

ADIA Policy Statement –

Policy	R5 – Medical Device Regulation (Regulatory Enforcement & Infringement Notices)
Statement	That the Therapeutic Goods Administration (TGA) be empowered to use infringement notices in circumstances where a minor infringement of the <i>Therapeutic Goods Act (Cth) 1989</i> is alleged.
Principle/s	The <i>Therapeutic Goods Act (Cth) 1989</i> should contain provisions to deal with both high-level and low-level instances of illegal supply of dental products and other therapeutic products.
Background	<ul style="list-style-type: none"> ▪ The TGA's role is to safeguard and enhance the health of the Australian community through effective and timely regulation of dental products and other therapeutic goods. It does this through the application of the <i>Therapeutic Goods Act (Cth) 1989</i> and subordinate legislation. ▪ The TGA also actively monitors unlawfully supplied products and claims it takes appropriate regulatory action where these are identified. ▪ For serious breaches, the <i>Therapeutic Goods Act (Cth) 1989</i> includes provisions that establish criminal offences and civil liabilities; however, the TGA is less likely to pursue matters that are one-off events, unless non-compliance is a deliberate and a blatant breach of the law and / or there are public health consequences. The consequence is the current regulatory standards are more suited to an individual illegally supplying ten thousand products rather than ten thousand individuals illegally supplying one product. ▪ Regulators in other sectors of Australian society use infringement notices when low-level offences are committed (e.g. traffic fines for low-range speeding offences). Such arrangements would strengthen enforcement of the <i>Therapeutic Goods Act (Cth) 1989</i>. ▪ Although the <i>Therapeutic Goods Act (Cth) 1989</i> does contain provisions that permit the use of infringement notices, arrangements pertaining to support the issuance of an infringement notice are commensurate with the civil penalty provisions under the <i>Therapeutic Goods Act (Cth) 1989</i>, the legal test being proof beyond reasonable doubt that the use of the therapeutic goods would be likely to result in harm or injury to a person. Current arrangements associated with the use of infringement notices are currently irrelevant insofar as low-level breaches are concerned thus amendments are required.
Framework Documents	<ul style="list-style-type: none"> ▪ ADIA Advocacy Agenda ▪ ADIA Stakeholder Engagement Strategy
Engagement & Advocacy Partner/s	<ul style="list-style-type: none"> ▪ <u>Internal:</u> ADIA-DRC Dental Regulation Committee ▪ <u>External:</u> TGA
Currency	ADIA-DRC Endorsement: 28/1/2015 ADIA Board Approval: 18/2/2015 (Reference 1.9.2)



Australian Dental Industry Association Limited
ABN 32 003 314 396

National Office: GPO Box 960, Sydney, NSW, 2001
Government Affairs: GPO Box 1, Canberra, ACT, 2601

e: national.office@adia.org.au www.adia.org.au
t: 1300 943 094 f: 1300 943 794