

## Recalls of Medical Devices Requested by Health Canada: The Legal Landscape

Recalls of medical devices in Canada may be initiated voluntarily by a device manufacturer or may be requested by the Health Products and Food Branch Inspectorate (the Inspectorate) of Health Canada. Recalls may be necessary if a device (i) poses a health hazard; (ii) fails to meet claims about its effectiveness or safety; or (iii) fails to meet the requirements of the Food and Drugs Act (the Act) or the Medical Devices Regulations (the Regulations). Although manufacturers are responsible for carrying out recalls, the Inspectorate will monitor their progress and may intervene if necessary.

Recalls are typically requested as a result of information that comes to the Inspectorate's attention and that suggests that a device does not meet the safety and effectiveness requirements of the Act or Regulations. The Inspectorate may conduct a Health Hazard Evaluation (HHE) of the device, which involves gathering, correlating and evaluating all known information on the nature and extent of a possible health risk of the device. The results of the HHE may lead the Inspectorate to request a recall of the device. The evaluation can be conducted without the knowledge of the manufacturer, who may learn of it only when informed of the decision to request a recall. Failure by the manufacturer to comply with the recall request may lead to the Inspectorate's escalating its enforcement activities.

No formal mechanism exists for appealing the Inspectorate's recall decision, but an informal procedure is available. The Inspectorate's Compliance and Enforcement Policy (PoL-0001) states that the Inspectorate has an internal appeal procedure to resolve issues that arise from its decision making. According to the policy, such internal appeals will not compromise the Inspectorate's compliance and enforcement activities, which means that the Inspectorate expects the recall to go ahead during the course of the informal appeal procedure.

The Medical Devices Bureau has indicated that the informal appeal procedure may consist of two steps: first, speaking with the direct manager of the inspector

requesting the recall; second, if the matter remains unresolved, speaking with the manager of the Operational Centre at which the inspector works. If an HHE was conducted, the Inspectorate may have information about alleged defects or risks of the device that are unknown to the manufacturer. Communicating with the Inspectorate may help reveal more about its position and about the HHE. Submitting further safety and effectiveness information to supplement the HHE, or agreeing to regular submissions in the future, might change the Inspectorate's recall decision.

Another means of appealing a recall decision would be to apply for a judicial review of the decision. Applications for judicial review must be made within a specified time frame following issuance of the Inspectorate's decision. Arguably, while the informal appeal procedure is in progress, a final decision has not yet been reached, thereby extending the deadline to request judicial review.

For further information on recalls, see the Inspectorate guidance documents and policies, available on its website at: [www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/medical\\_devices\\_e.html](http://www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate/medical_devices_e.html)



*Michelle Kisluk is a student-at-law and has worked in the Food and Drugs Regulatory Group, in the Toronto office of Torys LLP.*



*Ingrid VanderElst is an associate in the Intellectual Property Group in the Toronto office of Torys LLP. Her practice focuses on food, pharmaceutical, biotechnology and medical device matters.*

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