

COVID-19: (AUSTRALIA) ILLEGAL THERAPEUTIC GOODS ADVERTISING AND COVID-19

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Corporate

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**This information is accurate as of 1.30 pm Wednesday 25 March 2020 and is subject to change as this situation evolves.*

The Therapeutic Goods Administration (TGA) has issued a warning to businesses and consumers about the false and misleading advertising of unregistered therapeutic goods.

In response to a recent rise in advertisements for products (such as air purifiers and vitamins) claiming to 'kill COVID-19', the TGA warns that it will continue to monitor non-compliance with the Therapeutic Goods Advertising Code, particularly in relation to the advertising of any products that claim to "cure" or "prevent" COVID-19.

Following the TGA's announcement, businesses should remember:

THERAPEUTIC CLAIMS MAY RESULT IN YOUR PRODUCTS BEING CONSIDERED THERAPEUTIC GOODS

Any product (even if not ordinarily considered a medicine or medical device) which is advertised to the public as having a therapeutic application – such as curing or preventing viruses or disease – can be considered a "therapeutic good" which must be listed or registered with the TGA on the Australian Register of Therapeutic Goods (ARTG). Depending on the circumstances, selling products which make therapeutic claims without proper listing/registration can attract significant civil or criminal penalties under the *Therapeutic Goods Act 1989* (Cth), including imprisonment of up to five years and/or fines of up to AUD1.05 million for an individual and AUD10.5 million for a body corporate.

In light of the escalation of COVID-19 cases, the TGA is taking a pragmatic approach to issuing exemptions to listing or registering therapeutic goods on the ARTG. Most recently, the TGA issued an emergency exemption to support increased testing needs by allowing COVID-19 diagnostic tests to be immediately supplied to accredited pathology laboratories without requiring those tests to first be included on the ARTG.

ALL THERAPEUTIC GOODS ADVERTISED TO THE GENERAL PUBLIC MUST COMPLY WITH ALL REQUIREMENTS OF THE THERAPEUTIC GOODS ADVERTISING CODE

Businesses should ensure any advertisements:

- include only valid and accurate claims which can be substantiated by evidence
- do not exaggerate product efficacy or performance, and

- do not make any claims that the product is safe or effective in all circumstances (or that the product is a "cure" or "miracle").

Failure to comply with the TGA's advertising requirements may result in criminal and/or civil penalties under the *Therapeutic Goods Act 1989* (Cth) and the Therapeutic Goods Advertising Code. These penalties may include imprisonment of up to five years and fines of up to AUD1.05 million for an individual and AUD10.5 million for a body corporate.

Over the past 12 months the TGA has increased its activity in prosecuting breaches of therapeutic goods advertising requirements, including a recent successful prosecution in the Federal Court which resulted in a \$10 million penalty to a peptides retailer for advertising prescription medication on its website, Facebook and Instagram where such advertisements breached TGA regulatory requirements.

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