Regulation of Nutraceuticals in Australia and New Zealand

Rhian B. Cope

Abstract

In the Australian and New Zealand regulatory landscape, nutraceuticals fall at the potentially very complex human food-medicine interface. Both countries have a very complex set of legislation, legislative instruments, regulations, and guidance documents. In addition, multiple different regulatory bodies and agencies may be involved. In Australia, nutraceuticals may also be subjected to various state and territorial legislation and regulatory processes in addition to the Federal system. For the most part, three main regulatory agencies are likely to be involved: the Australian Therapeutic Goods Administration which is part of the Australian Commonwealth Department of Health, the transnational agency Food Standards Australia New Zealand, and Medsafe New Zealand. To organizations that are unused to the Australian and New Zealand systems, the requirements and processes can seem like a Gordian knot. Thus, this chapter hopes to provide an introduction to these regulatory ecosystems and to demystify some of the important concepts.

Keywords

Nutraceuticals · Veterinary nutraceuticals · Regulation in Australia and New Zealand

1 Introduction

Whether or not products at the human food-medicine interface are regulated as foods or medicines in Australia and New Zealand remains a somewhat complex issue. Within Australia, these products potentially fall either under the Australian Therapeutic Goods Act 1989 where they may be evaluated as a complimentary medicine or a medicine. In New Zealand, they may be regarded as a drug, or they may fall under the Dietary Supplements Regulations 1985, which, in turn, falls under the Food Act 2014. However, depending on the health effects claimed, they may potentially be regarded as a "novel food" or a "food for special medical purposes" under the Food Standards Code, administered by the transnational agency Food Standards Australia New Zealand and by a second-tier layer of legislation at the New Zealand and Australian state and territory level. In New Zealand, they could also be classified as a dietary supplement which is regulated under the Dietary Supplements Regulations 1985, which fall under the Food Act 2014. It could also be regulated as a supplemented food as per the New Zealand Food (Supplemented Food) Standard 2016.

As can already be comprehended by reading the above paragraph, the decisions on what laws, regulatory processes, and regulatory standards apply to a specific nutraceuticals product in Australia and New Zealand can be very confusing.

The objective of this chapter is to (hopefully) demystify some of these issues.

2 What Is and Is Not a Therapeutic Good in Australia

In Australia, a product that is ingested (i.e., swallowed) is regulated as either a food or as a therapeutic good (i.e., a medicine, a complementary medicine, or a medical device). The key issues of whether or not a product is a food or a medicine are the nature of the health benefit claims made by the product. Critically, just because a product is ingested by mouth and makes some type of health-based claim does not automatically make it a therapeutic good. Likewise, just because the physical form of the product is "medicine-like" (e.g., a capsule, a tablet, a powder, etc.) also does not

R. B. Cope (✉)
Australian Pesticides and Veterinary Medicines Authority, Armidale, NSW, Australia
e-mail: rhian.Cope@apvma.gov.au

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automatically make it either a therapeutic good, a dietary supplement, or a food.

Therapeutic goods in Australia are regulated by 26 different Acts, Regulations, and Legislative Instruments (!). Within Australia, a therapeutic good is specifically defined in Section 3 of the Therapeutic Goods Act 1989 act as the following:

> therapeutic goods means goods:
>
> (a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:
> (i) for therapeutic use; or
> (ii) for use as an ingredient or component in the manufacture of therapeutic goods; or
> (iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or
> (b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a) (ii) or (iii);
>
> and includes biologicals, medical devices and goods declared to be therapeutic goods

The above is generally interpreted to cover any product for use in humans in connection with:

1. Preventing, diagnosing, curing, or alleviating a disease, ailment, defect, or injury
2. Influencing inhibiting or modifying a physiological process
3. Testing the susceptibility of persons to a disease or ailment
4. Influencing, controlling, or preventing conception
5. Testing for pregnancy
6. Helping protect the skin from the damaging effects of UV radiation

This also includes things that:

1. Are used as an ingredient or component in the manufacture of therapeutic goods
2. Are used to replace or modify of parts of the anatomy
3. Make therapeutic claims on a label or in advertising (including packaging)

The following dichotomous key works through the seven fundamental questions that producers of nutraceuticals for the Australian market need to answer in order to determine where their product falls on the therapeutic good-nutraceutical interface.

