

Grey Market and Non-Compliant Dental Products

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Context

The dental profession is becoming increasingly aware of the potential harm from using non-compliant, grey and black market dental products. Dental providers are ultimately responsible for providing safe and effective oral healthcare and ensuring that the dental products used on their patients comply with professional specifications, international standards and government regulations.

Substandard dental materials, instruments and devices are potentially dangerous for patients, dentists, providers and users. Products that have been diverted outside of an authorized distribution channel may have changed hands numerous times. They may not have been handled and stored in the required conditions. The diverted products may no longer meet the manufacturer's original specifications or national regulatory requirements. For example, a supplier may purchase products intended for a specific market with less stringent regulations, then import and sell the product in another country outside of the normal distribution channels. The manufacturer may not have intended the product to be sold in another country. The product may not comply with the regulations in the country where it is now being sold.

Products outside of the authorized distribution channels can be improperly stored, repackaged or relabeled with false expiration dates. Some non-compliant products outside the authorized channels continue to be sold long past their real expiration dates and can result in poor clinical outcomes from improper handling, contamination, chemical decomposition and altered physical/mechanical properties. Illegal copies of manufacturers' original, safety-tested products with added counterfeit labels, and false expiration dates do not conform to international standards and regulations.

Scope

This policy statement covers key issues related to the manufacture, distribution, sale and use of dental products. The policy should be considered by FDI National Dental Associations, the dental industry, government regulators and dental professionals. The policy is intended to help ensure dental products are safe for patient care and conform to manufacturers' specifications, international standards and government regulations.

Definitions

- Grey market is sometimes called a parallel market and is the trade of a commodity outside the established distribution channels. Outside distribution and marketing channels are legal but are unintended, unauthorized and uncontrolled by the original manufacturer or distributors.
- Black market is the illegal manufacture, trade or sale of a product.
- Grey market product is a generic term that primarily refers to a product that is traded or sold outside of the manufacturer's authorized distribution channels.

- Black market product is an illegally manufactured, distributed or sold product.
- Counterfeit product is a fake replica of a real product that has value.
- Non-compliant product is a generic term for a black market or grey market product that does not conform to local, national or international regulations. It may be a counterfeit or illegally manufactured, distributed or sold product.^{1,2,3,4}

Principles

FDI supports the appropriate use of safe and effective dental products in oral healthcare. Helping to ensure patient and provider safety minimizes risks, improves oral health outcomes and reinforces the importance of purchasing products that comply with standards and regulations from reputable distributors and suppliers. Selling or purchasing products on the grey market isn't necessarily illegal, but providers and patients may not be receiving what they think they purchased. FDI is also concerned that individuals who are not properly licensed to practice dentistry are able to purchase professional dental products from grey, non-compliant, black and counterfeit market suppliers and/or the internet, for the illegal practice of dentistry.

Policy

FDI urges all dentists and dental team members to understand and be aware of the risks they take by purchasing non-compliant products. FDI recommends that:

- Regulatory agencies develop and enforce policies governing the purchase of dental products to ensure that professional items sold for dental care meet regulatory standards and are restricted to licensed dentists and/or registered dental practices.
- Manufacturers collaborate with industry stakeholders to certify supply-chain integrity. This includes proper labeling of the products to fully include the chemical composition of dental materials.
- Manufacturers support policies to combat the sale and distribution of noncompliant and grey market products with the goal of protecting patient safety.
- FDI National Dental Associations, manufacturers and regulators help to coordinate professional educational programmes for dentists, the dental industry and stakeholders on the risks and pitfalls of purchasing non-compliant and grey market dental products.
- FDI National Dental Associations, manufacturers and regulators reinforce the adoption of ISO standards to ensure that dental products and equipment sold to dentists are of high quality.
- Dental providers and all responsible parties use only regulated and compliant dental products that conform to manufacturers' specifications and international dental standards.
- Dental providers refrain from purchasing non-compliant products.
- Dental providers report suspect materials, instruments and devices to the appropriate regulatory agencies and professional authorities in a timely manner.

Disclaimer

The information in this Policy Statement was based on the best scientific evidence available at the time. It may be interpreted to reflect prevailing cultural sensitivities and socio-economic constraints.

References

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3. Inside Dentistry. Gray Market vs Black Market. Vol 7, Issue 4. April 2011. Available from: <https://www.dentalaegis.com/id/2011/04/gray-market-versus-black-market>
4. Santerre P. Conn A. Teitelbaum B. Toronto Academy of Dentistry winter clinic panel discussion on grey market and counterfeit dental materials. *J Can Dent Assoc*2008; 74(3): 233-235.