ADAPTING TO CHANGE: KEY INSIGHTS INTO RECENT MEDICAL DEVICE REGULATORY UPDATES

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During the COVID-19 pandemic, Health Canada's Medical Devices Compliance Program ("**MDCP**") pivoted resources to address urgent needs, such as ventilators and test kits. The pandemic necessitated remote work, impacting how compliance programs were managed. Remote inspections became the norm, with 131 domestic onsite inspections and 41 COVID-related remote inspections conducted.

The pandemic heightened awareness regarding the necessity for swift regulatory responses and placed increased emphasis on post marketing monitoring for safety and performance. Illustrative of this are the proposed regulatory changes by the MDCP which include a 24-hour notification requirement for recalls, updates to recall record retention periods, and, most importantly, the exclusion of type three recalls from mandatory reporting.

Please note that the requirement to provide 24 hour notification is only contained within the guidance issued by Health Canada but will likely be incorporated into the regulation in the near future.

The Good News: Type III Recalls Exempt From Mandatory Reporting.

Traditionally, recalls have been categorized into three types based on the level of risk they pose to consumers' health:

- Type I: Recalls involve products that could cause serious health problems or death.
- Type II: Recalls pertain to products that may cause temporary health problems or pose a slight threat.
- Type III: Recalls include products that are unlikely to cause any adverse health consequences.

The MDCP is proposing to eliminate mandatory reporting of type three recalls. This change would align the reporting requirements in Canada with international standards set by organizations like the International Medical Device Regulators Forum, as well as counterparts such as the United States and the European Union. This change stems from industry stakeholders' concerns about the administrative and reputational burdens associated with these recalls.

Implications for Industry.

Eliminating the requirement to report Type III recalls to Health Canada streamlines the reporting process for industry players. The hope is that by reducing the administrative obligations imposed on industry and Health Canada associated with Type III recalls will lead to increased efficiency in managing safety recalls.

Furthermore, the move aligns Health Canada's regulations with global standards, facilitating smoother collaboration and trade with international partners. This alignment is particularly significant for companies operating in multiple jurisdictions.

Additionally, with Type III recalls no longer being mandatorily reported, Health Canada can concentrate its resources on more critical recalls that pose substantial risks to public health. This strategic shift allows for a more targeted and efficient regulatory response.

While eliminating the mandatory reporting of type III recalls, Health Canada has signalled that it will continue to routinely and proactively inspect companies to ensure compliance with the general requirements relating to importing, advertising, and distributing medical devices. Maintaining meticulous records is essential for Companies to effectively respond to an audit, providing a comprehensive and accurate account of compliance measures.

What does this mean for you?

In today's dynamic and ever-changing regulatory landscape, it is of paramount importance for organizations to stay abreast of the latest developments to ensure that their policies remain compliant. In anticipation of these changes, it is recommended that companies review their existing policies to ensure that they align with the evolving regulatory landscape. Proactively reviewing and revising policies in response to anticipated regulatory changes demonstrates a commitment to staying ahead of the curve and cultivating a resilient and responsible operational framework.

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A Cautionary Note