1. Is the product for oral use in humans?
   (a) Yes: Go to 2.
   (b) No: The issue of the food-medicine interface does not apply and the product may be a therapeutic good.
2. Has the Secretary of the Australian Commonwealth Department of Health declared that particular goods or classes of goods are therapeutic goods (called a Section 7 Declaration under the Therapeutic Goods Act 1989)?
   (a) Yes: The issue of the food-medicine interface does not apply and the product is a therapeutic good.
   (b) No: Go to 3.
3. Has the Secretary of the Department of Health declared that particular goods or classes of goods are foods (called a Section 7AA declaration under the Therapeutic Goods Act 1989)?
   (a) Yes: The product is not a "therapeutic good." It is likely to be "food" within state/territory food regulation legislation and/or regulated under other state/territory legislation.
   (b) No: Go to 4.
4. Does the product fit into one of the standards in the Food Standards Code (food additive, vitamins and minerals, processing aid, novel foods, etc.; see http://www.foodstandards.gov.au/code/Pages/default.aspx)
   (a) Yes: The product is not a "therapeutic good." It is likely to be "food" within state/territory food regulation legislation and/or regulated under other state/territory legislation.
   (b) No: Go to 5.
5. Does the product have a tradition of use as a food for humans in Australia and the form of the product has not been substantially altered (e.g., not purified, refined, compositionally altered, etc.)?
   (a) Yes: The product is not a "therapeutic good." It is likely to be "food" within state/territory food regulation legislation and/or regulated under other state/territory legislation.
   (b) No: Go to 6.
6. Do any of the following apply: (a) is the product represented in *any way* to be for therapeutic use (is it a therapeutic good or a therapeutic device)?; (b) likely to be *taken for therapeutic use* because of the way that it is presented?; and (c) likely to be *taken for therapeutic use* for any other reason?
   (a) Yes: The product is a therapeutic good and is assessed and regulated as per the Therapeutic Goods Act 1989.
   (b) No: Go to 7.
7. Is the product in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use?
   (a) Yes: The product is a therapeutic good and is assessed and regulated as per the Therapeutic Goods Act 1989.
   (b) No: If it is not a biological or medical device, the product is not a "therapeutic good." It may be "food" within state/territory food regulation legislation.

If the above dichotomous key determines that the product is a therapeutic good, then some specific regulatory consequences apply:

1. The Therapeutic Goods Act 1989 enables the Therapeutic Goods Administration to regulate therapeutic goods that are imported into Australia and/or those which are shipped, transported, or sold across state or territory borders. It does not regulate products that are formulated or compounded within a state or territory that are not shipped, transported, or sold across a national, state, or territory border (e.g., compounded and sold by a practitioner only within a state or territory of Australia, also called extemporaneously compounded). Extemporaneously compounded substances are regulated by state and territory authorities.
2. Therapeutic goods intended solely for the purpose of export are required to be listed (not registered) on the Australian Register of Therapeutic Goods before export is commenced.
3. The Therapeutic Goods Administration may take against the importer, exporter, manufacturer, or supplier if the product is not included in the Australian Register of Therapeutic Goods (ARTG) or is otherwise not exempt or approved under the Therapeutic Goods Act 1989.
4. If the product may be a health risk to the public (e.g., it contains substances that are only available when prescribed by a health professional), the TGA can publish an alert to the public, and if necessary, order a recall of the product.
5. If a product is not a therapeutic good and it is in the ARTG, the TGA can take action under Section 9F of the Therapeutic Goods Act 1989 to remove the product.

3 What is a Complementary Medicine in Australia?

Some classes of nutraceuticals, which meet the definition of a therapeutic good, may be classified as a complementary medicine in Australia. As a general rule, the regulatory rigor applied to complementary medicines is lower than that applied to a medicine or medical device. The pre-market approval evaluations of complementary medicines are typically focused on product safety and manufacturing quality. The standard of evidence to demonstrate efficacy is much lower than that required for a medicine or drug: the focus of the pre-market evaluation is on human safety and manufacturing quality and consistency. They may be listed on the ARTG if certain requirements are met.

