



Australian Government
Department of Health
Therapeutic Goods Administration

Declaration that certain sports supplements are medicines

Understanding the declaration



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November 2020

Welcome

- This webinar is being **recorded**
- **Slides** will be made available on the **TGA website**
- To ask a question, use the **Q&A** tool located lower left of your screen
 - Messages will only be visible to the moderator and speaker
 - Questions will be answered at the end of the presentation
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Background – sport supplements issues in Australia

- **Serious adverse events** in Australia and internationally associated with use of sports supplements – including deaths, liver transplants, kidney transplants.
- Undeclared **ingredients that are not appropriate for food**.
- **Presentation as medicines** rather than as a food.
- Presence of **substances banned in sport** that are not declared on the label.
- Lack of legal clarity – application of Food Standard 2.9.4 Formulated Supplementary Sports Food

Full background on the TGA website and in the Regulatory Impact Statement:
<https://www.tga.gov.au/changes-regulation-sports-supplements-australia>

Declaration under the *Therapeutic Goods Act 1989*

- Declaration clarifies that certain sports supplements are therapeutic goods (medicines)
- The declaration is in a legislative instrument:
Therapeutic Goods (Declared Goods) Order
- For products to be considered therapeutic goods, **both Column 2 and 3 must be satisfied**

Not just *any* product meeting,
 Column 3 is declared to be a
 therapeutic good

Part 2—Therapeutic goods when used, advertised, or presented for supply in a particular way

Goods that are therapeutic goods when used, advertised, or presented for supply in a particular way		
Column 1	Column 2	Column 3
Item	Goods or classes of goods	Use, advertising or presentation
	<p>goods for oral administration that are represented (expressly or by implication) as being for the improvement or maintenance of physical or mental performance in sport, exercise or recreational activity, and that:</p> <p>(a) contain, or are represented (expressly or by implication) to contain, one or more of the following substances (however described or named):</p> <p>(i) a substance included in a schedule to the current Poisons Standard; or</p> <p>(ii) a substance expressly identified on the Prohibited List that is added as an ingredient to the goods; or</p> <p>(iii) a relevant substance that is added as an ingredient to the goods; or</p> <p>(iv) a substance with equivalent pharmacological action to a substance mentioned in subparagraph (i), (ii) or (iii), including those that may be characterised as an active principle, precursor, derivative, salt, ester, ether or stereoisomer; or</p> <p>(b) on or after 30 November 2023, are supplied in the dosage form of a tablet, capsule or pill, other than those goods containing glucose only</p>	<p>when the goods are used, advertised, or presented for supply:</p> <p>(a) for therapeutic use; or</p> <p>(b) in a way that is likely to be taken to be for therapeutic use;</p> <p>including, but not limited to, one or more of the following therapeutic uses:</p> <p>(c) gaining muscle;</p> <p>(d) increasing mental focus;</p> <p>(e) increasing metabolism;</p> <p>(f) increasing stamina;</p> <p>(g) increasing testosterone levels, reducing oestrogen levels or otherwise modifying hormone levels;</p> <p>(h) losing weight or fat;</p> <p>(i) preparing for workout;</p> <p>(j) recovering from workout</p>

What products are unaffected?

- Sports supplements presented as foods:
 - with ingredients that are appropriate for foods; and
 - which only make health claims compliant with health claims permitted by FSANZ
- A product in the form of a **tablet** or **capsule** that does NOT make any claims regarding improving physical or mental performance in sport, exercise or other recreational activity (e.g. artificial sweeteners, rennet tablets)



What products have been declared to be medicines (in scope)?

- Products that are used, advertised or presented for supply to **improve or maintain physical or mental performance in sport, exercise or other recreational activity** (therapeutic use)
- **AND either:**
 - contain **ingredients*** that are not appropriate for a sports supplement food; **OR**
 - are presented in a form associated with medicines rather than foods (i.e. a **tablet, capsule or pill**)



When does the declaration take effect?

