

Dental Supplies — Confirm Your Source

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A situation exists in Canada today that is undermining your ability to treat patients with complete confidence in the dental products you use — the sale of products to Canadian dentists by unauthorized companies.

Products sold through these unauthorized companies may in fact be “versions” of licensed products, manufactured for distribution outside of North America and then rerouted. In this situation, the products may not meet standards established for Canada and may not be covered by a Canadian medical device license. This license is mandatory for the legal sale of medical and dental goods in Canada. Furthermore, such products will not have been evaluated according to the high standards used for evaluation of products licensed by Health Canada (and sold through authorized channels) and therefore will not carry the same assurance of safety and effectiveness.

In fact, it is a requirement of the Medical Devices Regulations, Section 27, Paragraph b) that “no person shall advertise a[n unlicensed] Class II, III or IV medical device for the purpose of sale unless... b) the advertisement is placed only in a catalogue that includes a clear and visible warning that the devices advertised in the catalogue may not have been licensed in accordance with Canadian law.”

Even if the product is licensed, and obtained by an unauthorized supplier by some other means, you would likely have only limited recourse if the product failed in clinical use, because your supplier will not have a relationship with the manufacturer (the actual Health Canada licensee), who in turn will have lost control of the transit and efficacy of its product.

Indeed it is a challenge to control product quality and consistency when “grey market” products (health care products being distributed through unauthorized channels) are being sold in the marketplace. And the challenge will become even greater as new technological advances by e-business providers create a broader range of purchasing alternatives.

For many purchases made through unauthorized suppliers, the procurement price is more attractive than the manufacturer’s suggested retail price or the published price of authorized distributors. However, you should pause if you are tempted to make purchase decisions on the basis of price alone, remembering that price is a one-time factor, whereas real cost is a lifetime circumstance.

We are all stakeholders in the process. The manufacturers invest substantially to ensure that their product or products are in compliance with the Medical Devices Regulations. The manufacturers then choose to sell directly to the dental profession, or they appoint a dealer channel for distribution. Those selecting the dealer channel mindfully evaluate their distribution partners, measuring the selected companies’ ability to ensure that the products are labelled, stored, picked, packed and shipped in compliance with their direction, and that effective distribution records and procedures for handling complaints are in place and are being followed. In fact, these latter are requirements of the Medical Devices Regulations.

The distributor, in turn, goes to extensive and expensive lengths to ensure that goods in its care are handled according to the manufacturer’s guidelines. This step is critical, because product performance may be compromised if these conditions are not met.

The dental practitioner plays the most critical role by determining that the products they use can deliver safe, quality patient care and by ensuring that any “bargain” they are receiving is not the result of avoiding the costs of regulatory compliance.

These processes have been set in place to protect you and your patients. If Canadian dentists use products that are not compliant with Canada’s Medical Devices Regulations, they may be positioning themselves for future liability, especially if licensing information is readily available from industry or government sources, or obtained and merely ignored.

If you are uncertain whether your dental supplies are coming from an authorized channel, contact the

manufacturer directly. The sales representatives of companies who sell devices and materials in Canada should be able to provide you with evidence of compliance on request.

For more information, contact your provincial dental association or the Health Canada hotline at (800) 267-9675.

Give yourself the security of knowing you have purchased from an authorized channel. Reduce the risk! Confirm your source! ➤

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