

Understanding Grey Market and Non-Compliant Dental Products: What Dentists Should Know

Dental practices are increasingly navigating cost pressures while striving to maintain high standards of patient care. In this environment, discounted dental products promoted through non-traditional sales channels may appear attractive. However, some of these products may be non-compliant or lack authorized traceability (grey market), which may present a significant risk to the dental professional and patient. This should be an important consideration for dental professionals when sourcing supplies or servicing equipment.

What Are Grey Market Dental Products?

A grey-market dental product is a legitimate branded product that has been diverted from the manufacturer's authorized distribution channel, sold without manufacturer approval, warranty, or regulatory assurance. These products are often intended for sale in different geographic regions and may be imported and sold in Canada without the manufacturer's authorization.

Grey market products differ from counterfeit or non-compliant black-market products, which are typically unauthorized imitations and may not meet quality or safety standards. However, grey market products may still present risks because they are not always traceable and/or screened and/or required to meet Canadian regulatory requirements or distribution standards.

What are Non-Compliant Dental products?

These are medical devices, natural health products, and drug products that are brought to the Canadian market through illegitimate unauthorized channels and have not been tested or approved for use in Canada. Often these can be variations of legitimate, authorized or approved Canadian products, including similar or the same brand trade names but lacking specific testing or claims.

Why Are Grey Market Products Less Expensive?

Grey market products are often priced lower due to:

- Variations in regulatory and compliance requirements
- Lower distribution and support costs
- Products intended for regions with different economic conditions
- Short-dated or returned product
- Differences in pricing structures across global markets

While lower prices can be appealing, the total value of a product extends beyond its purchase cost.

Potential Risks and Considerations

Regulatory Compliance

Dental products sold in Canada must meet Health Canada regulatory requirements. Products sourced through unauthorized channels may not fully comply with Canadian licensing, labelling, or documentation requirements. This can create compliance challenges for dental practices.

Storage and Handling

Authorized distributors follow strict standards for transportation, storage, and environmental controls. Products entering Canada through unauthorized channels may not have been stored or transported according to the manufacturer or regulatory specifications, which can affect product performance and safety.

Product Traceability and Recalls

Authorized supply chains allow manufacturers and regulators to quickly trace products during safety alerts or recalls. Grey market products may be more difficult to track, potentially limiting access to recall notifications or safety updates.

Warranty and Technical Support

Manufacturers may restrict warranties, training, and technical support for products purchased outside authorized distribution networks. This can impact troubleshooting, equipment servicing, and product replacement.

Patient Safety and Clinical Performance

Variations in packaging, formulation, or instructions may exist for products designed for different global markets. These differences may influence product performance, infection control protocols, or clinical outcomes.

Best Practices for Dentists

Dentists can take several steps to help ensure product quality and regulatory compliance:

- Verify authorized distributors through manufacturer websites or by contacting manufacturers directly
- Review product packaging and labelling carefully
- Maintain documentation of product sourcing and purchase records
- Ask suppliers about storage, transportation, and regulatory compliance
- Consult manufacturers or trusted distributors when evaluating unusually low pricing

Cost and Quality

Cost management is an important consideration for dental practices. Working with authorized distributors and manufacturers can often provide opportunities to discuss pricing, bulk purchasing options, or alternative product solutions while maintaining confidence in product quality and compliance.

Supporting Safe and Reliable Dental Care

Reliable supply chains play an important role in maintaining patient safety, regulatory compliance, and clinical effectiveness. By understanding the potential risks associated with grey market products, dental professionals can make informed purchasing decisions that support both practice operations and high standards of patient care.