- From **30 November 2020**, products for therapeutic use in sport, exercise or other recreational activity that contain **ingredients** not appropriate for a sports supplement food will be therapeutic goods (medicines) in law
- From **30 November 2023**, products for therapeutic use in sport, exercise or other recreational activity that are presented as **pills, tablets and capsules** will be therapeutic goods (medicines) in law

Can food sports supplements still make health claims relating to performance in sport ?

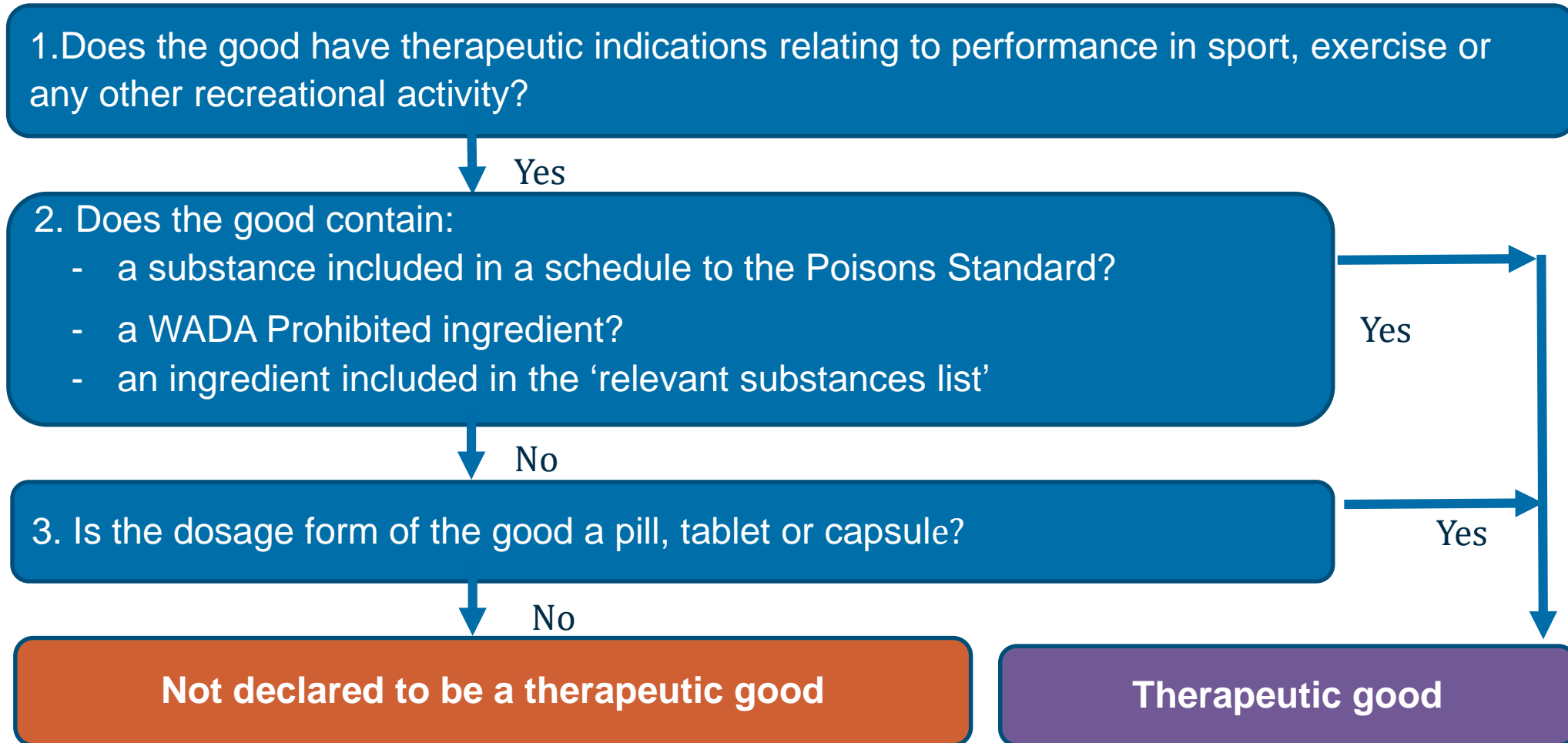
- Yes - foods that are compliant with the relevant food standards can still make the health claims permitted by those standards.
- It is recognised that there is some overlap of the health claims that sports supplement foods and medicines can make.





