Policy Statement 6.12 – Medical Devices in Dentistry

Position Summary

The ADA supports cost effective supply of dental materials and devices while ensuring they are safe to use and appropriately regulated. Medical Device Production Systems should have the ability to use any appropriate/approved dental material.

1. Background

1.1. The fitting and intra-oral adjustment of dental devices is part of the practice of dentistry.

1.2. Dental devices include not only removable prostheses but also fixed direct and indirect restorations.

1.3. Australian dental laboratories are regulated by the business constraints of Commonwealth, state and local government legislation. These regulations address occupational health and safety, infection control, quality of materials used and waste management.

1.4. All medical devices used in dentistry, whether manufactured in Australia or overseas, must comply with the requirements of the Therapeutic Goods Administration (TGA).

1.5. Australian Governments support free-trade agreements and universal application of competition policy.

1.6. The TGA regulates the standards of dental materials, instruments and equipment, mostly recognising standards of the International Organization for Standardization (ISO).

1.7. Onsite fabrication of dental devices in dental practices is becoming more common.

1.8. Refining of the regulatory framework is planned to continue until 2024.

Definitions

1.9. DENTAL PRACTITIONER is a person registered by the Australian Health Practitioner Regulation Agency via the Board to provide dental care.

1.10. MEDICAL DEVICE PRODUCTION SYSTEMS is a collection of the raw materials and main production equipment intended to be used by a healthcare provider, or healthcare facility, to produce a specific type of medical device at the point of care, for treating their patients.

2. Position

2.1. Dental practitioners have a responsibility to be aware of current legislative requirements for the supply of medical devices.

2.2. Dental laboratories and suppliers have a responsibility to ensure and guarantee that laboratory work complies with the appropriate regulation.

2.3. Medical Device Production Systems (MDPS) should have the ability to use any appropriate/approved dental material.

2.4. Cost-effective dental services require a competitive supply chain.

2.5. As regulators fees have an impact on the cost of dentistry, they should not be so high as to impede the delivery of appropriate care.

2.6. Reduced regulatory fees should apply to items that are imported in small volumes, as they fulfil special needs and broaden treatment options.

Policy Statement 6.12

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