Use of Unapproved Dental Products in Australia: A Warning for Dental Practitioners

Reading time:
MIPS Education
Date created: 11/12/2024

Product and medical device regulation sets important standards that ensure patient safety and maintain the integrity of the dental profession. The recent case of **Dental Board of Australia v Pathmaperuma [2024] ACAT 49** highlights the critical importance of compliance with the requirements of the Therapeutic Goods Administration (TGA) regarding the use of therapeutic goods in Australia.

Background of the Case

The Australian Register of Therapeutic Goods (ARTG) ensures that therapeutic goods meet safety, quality, and efficacy standards before they are supplied in the Australian market. Products not listed on the ARTG cannot legally be marketed or sold as therapeutic goods in Australia. The case involves a dentist who imported and supplied dental products between 2018 and 2021 that were not listed on the ARTG. The products in question included collagen membranes, bone fibres, implants, and implant abutments—all components in common dental procedures. The dentist was investigated by both the TGA and the Dental Board of Australia.

Allegations Against the Dentist

The allegations against the dentist were that the use of unregistered goods constituted a significant departure from professional standards, potentially compromising patient safety. The regulators argued that patients expect their dental providers to use goods that have undergone rigorous evaluation by regulatory authorities, ensuring their safety and effectiveness.

One of the key points raised in the case was the dentist's failure to inform patients about the unregistered nature of the products used in their treatments. This lack of transparency was deemed a "serious matter," as it directly impacted the patients' right to make informed choices about their healthcare.

Additionally, the dentist's records were found to be inadequate, not only in relation to the treatment provided, but also in relation to the consent process. Proper documentation is crucial in dental practice, not only for legal compliance but also for providing continuity of care and ensuring patient safety. In this instance, the shortcomings in record-keeping further compounded the issues at hand.

Mitigating Factors

Despite the serious nature of the allegations, several mitigating factors were considered. First, while the products used by the dentist were not approved for use in Australia, they had received approval from the United States (US) Food and Drug Administration. Second, evidence for the use of the products in clinical practice was supported by research. These two factors were significant, as they indicated that the risk to the public was low, despite not being registered for use in Australia. Third, the dentist had trained in the US and genuinely believed that he was providing best-practice care to his patients. Importantly, there was no evidence to suggest that any patient had been harmed because of the treatments provided.

Outcome of the case

The TGA's investigation into the matter included the seizure of the unapproved items from the dentist's clinic. This resulted in the TGA issuing 20 infringement notices that amounted to an AUD$266,400 fine.

The Dental Board of Australia referred the matter to the ACT Civil and Administrative Tribunal, which imposed conditions on the dentist's registration, requiring him to undertake education on maintaining adequate medical records. The Tribunal also ordered

the dentist to pay the Dental Board's costs.

Together, these sanctions reinforce the financial and professional consequences of failing to comply with regulatory standards.

Conclusion

The case serves as a critical reminder for dental practitioners about the importance of adhering to TGA regulations and maintaining the highest standards of professional conduct. It highlights the essential nature of informed consent, the necessity for adequate record-keeping, and the need for diligence in ensuring that all products used in patient care are appropriately registered and approved.