Understanding the operation of the declaration

Understanding the operation of the declaration



What does it mean for a substance to be ‘included’ in the Poisons Standard?

- A substance is included in the schedule to the Poisons Standard, also known as “scheduled”, if it meets the criteria to be any of the Schedules. That occurs when it is
 - mentioned in a Schedule **and**
 - not specifically exempted or excluded from the Schedule (including by the operation of Part 1(2) and (3)).
- If exemption or exclusion criteria apply to the substance, then the substance is not included in the Schedule.
- This means the Poisons Standard needs to be read in full for each substance, to understand if it is, or is not, “included” in the Schedule (“scheduled”).

What does it mean for a substance to be ‘included’ in the Poisons Standard?

- For example, the substance FOLIC ACID is scheduled if the substance
 - is administered by injection (prescription only medicine) or
 - in a preparation containing more than 500 micrograms (pharmacy only medicine).
- If neither circumstance applies, then FOLIC ACID is unscheduled and may be contained in a multi-vitamin product available for purchase at the supermarket.

What does it mean for a substance to be ‘included’ in the Poisons Standard?

- The declaration includes the term “however described or named” in relation to substances included in the Poisons standard
 - This reflects the degree of variation provided in section 1(2) of the current Poisons Standard (as is appropriate and necessary in the circumstances).
 - The purpose of including this statement is to ensure that sponsors will not be able to refute the presence of a scheduled or prohibited substance on the basis of a naming technicality, for example, naming a pure caffeine ingredient ‘Camellia sinensis concentrated extract’.

World Anti-doping Code (WADC) Prohibited List

- WADC Prohibited substances as ingredients are a safety concern and sports supplements containing these are appropriately regulated as medicines.
- High correlation between substances in the WADC Prohibited list and those included in a schedule to the Poisons Standard.

Implications for products in scope of the declaration

Options for owners of affected products

1. Modify their product, as required, to be regulated as a food:
 - change the product claims
 - change the product formulation
 - change the product dosage form from tablet, capsules or pills
2. List or register their product in the Australian Register of Therapeutic Goods (ARTG) and comply with all relevant regulatory requirements for therapeutic goods
3. Withdraw their product from the market



Who may have obligations under the *Therapeutic Goods Act* from the date of effect?

Sponsors

- *person or company who arranges for, or conducts, the export, import or manufacture for supply*
- Inclusion of the product in the ARTG and other requirements

Manufacturers

- Obtaining TGA licensing or clearance for manufacturing according to GMP

Advertisers

- Compliance with all advertising requirements including the Advertising Code

Therapeutic goods regulation basics:

<https://www.tga.gov.au/industry>

Consequences of not complying with requirements

- **Civil penalties or criminal offences** under the *Therapeutic Goods Act 1989* :
 - Notably in relation to therapeutic goods not included in the ARTG — ‘unapproved’ therapeutic goods
 - Supply (includes sale, exchange, gift)
 - Importation
 - Exportation
 - Manufacture
 - Advertising

TGA's monitoring and enforcement of sport supplements

- The declaration enables the TGA and its partners to take more rapid and decisive action against inappropriate products advertised on-line and imported in to Australia for supply
- The TGA will take a risk based approach to the enforcement of affected products, where safety concerns come to our attention
- The TGA is empowered to require the recall of in scope products that pose an unacceptable risk to public health
- Industry is advised to seek advice from a lawyer or regulatory affairs consultant to ensure compliance with their obligations

How are retailers affected?

