Health Canada Santé Canada

Health Canada Info Bulletin #1 – Medical Devices

Health Canada regulates the sale, advertising for sale and importation for sale of medical devices under the *Medical Devices Regulations* (the Regulations) of the *Food and Drugs Act* (the Act). The Regulations set out a system for classifying medical devices into one of four classes; Class I representing the lowest risk and Class IV representing the highest risk. The goal of the Regulations is to ensure that medical devices distributed in Canada are safe, effective and meet quality standards.

Health Canada recognizes that it may be challenging to keep up to date with medical devices regulatory decisions, changes and sector developments in general. In the spirit of increased transparency and efficiency, this information bulletin highlights medical devices issues that may be of interest to provincial and territorial health care systems. Subsequent bulletins may be issued if additional topics of interest arise. You are invited to subscribe to the Really Simple Syndication (RSS) feed to obtain links to new Medical Devices information when it is posted online. Questions or concerns regarding this Bulletin should be directed to hc.mdb.enquiries-enquetes.bmm.sc@canada.ca

In this issue:

1. Transition to the Medical Devices Single Audit Program (MDSAP)

The medical devices ecosystem is a rapidly changing economic environment and compliance with multiple jurisdictions' specific certification requirements adds complexity to this system. MDSAP moves us away from a Canada-only certification program (the Canadian Medical Devices Conformity Assessment System (CMDCAS)) to one that is in line with other major markets, like the U.S. and Brazil, using the same ISO standard. This paves the way for Canadian companies to expand their business to other markets while reducing red tape for companies looking to come to Canada.

MDSAP is not a new regulation and does not introduce new requirements for manufacturers – it is changing the way quality management system audits are performed and it continues to be based on ISO 13485. Manufacturers are already complying with these regulatory requirements. As of January 1, 2019, all medical devices manufacturers will have to have completed their MDSAP certification or, at a minimum, begun their transition to MDSAP (this is a requirement for the validity of a medical device licence). Health Canada has implemented mitigation measures to facilitate the transition to MDSAP and announced reductions to audit duration for small-sized manufacturers meeting certain criteria.

The transition to MDSAP is well underway and on track. The decision to transition to MDSAP is a business decision informed by the value of market access to Canada and the costs associated with the transition. Health Canada invites you to pay particular attention to the requirement for medical devices manufacturers to have valid medical device licences in order to have the right to sell their medical devices

in Canada. A complete searchable database of medical devices that are licensed for sale in Canada is available to the public on the MDALL website.

2. Classification and Licensing of High-Level Disinfectants and Sterilants as Medical Devices

Since March 16, 2018, high-level disinfectant and sterilant solutions (including contact lens disinfectants) intended for use on medical devices are classified by Health Canada as Class II medical devices. Manufacturers of market authorized disinfectants and sterilants have until September 2019 (i.e. 18-month transition period during which their authorized products will be allowed to remain on the market) to obtain quality management system (QMS) certificates and medical device licences.

Health care authorities should ensure that relevant stakeholders are made aware of this change as manufacturers of disinfectants and sterilants will require medical device licences as of September 16, 2019 to sell their products.

3. Laboratory Developed Tests

Health Canada regulates the sale, advertising for sale and importation for sale of medical devices such as test kits under the Regulations. Canadian companies and laboratories offering testing using commercially available test kits should be using only licensed medical devices.

However, companies or laboratories offering testing services (using tests referred to as laboratory developed tests, home brew tests, direct to consumer tests) are not regulated by Health Canada. They are regulated under provincial and/or territorial jurisdictions as they are responsible for the delivery and administration of health care services (which includes laboratory services). Provinces and territories may require that testing laboratories be accredited in order to validate a laboratory's competence in testing and conformity to applicable standards. The Standards Council of Canada (SCC) offers internationally recognized accreditation programs for laboratories.

When making decisions on testing services, keep in mind that laboratory developed tests, for use in house, are not subject to review and approval by Health Canada under *the Medical Devices Regulations.* A complete list of medical devices that are licensed for sale in Canada is available to the public at http://www.mdall.ca

4. Open Government – Application programming interface (API) for the Medical Devices Active Licence Listing (MDALL)

An Application Programming Interface (API) is a broad term. In the context of Government of Canada's Data Portal, it refers to internet connected software interfaces that provide access to open data. APIs provide on-demand access to large, timely or complex data allowing developers to mash data from multiple sources and create new views on information through applications or visualizations. In the context of the Open Government initiative, Health Canada developed an API for MDALL. The creation of this API allows any organization to access MDALL via its own IT system. MDALL contains product-specific information on all medical devices that are currently licensed for sale in Canada, or have been licensed in the past. For more information on how to work with open data and APIs, please visit the open government website.