A complementary medicine is defined as a therapeutic good consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and each of which has a traditional use. Designated active ingredients may include (but are not limited to):

1. An amino acid
2. Charcoal
3. A choline salt
4. An essential oil
5. A homeopathic preparation
6. A microorganism, whole or extracted, except a vaccine
7. A mineral including a mineral salt and a naturally occurring mineral
8. A mucopolysaccharide
9. Nonhuman animal material (or a synthetically produced substitute for material of that kind) including dried material, bone and cartilage, fats and oils, and other extracts or concentrates
10. A lipid, including an essential fatty acid or phospholipid
11. A substance produced by or obtained from bees, including royal jelly, bee pollen, and propolis
12. A sugar, polysaccharide, or carbohydrate
13. A vitamin or provitamin

Complementary medicines are regulated as per the Australian Regulatory Guidelines for Complementary Medicines (https://www.tga.gov.au/publication/australian-regulatory-guidelines-complementary-medicines-argcm). As discussed above, extemporaneously compounded and dispensed substances may be exempt from Australian Federal Regulation under specific conditions; however, they may be subject to regulation by state and territory authorities.

4 What Is and Is Not a Therapeutic Product in New Zealand and How Are They Regulated?

Therapeutic products and medical devices in New Zealand are potentially regulated by up to 19 different pieces of legislation (!). New or changed medicines and related products that are classifiable as therapeutic products require pre-market evaluation to establish safety, quality, and efficacy as well as being subjected to a post-market assessment process. The term "therapeutic product" is a comprehensive term that is applied to products that are intended to be used in or on humans for a therapeutic purpose as defined by Section 4 of the Medicines Act 1981. A therapeutic product is designed to:

1. Prevent, diagnose, monitor, alleviate, treat, cure, or compensate for a disease, ailment, defect, or injury.
2. Influence, inhibit, or modify a physiological process.
3. Test the susceptibility of persons to a disease or ailment.

4. Influence, control, or prevent conception.
5. Test for pregnancy
6. Investigate, replace, or modify parts of the human anatomy.

Under the New Zealand approach, products are regarded as having a therapeutic purpose if:

1. The product contains one or more ingredient(s) that have a pharmacological action.
2. A therapeutic purpose is claimed for the product (usually on the label or in promotional material).
3. A therapeutic purpose is implied for the product (usually on the label or in promotional material).
4. The product contains a medicine listed in the First Schedule to the Medicines Regulations or a Notice in the New Zealand Gazette issued under Section 106 of the Medicines Act 1981 (unless the product is in a form that cannot be administered to a human being for a therapeutic purpose).

In order for a product not to be regarded as having a therapeutic purpose, the label and promotional material must (at the very least) avoid the following:

1. A trade name that conveys an intended therapeutic purpose
2. Words such as remedy, medicated, or therapeutic
3. Statements that a product will/can/may prevent or treat a disease or condition or give relief from symptoms of a disease or condition
4. Statements of traditional therapeutic use or use by ethnic groups for a therapeutic purpose
5. Directions for use that infer a therapeutic purpose such as "dosing instructions" or instructions to "apply to the affected area"
6. Statements to the effect that the law prevents the supplier from making therapeutic claims that they consider they should be able to make about the product

Critically, nutritional statements (i.e., statements regarding a normal biochemical or nutritional characteristic of a product) are not regarded as therapeutic claims.

Section 2 of the Medicines Act 1981 treats herbal remedies as a subcategory of therapeutic products provided that they do not contain a prescription, restricted or pharmacy-only medical ingredient. To be defined as an herbal remedy, the product must be derived from a plant material that has been dried, crushed, subjected to aqueous or ethanolic extraction, or be a mixture of the plant-derived material with an inert substance.

Section 94 of the Medicines Act 1981 also identifies another class of substances termed "related products." These are products that are primarily foods, dentifrices, or cosmetics that also have a therapeutic purpose. Related products much not contain a prescription, restricted or pharmacy-only medicine ingredient.

In New Zealand, dietary supplements are controlled by the Dietary Supplements Regulations 1985. These products are defined by Regulation 2 as an edible substance, in a controlled dosage form, which is intended to supplement the intake of substances normally derived from food. These substances must not be marketed or promoted for a therapeutic purpose.