- Retailers must be aware of their responsibilities under their relevant state and territory laws
- Sports supplements that contain ingredients appropriate for foods and that are presented as foods will be able to continue to be sold as food at retail stores (as long as they comply with all relevant food regulation)
- Retail supply of products not on the ARTG is a criminal offence or subject to civil penalties in some states and territories
 - From 30 November 2020 it may be illegal for retailers to sell sports supplements that contain the ingredients identified in the declaration, if these are not included in the ARTG as medicines.
 - Sports supplements that are in the presentation of a tablet, capsule or pill (but do not contain ingredients identified in the declaration) can continue to be sold from retail stores until the end of the 3 year transition
- The TGA does not anticipate the forced removal of these products from store shelves and will take a risk based approach to any regulatory activity in cooperation with state and territory regulators. ²⁰

How will the declaration affect the importation of affected sports supplements by consumers?

- The TGA consistently advises consumers to only use products that are regulated by the TGA rather than purchasing goods over the internet, as the safety of these unregulated goods cannot be guaranteed.
- Consumers need a doctor's prescription to import products containing scheduled substances.

Caffeine in sports supplements

Caffeine for internal human therapeutic is included in **schedule 4 (prescription only)** of the Poisons Standard **except:**

- a) in divided preparations when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or
- b) in undivided preparations with a concentration of less than 5 % of caffeine and when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine.

Caffeine included in **schedule 6** (Poison- requiring distinctive packaging) of the Standard except:

- a) when included in Schedule 4; or
- b) in divided preparations for internal human therapeutic use when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or
- c) in undivided preparations for internal human therapeutic use with a concentration of less than 5 % of total caffeine and when labelled with a maximum recommended daily dose of no greater than 600 milligrams of total caffeine; or
- d) in preparations for external use; or
- e) in other preparations with a concentration of less than 5 % of caffeine.

Therapeutic goods advertising requirements



Definition of ‘advertise’

*“... includes make any statement, pictorial representation or design that is **intended, whether directly or indirectly, to promote the use or supply of the goods**, including where the statement, pictorial representation or design:*

- (a) is on the label of the goods; or*
- (b) is on the package in which the goods are contained; or*
- (c) is on any material included with the package in which the goods are contained.” **



* <https://www.legislation.gov.au/Series/C2004A03952>

Therapeutic goods advertising requirements

- Advertising to consumers for therapeutic goods must comply with:
 - *Therapeutic Goods Act 1989*
 - Therapeutic Goods Advertising Code
- Both specify key requirements around what you can and can't say in relation to a therapeutic good
- Advertising must
 - be accurate, balanced & verified
 - not mislead nor arouse unwarranted expectations (incl. through the use of imagery)
 - not lead to self diagnosis and/or inappropriate treatment
 - not make reference to serious forms of diseases, ailments or conditions



Other advertising requirements include

- advertising must be consistent with ARTG entry
- must not advertise goods as ‘safe’
- no endorsements by health professionals or government (e.g. TGA approved) in ads
- any testimonials in ads must comply with the requirements of the Code

Social media responsibilities

You are responsible for any comments posted to your social media channels.

➤ You must **remove** any non-compliant comments

Examples of non-compliant comments include:

- comments that don’t illustrate results typically expected by using the product
- comments that may lead a consumer to not seek the advice of a health professional
- comments that mention restricted representations

Education and resources

Before you advertise – get the basics in place

- The TGA advertising hub contains a range of educational resources to assist advertisers to comply including:
 - Australian Regulatory Guidelines on Advertising Therapeutic Goods
 - Advertising Code guidance and check-lists
 - Fact sheets
 - Case studies and examples
 - Decision trees – Can I advertise this good? Requirements for mandatory information
- Webinars and face-to-face training seminars e.g. SME assist
- Subscribe to the TGA Advertising email list to receive news and information

Reviewing Standard 2.9.4 Formulated Supplementary Sports Foods

P1010

Emma Breen
Senior Nutritionist

November 2020

What is P1010?

