



## FDI DRAFT POLICY STATEMENT

### Grey Market and Non-Compliant Dental Products

Submitted for adoption by the FDI General Assembly:  
September 2016, Poznan, Poland

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#### CONTEXT

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

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

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

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#### SCOPE

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

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#### DEFINITIONS

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- 37 • Grey market is sometimes called a parallel market and is the trade of a commodity  
38 outside the established distribution channels. Outside distribution and marketing  
channels are legal but are unintended, unauthorized and uncontrolled by the



- 39 original manufacturer or distributors.
- 40 • Black market is the illegal manufacture, trade or sale of a product.
  - 41 • Grey market product is a generic term that primarily refers to a product that is
  - 42 traded or sold outside of the manufacturer's authorized distribution channels.
  - 43 • Black market product is an illegally manufactured, distributed or sold product.
  - 44 • Counterfeit product is a fake replica of a real product that has value.
  - 45 • Non-compliant product is a generic term for a black market or grey market product
  - 46 that does not conform to local, national or international regulations. It may be a
  - 47 counterfeit or illegally manufactured, distributed or sold product. <sup>1,2,3,4.</sup>

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## 49 **PRINCIPLES**

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

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## 60 **POLICY**

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

- 63 • Regulatory agencies develop and enforce policies governing the purchase of
- 64 dental products to ensure that professional items sold for dental care meet
- 65 regulatory standards and are restricted to licensed dentists and/or registered
- 66 dental practices.
- 67 • Manufacturers collaborate with industry stakeholders to certify supply chain
- 68 integrity. This includes proper labeling of the products to fully include the chemical
- 69 composition of dental materials.
- 70 • Manufacturers support policies to combat the sale and distribution of non-
- 71 compliant and grey market products with the goal of protecting patient safety.
- 72 • National Dental Associations, manufacturers and regulators help to coordinate
- 73 professional educational programmes for dentists, the dental industry and
- 74 stakeholders on the risks and pitfalls of purchasing non-compliant and grey market
- 75 dental products.
- 76 • National dental associations, manufacturers and regulators reinforce the adoption
- 77 of ISO standards to ensure that dental products and equipment sold to dentists are
- 78 of high quality.
- 79 • Dental providers and all responsible parties use only regulated and compliant
- 80 dental products that conform to manufacturers' specifications and international
- 81 dental standards.
- 82 • Dental providers refrain from purchasing non-compliant products.



- 83 • Dental providers report suspect materials, instruments and devices to the  
84 appropriate regulatory agencies and professional authorities in a timely manner.  
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86 **DISCLAIMER**

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

90 **REFERENCES**

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