

Talking Ethics

Counterfeit and Non-Compliant Dental Products an Increasing Issue: How Much Do You Know About the Products You Use Every Day?

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As dental hygienists, you should take time to get to know the source of products and materials used in your practice. Too often price dictates buying decisions. Everyone is looking for a good deal, but do you really know the product you are using and understand the support system behind the product? What would happen if an adverse client event took place?

To help protect clients, Health Canada governs the sale of dental products in Canada by requiring all manufacturers to license their Class II to IV products and (bilingual) packaging.

Distributors and dealers must have a medical device establishment licence that permits them to sell only licensed products. How can you determine if the product or

organization is licensed? If you are concerned about who you purchased the product from, you can search the active licensing registry through the Health Canada Medical Device Active Licence Listing: health-products.canada.ca/mdall-limh/

Licensed distributors work with manufacturers to ensure not only that the goods they sell are licensed, but also that their shipping, storage, and handling are in compliance with manufacturers' specifications.

Manufacturers and their authorized distributors have a system of controls, which include country-specific branding, serial numbers, bar codes, lot numbers, expiry dates, and product records that allow them to recall or notify Health Canada of an adverse client event, should such notification be necessary. If you are unsure, the manufacturer should be contacted and they will assist with your enquiry. Manufacturers will be happy to send you a picture of their licensed products and packaging.

Unfortunately, the dental products market in Canada has seen increased distribution of many counterfeit and non-compliant products over the last two years of the pandemic, and nowhere is this more prevalent than in the manufacturing and distribution of personal protective equipment (PPE).

It's important to know what you are buying. Counterfeit is an illegal copy of a product whose patent, trademark or copyright is owned by another manufacturer, or not licensed for sale in Canada. But how can you tell what is or is not a legitimate product?




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Counterfeit and Non-Compliant Dental Products...cont'd

To ensure you are reducing risk and maintaining the highest standards of client safety, buy from reputable distributors who partner with manufacturers. Follow this checklist when you receive a product:

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- ☐ Assign one knowledgeable person to check all product purchases when they arrive in the office.
 - ☐ Keep all materials (catalogues, flyers, etc.) used in ordering the product(s) until the product has been checked in, and keep the package until the product has been entirely consumed.
 - ☐ Check each product when it arrives in the office for the following:
 - ☐ a. Is it the same product you ordered?
 - ☐ b. Does it have the same name as advertised?
 - ☐ c. Does it have the same product number?
 - ☐ d. Is it the same package that was advertised?
 - ☐ e. Are the contents the same as advertised?
(Quantity, sizes, shapes, colours, etc.)
 - ☐ Is the package text in English and French?
 - ☐ Have any markings been removed or scratched out?
 - ☐ Is the product in its original package (or in a resealable bag or other substitute container)?
 - ☐ Do the lot number and expiry date on the package match those on the contents?
 - ☐ Does the package or contents have markings that indicate it may have been rerouted (e.g., "India only" or "not for sale in North America")?
 - ☐ Is equipment CSA approved (or equivalent)?

Other resources for your information and protection are available from the following websites:

www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/activities/policy-counterfeit-health-products-0048.html

health.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/problem-reporting/health-product-complaint-form-0317.html