✓ Review of **Standard 2.9.4** + related Schedules

✗ Standard 2.9.4 does not currently include *electrolyte drinks*

- parallel review underway (P1030)

Standard 2.9.4 Formulated supplementary sports foods																																	
Note 1 This instrument is a standard under the Food Standards Australia New Zealand Act 1991 (Cth). The standards together make up the Australia New Zealand Food Standards Code. See also section 1.1.1–3.																																	
Note 2 The provisions of the Code that apply in New Zealand are incorporated in, or adopted under, the Food Act 2014 (NZ). See also section 1.1.1–3.																																	
Division 1 Preliminary																																	
2.9.4–1 Name	This Standard is Australia New Zealand Food Standards Code – Standard 2.9.4 – Formulated supplementary sports foods.																																
Note Commencement: This Standard date in notice Standards Au																																	
Division 2 Formulated																																	
2.9.4–2 Definitions	S29–17 Additional permitted forms for vitamins and minerals in formulated supplementary sports foods and in formulated meal replacements For sections 2.9.3–3 and 2.9.4–3, the table is:																																
Note In this Code (see sections 1.1.2– formulated supplement sports people in activ one-day quantity, in food which is to be co	<table><tr><th colspan="2">Additional permitted forms</th></tr><tr><th>Column 1</th><th>Column 2</th></tr><tr><th>Vitamin or mineral</th><th>Permitted forms</th></tr><tr><td>Biotin</td><td>d-biotin</td></tr><tr><td>Pantothenic acid</td><td>d-sodium pantothenate</td></tr><tr><td>Calcium</td><td>Calcium hydroxide</td></tr><tr><td>Chromium:</td><td></td></tr><tr><td>inorganic forms</td><td></td></tr><tr><td>organic forms</td><td></td></tr><tr><td>Copper:</td><td></td></tr><tr><td>inorganic forms</td><td></td></tr><tr><td>organic forms</td><td></td></tr><tr><td>Magnesium</td><td></td></tr></table>	Additional permitted forms		Column 1	Column 2	Vitamin or mineral	Permitted forms	Biotin	d-biotin	Pantothenic acid	d-sodium pantothenate	Calcium	Calcium hydroxide	Chromium:		inorganic forms		organic forms		Copper:		inorganic forms		organic forms		Magnesium							
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Note 2 Average energy content is calcu																																	
2.9.4–3 Composition c	S29–18 Amino acids that may be added to formulated supplementary sports food For paragraph 2.9.4–3(1)(b), the table is: Amino acids that may be added to formulated supplementary sports food																																
	<table><tr><th>Column 1</th><th>Column 2</th></tr><tr><th>Amino acid</th><th>Maximum amount that may be added to a one-day quantity</th></tr><tr><td>L-Alanine</td><td>1 200 mg</td></tr><tr><td>L-Arginine</td><td>1 100 mg</td></tr><tr><td>L-Aspartic acid</td><td>600 mg</td></tr><tr><td>L-Cysteine</td><td>440 mg</td></tr><tr><td>L-Glutamine</td><td>1 900 mg</td></tr><tr><td>L-Glutamic acid</td><td>1 600 mg</td></tr><tr><td>Glycine</td><td></td></tr><tr><td>L-Histidine</td><td></td></tr><tr><td>L-Isoleucine</td><td></td></tr><tr><td>L-Leucine</td><td></td></tr><tr><td>L-Lysine</td><td></td></tr><tr><td>L-Methionine</td><td></td></tr><tr><td>L-Ornithine</td><td></td></tr><tr><td>L-Phenylalanine</td><td></td></tr></table>	Column 1	Column 2	Amino acid	Maximum amount that may be added to a one-day quantity	L-Alanine	1 200 mg	L-Arginine	1 100 mg	L-Aspartic acid	600 mg	L-Cysteine	440 mg	L-Glutamine	1 900 mg	L-Glutamic acid	1 600 mg	Glycine		L-Histidine		L-Isoleucine		L-Leucine		L-Lysine		L-Methionine		L-Ornithine		L-Phenylalanine	
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	S29–19 Substances that may be used as nutritive substances in formulated supplementary sports food For paragraph 2.9.4–3(1)(c), the table is: Substances that may be used as nutritive substances in formulated supplementary sports food																																
	<table><tr><th>Column 1</th><th>Column 2</th></tr><tr><th>Substance</th><th>Maximum amount that may be added to a one-day quantity</th></tr><tr><td>L-carnitine</td><td>2g</td></tr><tr><td>Choline</td><td>10 mg</td></tr><tr><td>Inosine</td><td>10 mg</td></tr><tr><td>Ubiquinones</td><td>15 mg</td></tr><tr><td>Creatine</td><td>3 g</td></tr><tr><td>Gamma-oryzanol</td><td>25 mg</td></tr></table>	Column 1	Column 2	Substance	Maximum amount that may be added to a one-day quantity	L-carnitine	2g	Choline	10 mg	Inosine	10 mg	Ubiquinones	15 mg	Creatine	3 g	Gamma-oryzanol	25 mg																
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Stage One - *Complete*

