

Regulation of Cosmetics in Australia

Stephens Lawyers & Consultants

Introduction

The importation, manufacture, advertising and supply of cosmetics in Australia is highly regulated and complex. Before a cosmetic product or range can be launched in the Australian market – product assessment is required to determine the approvals and registrations required, trade mark and/or patent clearances should be undertaken to minimise the risk of infringing third party intellectual property rights and labelling, packaging and advertising should be reviewed for compliance with the Australian Consumer Law and relevant advertising codes.

The regulation of cosmetics in Australia is administered by three government regulators – the Therapeutic Goods Administration (**TGA**), the Australian Government, Department of Health under the Australian Industrial Chemicals Introduction Scheme (**AICIS**) and the Australian Competition and Consumer Commission (**ACCC**).

Dealing with three regulators adds to the complexity and expense of getting cosmetics to market.

A. Regulatory Bodies/Authorities

1. Therapeutic Goods Administration (TGA)

The TGA is Australia's regulatory authority responsible for the administration of the Therapeutic Goods Act which regulates the marketing and supply of '**therapeutic goods**' - medicines and products that are marketed as having a '**therapeutic effect**'.ⁱ

Cosmetic products that make a '**therapeutic claim**' such as a claim that the cosmetic product will change the way the human body works – i.e. it will have a '**therapeutic effect**' on the bodyⁱⁱ or are declared to be a therapeutic good under the *Therapeutic Good Act*, will be regulated by the TGA as well as the AICIS and ACCC.

An example of a cosmetic being classified as a therapeutic good could be a moisturiser that contains sunscreen and has been stated to have a therapeutic purpose such as protecting the skin from damaging effects of UV radiation.ⁱⁱⁱ

2. Australian Industrial Chemicals Introduction Scheme (AICIS)

AICIS replaced the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) on 1 July 2020.^{iv} AICIS is a regulatory scheme that regulates chemicals that are imported or manufactured (introduced) for '**industrial**' use. AICIS is part of the Australian Government, Department of Health.

The ingredients in cosmetic products, even if they are described as '**natural**', are regulated as industrial chemicals under the *Industrial Chemicals Act 2019* (Cth) and administered under the AICIS.^v

AICIS does not regulate 'therapeutic goods' and does not set or enforce labelling and advertising requirements for cosmetics in Australia.

3. Australian Competition and Consumer Commission (ACCC)

Cosmetic product labelling or product safety is regulated by the ACCC and must be in accordance with the *Consumer Goods (Cosmetics) Information Standard 2020*.^{vi} Further, claims about the product and advertising must not contain false or misleading representations about the product or supplier that contravene Australian Consumer laws.^{vii}

B. What is a 'cosmetic'?

A cosmetic is a product or substance designed to be used on any external part of the body to change its odour or appearance, cleanse it, keep it in good condition or protect it.^{viii}

Is your product a 'cosmetic' or a 'therapeutic good'?

Factors that need to be considered when determining whether the product is a 'cosmetic' or a 'therapeutic good' include:^{ix}

1. The primary use of the product;
2. The ingredients in the product;
3. The claims made about the product;
4. Whether the product has been declared as a 'therapeutic good' under the *Therapeutic Goods Act*.

Cosmetic

If the product is a 'cosmetic' and not a 'therapeutic good', the business that will import, manufacture or supply the cosmetics into Australia must be registered with AICIS before the product can be imported, manufactured or supplied in Australia.^x This allows AICIS to regulate and keep track of people who import or manufacture or supply industrial chemicals in Australia.

Once the business is registered, it will have to use the AICIS tools to assess whether the ingredients can be used in the cosmetic without requiring evaluation by AICIS for safety. Registered businesses also have to comply with all regulatory requirements and submit an annual declaration about all the chemicals that have been imported or manufactured or supplied in Australia.

