RISK NOTE

Resale of Medical Devices

Health Care Agencies (HCAs) often sell or donate medical devices and should be aware of associated risks.

Medical devices are classified into one of Classes I to IV as set out in the *Medical Devices Regulations (SOR/98-282)1* of the *Food and Drugs Act (the Act),* where Class I represents the lowest risk and Class IV represents the highest risk. Please check which category your device falls into as this will help the HCA determine the applicable regulatory requirements per *the Act.*

Prior to sale/donation in potential re-use situations, ensure the device is not recalled and meets all current regulatory requirements, including labeling requirements in accordance with section 21 of *the Act.* If selling devices with data storage, ensure proper data erasure and privacy security protocols are followed. The manufacturer should be contacted by the HCA to determine if the equipment is still considered marketable for use. If the manufacturer does not recommend continued use, this warning information should be passed along to the potential purchaser, and a decision "not to sell" should be considered by the HCA.

In accordance with the Safety and Effectiveness Requirements found in section 10 of *the Act, "During the projected useful life of a medical device, its characteristics and performance shall not deteriorate under normal use to such a degree that the health or safety of a patient, user or other person is adversely affected."2*

Simply declaring that medical devices are being sold as "parts", (rather than as a used and functioning device) would be insufficient to provide immunity from the statutory requirements of *the Act*. For these reasons we recommend the exercise of caution before selling any device as “parts” and check with Health Canada Medical Devices Division.

Additionally, this type of disclaimer, may in fact not coincide with the actual facts of the sale. Section 21 of *the Act* provides specific labelling requirements to ensure a device in not sold in a manner that is false, misleading or deceptive or is likely to create an erroneous impression

1 https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/
2 https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-2.html#h-1021426

regarding its design, construction, intended use, character, values, merit or safety.

It is therefore critical to obtain a waiver from the purchaser and retain any correspondence included with the purchase. The waiver should explicitly exclude any warranty and transfer all obligations for reconditioning and assuring fitness for use to the new owner. Where a standard applies, ideally it should be appended to the transfer material. If there is any doubt as to what is the current standard, the Medical Devices division of Drug & Health Products, Health Canada should be contacted.

Waivers and limits to warranty are important in any type of disposal or sale situation. Ideally the HCA should also seek indemnification from the purchaser from any/all claims, costs and penalties arising from further sale/re-use of equipment.

If the purchaser is a broker of medical devices or the piece of equipment is taken in a trade in by a manufacturer (other than the original supplier), the sophistication of these types of purchasers gives the HCA some comfort with respect to the brokers/manufacturers abilities to assess and refurbish the equipment prior to their re-sale. However, the HCA should still be obtaining comprehensive waivers in this situation. The HCA should make no representations about the device and get agreement that the purchaser will check and refurbish the device prior to re-sale. The HCA should obtain an indemnity for any and all claims/penalties/costs arising from the further re-sale/re-use of the equipment by the manufacturer/broker. The best alternative would be to return the device to the original manufacturer for credit.

In the case of re-sale/donation to a third party with little or no knowledge of the potential device risks (e.g. charitable groups, etc.), the equipment should be checked to ensure compliance with any applicable standards per *the Act* and that it is reasonably fit for use on the day of sale. The HCA should also obtain a waiver with a suitable hold harmless clause and make no warranty for fitness for use after the third party takes possession.

In a direct distribution situation to either another HCA or a physician and depending on the degree of sophistication of the purchaser, the HCA should assure that the device is reasonably fit for use as of the day of sale. Again, an absolute waiver with indemnity and hold harmless clauses is essential. There should also be assurances that the purchaser will check the device after installation and prior to use.

In summary, it is recommended that the HCA:

- Assess suitability of medical devices for re-sale/donation in accordance with *the Act*;
- Document the "intent" and limits of the sale in all cases
- Perform a risk assessment;
- Craft waivers/hold harmless clauses and indemnities accordingly;

- Have legal counsel review these agreements;
- Exercise due diligence by contacting the Medical Devices Division of Health Canada.

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