Regulatory framework of laboratory developed tests: Canada vs U.S.

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Lab-developed tests (LDTs) are diagnostic tests developed and used within a single laboratory. These tests are regularly used in healthcare to detect pathogens or to diagnose disease in patients. In Canada, LDTs are not regulated under the *Medical Device Regulations* and instead rely on provincial and territorial regulation of laboratories. Until very recently, the United States *Food and Drug Administration* (FDA) took a similar approach to LDTs. As of April 29, 2024, all LDTs used in the United States are subject to FDA oversight as medical devices. While there has yet to be any indication that Health Canada intends to mirror the FDA approach, for now, the LDT industry will want to monitor developments closely.

Background

Canadian health care professionals and facilities regularly use LDTs to detect conditions, diseases, and infections in patients. LTDs are a type of "*in vitro* diagnostic test" (IVD), which means that the test occurs in a vessel outside of a living organism (such as a test tube). While some IVDs are created in a lab and sold commercially, LDTs are generally designed, manufactured, and performed within the same laboratory.

LDTs in Canada

Health Canada does not currently regulate LDTs. While all commercially sold IVDs are medical devices and require appropriate licensing under the *Medical Device Regulations*, LDTs are not medical devices. LDTs are viewed as a "health care service" provided by a licensed laboratory. The *Medical Device Regulations* do not regulate the provision of services or the use of medical devices in Canada.

LDTs are instead primarily regulated through provincial and territorial laboratory regulation and accreditation, but these requirements can vary by province/territory. While the Standards Council of Canada released standards in April 2018 for the design, development, and validation of LTDs, these standards are voluntary. Some accreditation bodies have incorporated these standards (for example, the *Institute for Quality Management in Healthcare* which affects Ontario, New Brunswick, and Newfoundland and Labrador).

LDTs in the U.S.

Until recently, the United States took a similar approach to LDTs. LDTs did not require FDA approval if they were developed and used within a single laboratory. In response to an increase in the complexity of the types of LDTs that labs are capable of developing and a perceived increased risk to patients, the FDA decided to regulate LDTs. For example, the FDA identified concerns over some LDTs that lead patients to being over- or under-treated for heart disease, patients with cancer being exposed to inappropriate therapies, and incorrect diagnoses of some rare diseases.

As of April 29, 2024, all *in vitro* diagnostic products, whether they are LDTs or not, are deemed to be medical devices under the *Federal Food, Drug and Cosmetic Act*. The FDA's five stage "phaseout" plan will gradually introduce oversight of IVDs offered as LDTs over the next four years. Although the FDA intends to exercise some discretion when enforcing applicable requirements for some LTDs (*e.g.* forensic tests), LDTs will generally be expected to meet applicable requirements following the four-year period. The phaseout policy will begin on May 6, 2025.

The future of LDTs in Canada

There have been some calls by physicians and researchers for Health Canada to increase oversight of LDTs. Historical regulatory trends suggest that Health Canada could move in a similar direction as the FDA but there is yet no indication of such a change. The industry is encouraged to remain proactive to best prepare for what may lie ahead and to ensure compliance.

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