR now require recalls to be reported based on the level of risk. **Type I recalls** (where the device has a reasonable probability of serious adverse health consequences) and **Type II recalls** (where the device may cause temporary adverse health consequences, but without a significant probability of serious adverse health consequences) are still to be reported. The change better aligns with the reporting obligations of international regulatory agencies.
3. **Strengthen the reporting framework for recalls** : Clear requirements regarding information to be reported to Health Canada and timeframes are now established

for voluntary recalls. Manufacturers and importers must report the following under each of the FDR and MDR for voluntary recalls of drugs and medical devices:

FDR	MDR
Within **24 hours** of making the recall decision specific details must be provided: • lot numbers; • Dates of fabrication/expiration; • Quantity of affected drugs; • Importation and Distribution details; • Assessment of the risk of injury; • Contact information for the manufacturer and importer; • Recall start/end dates; and • Reasons for the recall and how the situation that prompted the recall was discovered.	Within **24 hours** of making the recall decision: • Specific device details; • Nature of defectiveness of the device; • Date on which defectiveness was discovered; • Assessment of the risk of injury; • Contact information for the manufacturer and importer; • Recall reason.
Within **72 hours** of making the recall decision: • Recall strategy and timelines for updating Health Canada; • Proposed measures to prevent a recurrence of the situation that prompted the recall.	On or before the day the recall begins: • Quantity of affected units; • Distribution details; • Recall strategy and start/end dates; • Proposed measures to prevent the recurrence of the situation.
Within **30 days** of completing the recall: • Results of the recall; • Measures that have or will be taken to prevent the recurrence of the situation that prompted the recall.	Within **30 days** of completing the recall: • Results of the recall; • Measures that were taken to prevent the recurrence of the situation.

Under both regulations, all communications that the manufacturer intends to use in connection with the recall must be provided to Health Canada. Similar reporting requirements exist for mandatory recalls ordered by Health Canada. The recalling party must notify Health Canada within 24 hours of the start and completion of the recall. Other reporting obligations described above must be reported in the time and manner specified by Health Canada.

4. **Clarifying the industry ’s record-keeping obligations for device recalls** : The amendments now require manufacturers, distributors, and importers of medical devices to record the details of all recalls (including low-risk) so that Health Canada can verify the details of the recall. These records must include details of the reason for conducting the recall, the actions taken to recall the device, and the outcome of the recall, and must be kept for the longer of the period the device is being sold in Canada or two years beyond its expected useful life.
5. **Granting Health Canada the authority to impose terms and conditions on a Medical Device Establishment Licence (MDEL)** : Health Canada may selectively provide additional oversight of potential risks, which broadens Health Canada’s enforcement tools–beyond a full suspension–in response to any non-compliance by an MDEL holder.
6. **Modernizing the MDEL application** : to reflect current practices, including a requirement to submit contact information to Health Canada.
7. **Creating a list of approved regulatory authorities outside Canada** : Drug establishment licences (DEL) are currently issued when a company demonstrates evidence of compliance with good manufacturing practices (GMP). Compliance with GMP may be demonstrated through inspections by regulatory authorities of countries with a mutual recognition agreement (MRA) with Canada. Amendments will create a continuously updated list of all the regulatory authorities in countries with an MRA. DEL holders can then use inspection results from these authorities, which will lessen the burden on importers and enhance drug availability in Canada.
8. **Offering exemptions from finished product testing** : Certain packagers, labellers, distributors, and importers of radiopharmaceuticals, gene, or cell therapies may be exempted from finished product testing requirements under the FDR.

Key takeaways

The recall amendments require manufacturers and importers of drugs and medical devices to be aware of the new reporting and record-keeping obligations, and precise timeframes when dealing with recalls. Establishment licence holders should also be aware of the amendments that have streamlined the application process and other aspects of their licence.

Our Product Liability Group can help your business navigate this complex area of regulation. If you would like to learn more about the recent regulatory amendments, please contact any of the authors or a member of our Product Liability team.

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