

Talking Ethics



Grey Markets: Do You Need to Be Concerned?

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Dental supplies are regulated products under the Food and Drugs Act and Medical Devices Regulations. When a company wishes to sell products from a specific manufacturer, and the manufacturer will not authorize them to sell those products, the company will often obtain the products through other means and sell them anyway. The marketplace for such unauthorized products is commonly referred to as the “grey market.”

Generally, almost any dental product that is sold in quantity (toothbrushes, fluorides, sealants, polishing pastes, composites, cements, etc.) may be sold on the grey market. Small equipment, like ultrasonic scalers that have not been certified by CSA or other equivalent standards, may also be found on the grey market. The sale of products on the grey market may involve lesser violations such as improper shipping, storage, and handling or more serious offenses including alterations to products and packaging and, in some cases, outright counterfeiting. Unregulated products (non-dental) that are nothing more than “grey”; that is, obtained from a source that is not in the manufacturer’s distribution chain, do not pose a risk to consumers and are not necessarily illegal, although their existence may compromise the manufacturer’s trademark.

According to CDHA’s biennial Job Market and Employment Survey, most dental hygienists report having an influence on the products that are purchased by the office where they are employed. However, they may not be the person who decides from where the products are purchased. As a result, dental hygienists are advised to check for the following:

1. Are the medical devices licensed by Health Canada?
2. Are they licensed in their packaging?
3. Do the drugs have a Drug Identification Number (DIN)?

4. Did the company where it was purchased have a valid Establishment License?
5. Did the product that was actually received in the practice meet with these requirements?
6. Products display license information on packaging. Defaced products and packaging, repackaged products, missing or defaced labelling, missing or defaced lot numbers and expiry dates, and labelling not in English and French are indications that the products may not be licensed for sale in Canada, and may in fact be counterfeit.
7. Does the equipment in the practice comply with CSA or equivalent standards for their province?

Legitimate manufacturers are now moving to the next step. Next generation products are now being developed for specific markets, so they cannot be brought back into North America without the package and/or the product or both being counterfeited.

In addition, the Dental Industry Association of Canada (DIAC) is currently lobbying Health Canada to become more aggressive in monitoring products that are being illegally imported and sold in Canada, particularly since the Protecting Canadians from Unsafe Drugs Act (Vanessa’s Law)—a law that would amend the Food and Drugs Act—is set to impose substantially greater penalties.

In the meantime, DIAC and CDHA suggest that dental hygienists take a proactive approach in their practice when receiving new products. Scrutinize the packaging carefully, raise questions about the source of products at staff meetings, and advocate for an office policy requiring that materials and equipment be purchased from known vendors.