June 8, 2018

INFECTION PREVENTION AND CONTROL CANADA (IPAC CANADA)
CANADIAN ASSOCIATION OF MEDICAL DEVICE REPROCESSING (CAMDR)

Comments on the Health Canada Notice:
Classification and Licensing of High-Level Disinfectants and Sterilants as Medical Devices [March 16, 2018]
https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-classification-licensing-high-level-disinfectants-sterilants.html

1. **Executive Summary of Appropriate Actions regarding Purchase of High-Level Disinfectants (HLDs) or Sterilants for reprocessing of Critical and Semi-critical Medical Devices:**

   Current Consideration:
   Read the *Regulatory Changes Notice* from Health Canada. A review of the relevant documents is provided below.

   Be aware there are changes to the categorization and labelling of HLDs and sterilants used for reprocessing of critical and semi-critical medical devices.

   Interim Considerations *(between March 16,2018 and Sept 16, 2019 when HLDs and Sterilants are classified as Type II Medical Devices)*:
   Be aware either a Drug Identification Number (DIN) or product 'identifier' number will be visible on the product to assist when making decisions about HLD or sterilant purchases for medical device reprocessing. The product identifier or the product name can be used to search the Medical Devices Active Licenses Listing (MDALL), a database of all licensed Class II, III and IV medical devices authorized for sale in Canada.

   Future Considerations *(when Health Canada changes the Medical Device Regulation and HLDs and Sterilants are classified as Type III Medical Devices)*:
   Be aware HLDs and sterilants must have an 'identifier' as well as a 'control' number when making decisions about HLD or sterilant (classified as a Class III medical device) purchases

for medical device reprocessing. Assurance of product authorization by Health Canada can be done by using the MDALL to verify a medical device license (MDL) is active.

2. **Overview of Background Related to this Change:**
   Historically HLDs and sterilants were regulated by the Canadian Food and Drug Regulations[1]. Manufacturers were required to submit supporting evidence for safety and efficacy, which was assessed by Health Canada prior to market authorization. This requirement remains unchanged with product reclassification.

Organizations including IPAC Canada and CAMDR recommended their members always require the DIN from the manufacturer whenever considering purchase of an HLD or sterilant product for use in healthcare.

Recently the regulation of HLDs and sterilants has changed with the Health Canada notification on March 16, 2018 (File number: 18-100650-351)[2].

Health Canada has indicated high level disinfectants and sterilants used on semi-critical and critical medical devices will no longer be regulated under the Food and Drug Regulations (FDR)[1]. Instead, they will be classified as medical devices and regulated under the Medical Devices Regulations (MDR)[2].

As of March 16, 2018, HLDs and sterilants will be categorized as Class II medical devices. However, Health Canada indicated[2] they will ultimately make changes to the Medical Device Regulations[1] so that HLDs and sterilants used on critical and semi-critical medical devices will be categorized as Class III medical devices.

What does this mean to you?
The following questions and answers have been provided to help understand the impact of this change:

Q1: Is this a good change?

Answer: It is the opinion of IPAC Canada and CAMDR (based on the currently available information) this IS a good change, as it will ensure tighter control on the quality and tracking of HLDs and sterilants. Instead of a DIN, all HLDs and sterilants will be deemed Class II medical devices, and as such will be required to have both a "*product name"* and *"identifier"* as defined in the MDR[2]. Furthermore, when the MDR is changed to categorize HLDs and sterilants as Class III medical devices, there will be an additional requirement for a *"control number"* that will allow tracking of all stages from manufacture, through all of quality control, distribution, and sale. This will improve the ability to track exactly where a product was manufactured, how it

was tested, where it was sold, and to whom[3,4] . In the event of a recall, it is critical such tracking is possible (this level of tracking is not currently required for DIN labelled products). Of course, it is important to ensure a device is authorized by Health Canada. Since it is not a requirement that the MDL be printed on a device label (whereas for drugs the DIN is printed on the label), it is necessary to consult the MDALL for confirming that the device is authorized by Health Canada.

Q2: How does this change compare to the requirements for HLDs and sterilants of the Food and Drug Administration in the USA?

Answer: This change is aimed at better aligning the Canadian regulations with those in the USA. It is part of the Canada-United States Regulatory Cooperation Council Work Plan for Medical Devices[2].

Q3: When will these changes show up on products that healthcare purchases?

Answer: Manufacturers of authorized products are given an 18 month transition period (effective from March 16, 2018). New products must be filed as device license applications. Following this transition period, manufacturers will be required to complete an Application for a Class II Medical Device License, including a Quality Management System Certificate and a device label in compliance with the MDR[2].

Q4: What has been revised regarding testing to show efficacy of disinfectants and sterilants[5]?

Answer: The Health Canada guideline for testing efficacy of disinfectants and sterilants[5] was adopted in 2014 and has been revised with an effective date of March 16, 2018. The details ensure standardized data must be generated under "Good Laboratory Practice" to show efficacy, potency, safety, simulated-use testing and in-use testing of HLDs and sterilants. The previous guidance has been modified to reflect the reclassification of disinfectants and sterilants used on semi-critical and critical medical devices from drugs to devices.

Q5: **What will change for currently marketed HLDs and sterilants?**

Answer: For HLDs and sterilants currently being sold with a DIN number, manufacturers will be required to obtain a Class II medical device license, comply with medical device labelling requirements, including product name and identifier. They must also show that the manufacturer of the HLD or sterilant complies with: Guidance Document GD207: Guidance on the Content of ISO 13485 Quality Management System Certificates Issued by Health Canada Recognized Registrars.

Q6: **What will change when HLDs and sterilants for critical and semi-critical medical devices are categorized as Class III medical devices?**

Answer: Manufacturers will be required to obtain a Class III medical device licence and comply with Class III medical device labeling, which includes the requirement for a control number for HLDs and sterilants (in addition to the product name and identifier).

References:

1. **Food and Drug Regulations, Health Canada (2017):** https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/acts-regulations/canada-food-drugs.html

2. **Health Canada Notice (2018)**: Classification and Licensing of High-Level Disinfectants and Sterilants as Medical Devices. Health Canada, released on March 16, 2018, File # 18-100650-351: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/activities/announcements/notice-classification-licensing-high-level-disinfectants-sterilants.html

3. **Medical Device Regulations**: Last amended Feb 13, 2017, current as of March 26, 2018. Published by the Minister of Justice: http://laws-lois.justice.gc.ca

4. **Health Canada Guidance Document (2015):** Guidance for the Labelling of Medical Devices, not including *in vitro* diagnostic devices - Appendices for the Labelling of Soft Contact Lenses, Decorative Contact Lenses, and Menstrual Tampons. Effective date: July 17, 2015: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/guidance-labelling-medical-devices-including-vitro-diagnostic-devices-appendices.html

5. **Health Canada Guidance Document (2018):** Safety and Effectiveness Requirements for High-Level Disinfectants and Sterilants for use on Reusable Semi-Critical and Critical Medical Devices (2018). Health Products and Food Branch (published): https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/disinfectants/safety-efficacy-requirements-high-level-disinfectants-sterilants-use-reusable-semi-critical-critical-medical-devices.html

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