- Significant scoping activity
 - Identifying opportunities and challenges in the regulation of sports foods in Australia and New Zealand
- Is the product a food or a medicine?
 - **New Zealand:** food, medicine and supplemented food regulatory frameworks
 - Trans-Tasman Mutual Recognition Arrangement (TTMRA)
 - **Australia:** food and medicine regulatory frameworks
 - Section 7 will impact the Australian supply chain only



Stage Two - *Underway*

- Revising the arrangements for the regulation of sports foods
 - Structure and definitions
 - Compositional permissions - consideration of safety and intended purpose
 - Labelling requirements
 - Product claims



- Consultation
 - Two statutory public consultations
 - Number of targeted and public consultations on specific aspects

Call for data on contemporary substances

- Planned for the first quarter of 2021
- ⚠ • Rapid innovation and lack of published data
- ✓ • Seeking technical, toxicological and nutrition data



Collaboration = Contemporary Food Standard

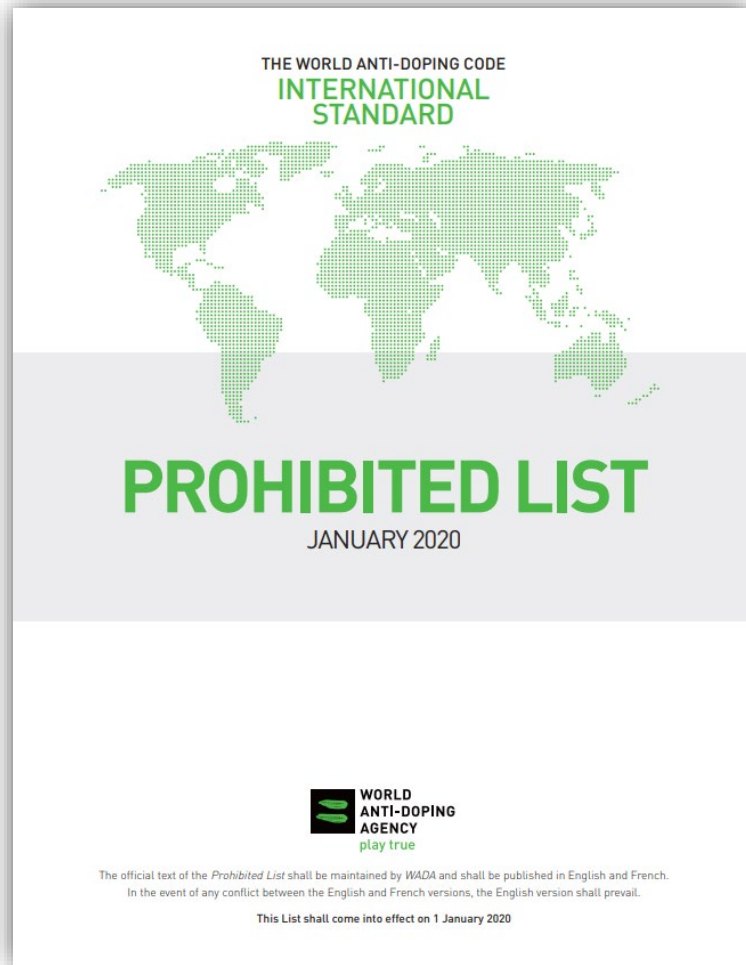
Thank you.



