

# Therapeutic Goods Administration classifies sports supplements as therapeutic goods effective 30 November 2020

6 October 2020

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Following a public consultation process in December 2019, a declaration under the *Therapeutic Goods Act 1989 (Cth)*<sup>1</sup> has been published specifying that certain sports supplements will be regulated as therapeutic goods.<sup>2</sup> These changes are scheduled to take effect on **30 November 2020**. Broadly, the declaration provides that sports supplements which contain ingredients that are not acceptable for food (eg. medicinal ingredients) or which are presented in a medicinal form (eg. tablets, capsules or pills) will be regulated in Australia as medicines and will be required to be registered on the Australian Register of Therapeutic Goods (**ARTG**) in order to be promoted and made available for sale in Australia.

Under the declaration, the following goods will be classified as therapeutic goods provided that they are used, advertised or presented for supply for a therapeutic use or in a way that is likely to be taken to be for a therapeutic use:

- goods for oral administration that are represented as being for the improvement or maintenance of physical or mental performance in sport, exercise or recreational activity where the relevant good contains, or is represented as containing:
  - a substance included in a schedule to the Poisons Standard;
  - a substance identified on the Prohibited List by the World Anti-Doping Authority that is added as an ingredient to the goods;
  - a relevant substance that is identified as an ingredient to the goods (i.e. dendrobium (*Dendrobium nobile*) or methylliberine); or
  - a substance with equivalent pharmacological action to a substance mentioned above (including those that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer); and
- from 30 November 2023, goods that are supplied in the dosage form of a tablet, capsule, or pill (other than those goods which contain glucose only).

Therapeutic claims to which the declaration will apply include, but are not limited to, claims regarding:

- gaining muscle;
- increasing mental focus;
- increasing metabolism;
- increasing stamina;

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<sup>1</sup> *Therapeutic Goods (Declared Goods) Amendment (Sports Supplements) Order 2020 (Cth)*.

<sup>2</sup> For background on the declaration, see our previous publication '[TGA proposal to declare various sports supplements are therapeutic goods: submissions close on 3 December 2019](#)'.

- increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels;
- losing weight or fat;
- preparing for workout; and
- recovering from workout.

Sports supplements that contain ingredients which are appropriate for food and are presented as foods will continue to be regulated as foods (such as protein powders, nutrition bars and energy drinks). The declaration will also not apply to any products that do not make therapeutic claims, such as artificial sweeteners and meal replacement shakes. Sports supplements that are compliant with the relevant food standards may continue to make health claims as permitted by the Food Standards Code. As noted in our previous “Insight on this topic, Food Standard 2.9.4 (“Formulated supplementary sports foods”) currently remains under review by Food Standards Australia New Zealand.<sup>3</sup>

After the declaration comes into effect, sports supplements covered by the declaration will be required to be entered in the ARTG (if intended to be marketed as medicines) or will be required to alter their product claims, ingredients and/or dosage forms (if intended to be marketed as foods). Sports supplements which are marketed as medicines will be required to comply with legislative requirements regarding manufacturing, formulation, labelling, evidence and advertising. It will be illegal for retailers to sell sports supplements covered by the declaration without them being included in the ARTG.

The declaration will also have a significant impact on the importation of sports supplements from New Zealand. Generally, the *Trans-Tasman Mutual Recognition Act 1997* (Cth) (**TTMRA**) permitted goods which are lawfully able to be sold in New Zealand to be sold in Australia (save to the extent that they are therapeutic goods). As such, sports supplements which become classified as therapeutic goods as a result of the declaration will no longer be able to rely on the TTMRA and will not be able to enter the Australian market in this way.

We will monitor closely the regulation of sports supplements in Australia once the declaration comes into effect on 30 November 2020.

**Jamie Nettleton** | Partner

D +61 2 8915 3030

E [jamie.nettleton@addisons.com](mailto:jamie.nettleton@addisons.com)

**Tim Clarke** | Special Counsel

D +61 2 8915 3001

E [tim.clarke@addisons.com](mailto:tim.clarke@addisons.com)

**Cate Sendall** | Special Counsel

D +61 2 8915 1027

E [cate.sendall@addisons.com](mailto:cate.sendall@addisons.com)

**Brodie Campbell** | Graduate

D +61 2 8915 0143

E [brodie.campbell@addisons.com](mailto:brodie.campbell@addisons.com)

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<sup>3</sup> See <https://www.foodstandards.gov.au/consumer/nutrition/sportfood/Pages/default.aspx>.



Level 12, 60 Carrington Street  
Sydney NSW 2000 Australia

ABN 55 365 334 124  
Telephone +61 2 8915 1000

[mail@addisons.com](mailto:mail@addisons.com)  
[www.addisons.com](http://www.addisons.com)

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