



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration



Regulation of sport supplement products in Australia: important information for importers / sellers

In 2020, the Therapeutic Goods Administration (TGA) amended the [Therapeutic Goods \(Declared Goods\) Order 2019](#) to provide greater clarity on the types of sport supplement products regulated by the TGA. It declares certain sport supplement products to be therapeutic goods where they are represented as being for the improvement or maintenance of physical or mental performance in sport, exercise or recreational activities.

In simple terms, a product is considered a therapeutic good under the *Therapeutic Goods Act 1989* (the Act) if it is legally declared to be one or represented as being for therapeutic use. A product has a therapeutic use if (among other things) it influences, inhibits or modifies a physiological process in the body. Although there are exemptions in the Act for goods with a tradition of use as foods or with applicable food standards, The Declared Goods Order overrules these exemptions.

The Act requires therapeutic goods to be entered in the [Australian Register of Therapeutic Goods](#) (ARTG) before they are imported, manufactured, supplied or advertised in Australia.

If you import, manufacture, supply or advertise sport supplement products for therapeutic use, you are responsible for ensuring compliance with the Act.

How to determine whether a sport supplement product is a therapeutic good

Check the ingredients in the sport supplement product

A sport supplement product for oral consumption is a therapeutic good if:

A. It contains ingredients that are:

- listed or found in a Schedule in the Poisons Standard such as:
 - caffeine dosage of 600 mg or greater daily
 - any prescription-only ingredient such as Deanol (DMEA), Levodopa, Rauwolfia Serpentina, Rauwolfia Vomitoria, Tryptophan (100mg or greater daily), 5-HTP (5-hydroxy-tryptophan), Vincamine, Yohimbine, Noopept (Omberacetam), oxedrine (greater than 30mg daily)
- a 'relevant substance' as defined in the Declared Goods Order
 - being dendrobium (*Dendrobium nobile*) and methyllicberine at the time of publication
- included on The Prohibited List by the World Anti-Doping Agency.
 - substances on this list are prohibited because they have the potential to enhance performance, mask detection of prohibited substances, pose actual or potential risk to athletes, or are not approved for use in humans.
 - **Note:** substances included in the Poisons Standard and WADA Prohibited List may be known by other names. Substances assessed to be chemically equivalent to an ingredient included on one of these lists are also considered to fall within the definition of a therapeutic good.

OR

- B.** It is in the dosage form of a tablet, capsule, or pill (other than those containing glucose only) (from 30 November 2023).



Check whether therapeutic claims are made about the sport supplement product

Making claims or statements on the label or in advertising that might lead a consumer to think a sport supplement product is for therapeutic use could result in the product being regulated as a therapeutic good.

For example, therapeutic claims for sport supplement products may include a description of how it will help, support or improve:

- gaining muscle
- increasing mental focus
- increasing metabolism
- increasing stamina
- preparing for a workout
- recovering from a workout
- modifying hormone levels
 - increasing testosterone levels
 - reducing oestrogen levels
- injury repair
- losing weight or fat.

You must not advertise sport supplement products that are therapeutic goods unless the product is entered in the ARTG. Even if entered in the ARTG, you must only advertise or make claims that are consistent with any requirements listed in the ARTG entry.

How to become compliant

If a sport supplement product is a therapeutic good, it must be entered in the ARTG before it is imported, manufactured, supplied or advertised in Australia.

See the TGA webpage 'Overview of the regulation of listed medicines and registered complementary medicines' for information on how to enter a sport supplement product in the ARTG.

The TGA website has a decision tree to assist you in deciding if your sport supplement product is a therapeutic good.

If you are still unsure, you may wish to engage the services of a regulatory affairs consultant to assist you.

Compliance and enforcement

The TGA undertakes intelligence-led, risk-based compliance and enforcement activities to ensure compliance with the Act.

We routinely review advertisements of sport supplement products and undertake laboratory testing of products sampled from the Australian market to determine the presence of scheduled or prohibited ingredients.

We will take a proportionate regulatory response to identified non-compliance. We have a range of enforcement tools that may be applied ranging from warnings through to issuing fines and applying to the court for criminal and civil penalties.

We encourage you to contact us if you suspect or are concerned that you may have breached one of our laws.

Further information

Therapeutic Goods (Declared Goods) Order 2019

- <https://www.legislation.gov.au/Details/F2023C00272>

Compliance and enforcement hub

- <https://www.tga.gov.au/how-we-regulate/compliance-and-enforcement-hub>

Australian Register of Therapeutic Goods

- <https://www.tga.gov.au/resources/artg>

Poison Standard

- <https://www.tga.gov.au/how-we-regulate/ingredients-and-scheduling-medicines-and-chemicals/poisons-standard-and-scheduling-medicines-and-chemicals/poisons-standard-susmp-0>

FSANZ: foods

- <https://www.foodstandards.gov.au/Pages/default.aspx>

Decision tree

- <https://www.tga.gov.au/resources/my-sports-supplement-therapeutic-good#node-451>

WADA Prohibited List

- <https://www.wada-ama.org/en/prohibited-list>

World Anti-Doping Agency

- <https://www.wada-ama.org/en>

Overview of the regulation of listed medicines and registered complementary medicines

- <https://www.tga.gov.au/resources/resource/guidance/overview-regulation-listed-medicines-and-registered-complementary-medicines>

Regulatory affairs consultant

- <https://www.tga.gov.au/resources/resource/guidance/regulatory-affairs-consultants>