Therapeutic Good

If the product is a 'therapeutic good' and not a 'cosmetic', the product will need to be registered with the TGA. Under the *Therapeutic Goods Act 1989* (Cth), therapeutic goods must be entered in the Australian Register of Therapeutic Goods (**ARTG**) by a '**sponsor**' before they can be lawfully imported, marketed or supplied in Australia, unless a specific exemption, approval or authority applies.^{xi} The ARTG contains information about the therapeutic good such as the product name, active ingredients, classification if it is a medical device, sponsor and manufacture.^{xii}

The **sponsor** is a person or company who either exports therapeutic goods from Australia, imports or manufactures therapeutic goods in Australia and must be based in Australia.^{xiii} The sponsor is responsible for applying and maintaining the ARTG entry and meeting the regulatory requirements of the Therapeutic Goods legislation.^{xiv}

C. Implications of non-compliance

The failure of a business to register a cosmetic product which is a 'therapeutic good' or a 'cosmetic' with the correct regulatory body can result in contravention of the above regulatory requirements and Australian laws which can lead to a business being fined for the contravention or breach, the product being recalled or other legal action.

For example, in June 2021, a dentist was fined \$5,328.00 for alleged unlawful importation of syringes containing hyaluronic acid that were not included in the ARTG. The cosmetic injections were medical devices used to change how parts of the skin look such as reducing lines and wrinkles on the face.^{xv}

How Stephens Lawyers and Consultants can assist:

Stephens Lawyers & Consultants can assist and provide advice in relation to getting cosmetic products to market in Australia and ongoing regulatory compliance including:

- i. Advice in relation to whether any of the chemicals/ingredients of the cosmetic product require approval on the Australian Industrial Chemicals Introduction Scheme (AICIS) before the cosmetic products can be marketed and used in Australia;
- ii. Trade mark and/or patent clearance searches to minimise the risk of infringement;
- iii. Trade mark registrations for your cosmetic brand;
- iv. Advice in relation to the labelling requirements for cosmetics in Australia and compliance with labelling requirements and the Australian Consumer laws; and
- v. Advice in relation to whether the cosmetic requires Therapeutic Goods Administration (TGA) approval before it can be marketed in Australia. A cosmetic would require approval from the TGA, if a therapeutic claim has been made about the cosmetic.
- vi. Review of advertising and marketing material for compliance with Australian Consumer Law, Therapeutic Goods Act, advertising codes and other relevant laws;
- vii. Responding to notifications received from TGA, ACCC and AICIS in respect of non-compliance;

Disclaimer: This information sheet is not intended to replace obtaining legal advice

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ⁱ TGA, basics <<https://www.tga.gov.au/tga-basics>>

ⁱⁱ TGA, cosmetics <<https://www.tga.gov.au/cosmetics>>

ⁱⁱⁱ TGA, what are Therapeutic Goods, <<https://www.tga.gov.au/what-are-therapeutic-goods>>

^{iv} AICIS, Transition from NICAS to AICIS <<https://www.industrialchemicals.gov.au/transition-from-nicnas-to-aicis>>

^v Ibid.

^{vi} ACCC, Cosmetic Ingredients Labelling <<https://www.productsafety.gov.au/product-safety-laws/safety-standards-bans/mandatory-standards/cosmetics-ingredients-labelling>>

^{vii} Ibid.

^{viii} AICIS, Cosmetics and Soap <<https://www.industrialchemicals.gov.au/cosmetics-and-soap/my-product-cosmetic>>

^{ix} Ibid.

^x AICIS, Basics of Importing and manufacturing chemicals <<https://www.industrialchemicals.gov.au/business/getting-started-registration-importing-and-manufacturing/basics-importing-and-manufacturing-chemicals>>

^{xi} *Therapeutic Goods Act 1989*, s9A

^{xii} Therapeutic Goods Administration, Sponsor, <https://www.tga.gov.au/role-sponsor>

^{xiii} Ibid.

^{xiv} Ibid.

^{xv} TGA, Media Release dated 3 June 2021 <https://www.tga.gov.au/media-release/dentist-fined-5328-alleged-unlawful-importation-injectables>