5 What is a Novel Food in Australia and New Zealand

Some nutraceuticals that are not therapeutic goods or therapeutic products may be classified as a novel food as per Australia New Zealand Food Standards Code—Standard 1.5.1. Like complementary medicines, these products require pre-market approval before sale and use. Typically, a very extensive and detailed pre-market evaluation is carried out by Food Standards Australia New Zealand, a transnational agency. Additional regulation may occur at the Australian state and territory level or in New Zealand.

A novel food is a substance or proposed food ingredient that has no history of traditional use. The term "no history of traditional use" is specifically defined as follows (https://www.legislation.gov.au/Details/F2017C00324):

> (a) a food that does not have a history of human consumption in Australia or New Zealand; or
> (b) a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or
> (c) any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.
> (d) The presence of a food in a food for special medical purposes or the use of a food as a food for special medical purposes does not constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of this section.

The pre-market evaluation of novel foods in Australia typically involves an in-depth and detailed assessment of the public health and safety considerations having regard to:

1. The potential for adverse effects in humans
2. The composition or structure of the food
3. The process by which the food has been prepared
4. The source from which it is derived
5. Patterns and levels of consumption of the food
6. Any other relevant matters

Typical categories of novel foods may include (a) plants or animals and their components; (b) plant or animal extracts; (c) herbs, including extracts; (d) dietary macro-components; (e) single chemical entities; (f) microorganisms, including probiotics; and (g) foods produced from new sources or by a process not previously applied to food.

6 Concluding Remarks and Future Directions

Taking a helicopter view, the critical issue that must be addressed by a nutraceutical producer in Australia and/or New Zealand is whether or not a therapeutic claim will be made by the product. Although the Australian and New Zealand regulatory landscapes are complex, the first overriding principle in both systems is that if a product makes any sort of therapeutic claim in any form of media (labeling, packaging, promotional, advertising, etc.) regarding the substance, then it will be potentially regulated as a therapeutic good or therapeutic product. The second overriding principle is that if the product contains any drug or pharmaceutical substance (including anything that is chemically related to a drug or pharmaceutical active substance), then it will potentially be regulated as a therapeutic good or therapeutic product. The third overriding principle is that, irrespective of what regulatory category a nutraceutical falls under in Australia and New Zealand, the human safety and quality characteristics of the product remain paramount. Both countries have very substantial legal and regulatory processes for the restriction and/or removal of products that have human safety concerns. If nutraceutical producers have any doubts about the legalities of their products and how they may be regulated, they should contact the Australian Therapeutic Goods Administration, Medsafe New Zealand, or Food Standards Australia New Zealand *before* producing, importing, or marketing their products.

References

Commonwealth of Australia Therapeutic Goods Act 1989. https://www.legislation.gov.au/Series/C2004A03952

Therapeutic Goods Administration Australia. TGA basics. https://www.tga.gov.au/tga-basics

Therapeutic Goods Administration Australia. How therapeutic goods are regulated in Australia. https://www.tga.gov.au/how-therapeutic-goods-are-regulated-australia

Therapeutic Goods Administration Australia. Food-Medicine Interface Guidance Tool (FMIGT). https://www.tga.gov.au/food-medicine-interface-guidance-tool-fmigt

Medsafe New Zealand. Introductory Regulatory Guidance. http://www.medsafe.govt.nz/regulatory/regguidance.asp

Medsafe New Zealand. Categorisation of products. http://www.medsafe.govt.nz/regulatory/categorisation-of-products.asp

The Association of New Zealand Advertisers. Therapeutic advertising pre-vetting service. https://www.anza.co.nz/Category?Action=View&Category_id=262

Food Standards Australia New Zealand. Regulation of novel foods. http://www.foodstandards.gov.au/industry/novel/Pages/default.aspx

Food Standards Australia New Zealand. Guidance tool for determining whether a food is novel or not. http://www.foodstandards.gov.au/industry/novel/documents/Guidance%20Tool%20-%20for%20website%20_2_.pdf

Food Standards Australia New Zealand. Advisory Committee Novel Foods. http://www.foodstandards.gov.au/industry/novel/novelcommittee/Pages/default.aspx