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Grey Goods – Caution Required When Purchasing Dental Materials

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Overview

Trade-marks

Grey Goods

Medical Device Regulations

- A trade-mark is a word, logo or combination thereof that distinguishes the goods and/or services of a business from those of its competitors
- Rights in a trade-mark arise from use of the trade-mark in association with specific goods and services

- Identifier of source
- Indication of quality
- Goodwill established in trade-marks are what make trade-marks valuable
- For some companies, their trade-marks are their most valuable assets

- Common law rights acquired where reputation in trade-mark can be established
- Rights limited to geographical location where reputation can be established
- Action can be taken against competitors who use a confusingly similar trade-mark

- trade-mark laws exist to protect the public
- Consumers have a right not to be confused as to the source of goods and services
- Consumers associate known trade-marks with a certain level of quality
- The use of confusingly similar trade-marks causes confusion as to the source and quality of goods and services

- Registration of trade-mark provides several advantages including Canada-wide protection
- Applications can be filed based on use or proposed use in Canada
- Trade-mark rights are country by country

Registering Trade-marks: Exclusions

Cannot be clearly descriptive or deceptively misdescriptive in the English or French language of the character or quality of the wares or services in association with which it is used or proposed to be used; or of the conditions of or the persons employed in their production or of their place of origin

Registering Trade-marks-Exclusions

- Cannot be primarily or merely the name or the surname of an individual who is living or has died within the preceding 30 years
- Cannot be the name in any language of any of the wares or services in connection with which it is used or proposed to be used
- Cannot be confusingly similar to a registered trade-mark

Adopting a Trade-mark

- Always conduct availability searches
- trade-marks that are less descriptive are stronger
- Descriptive terms are weaker trade-marks
- Kodak and Xerox are examples of terms that have no meaning

Grey goods are goods that are:

- a) labeled with a legitimate trade-mark of a company that is the source of those goods;
- b) imported into a different market than was intended by the trade-mark owner; and
- c) sold there by an unauthorized distributor without the consent of the trade-mark owner.

- Composition of goods vary from market to market due to local preferences
- Toothpastes, soaps and soft drinks are often formulated differently in different countries
- Packaging layout and labeling may be different in different countries

- Often sold at a lower price
- Goods imported from low price jurisdiction not being of the same standard as the goods produced for high price jurisdiction
- Different regulations allow for the same source to sell products of different quality in different markets
- Applies to many industries

- Trade-marked products intended for developing countries may not meet Canadian requirements
- Old stock imported from abroad may sit for long periods of time before being delivered to Canadian market
- The product can end up having a reduced quality as a result of the loss of shelf life



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Grey Goods – Trade-mark Law

- Sale of grey goods in Canada is generally not trade-mark infringement
- Right of first sale generally permits a purchaser to resell legitimate goods bearing a trade-mark anywhere in the world
- Under certain circumstances, sale of grey goods can be prevented under Canadian trade-mark laws – differentiated product

Regulatory Issues

 Dentists should not assume that products bearing the trade-mark of a reputable company have regulatory approval in Canada

Regulatory Issues

- Dental materials implanted in patients are typically classified as Class III or Class IV Medical Devices
- Such material requires regulatory approval from Health Canada before it can be sold in Canada
- Manufacturer must provide information including tests and studies to satisfy Health Canada of the safety, effectiveness and quality of the dental product

Regulatory Issues

- An authorized distributor must obtain an establishment license before distributing an approved medical device in Canada
- Health Canada maintains a list of distributors having a valid establishment license
- Dentists should consult this list to confirm that any distributor with whom she or he deals has a valid establishment license

 Dentists could face prosecution by Health Canada under the Food & Drugs Act if the dental material is not covered by a medical device license or does not emanate from a distributor having an establishment license

Section 20 of the Food & Drugs Act.

20. (1) No person shall label, package, treat, process, sell or advertise any device in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its design, construction, performance, intended use, quantity, character, value, composition, merit or safety.

Section 2 of the Food & Drugs Act.

"sell" includes offer for sale, expose for sale, have in possession for sale and distribute, whether or not the distribution is made for consideration

Section 31 of the Food & Drugs Act.

- 31. Subject to section 31.1, every person who contravenes any of the provisions of this Act or of the regulations made under this Part is guilty of an offence and liable
- (a) on summary conviction for a first offence to a fine not exceeding five hundred dollars or to imprisonment for a term not exceeding three months or to both and, for a subsequent offence, to a fine not exceeding one thousand dollars or to imprisonment for a term not exceeding six months or to both; and
- (b) on conviction on indictment to a fine not exceeding five thousand dollars or to imprisonment for a term not exceeding three years or to both.

- Beyond potential civil liability and disciplinary action by the Royal College of Dental Surgeons, dentists could face prosecution from Health Canada for using unsafe medical devices on patients
- We are not aware of Health Canada having undertaken such prosecutions to date but they have the authority to do so

Summary

It is important for dentists to be diligent in ensuring that:

- i) dental materials purchased for use on patients have a valid medical device license in Canada
- ii) dental materials are only bought from distributors having a valid establishment license in Canada
- iii) they do not rely on the fact that dental materials purchased bear a reputable trade-mark