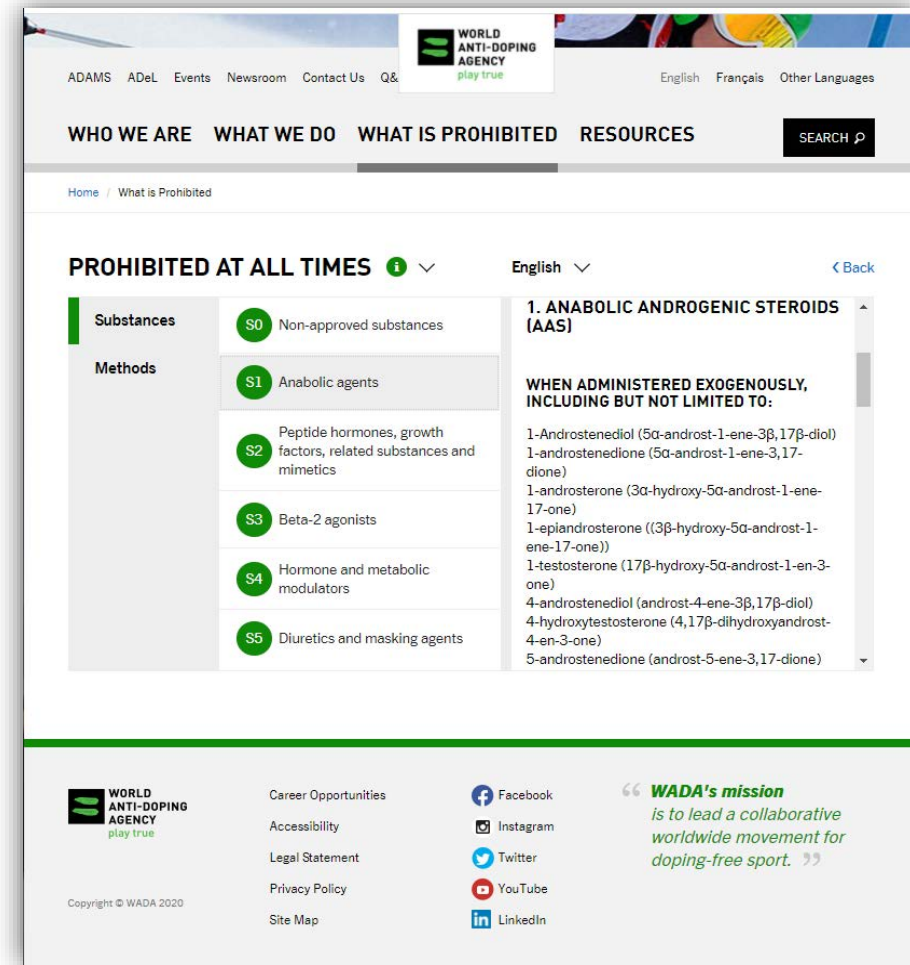
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World Anti-Doping Code Prohibited List





https://www.wada-ama.org/sites/default/files/wada_2020_english_prohibited_list_0.pdf



<https://www.wada-ama.org/en/content/what-is-prohibited>

GlobalDRO

 *Is your medication banned in sport?*



HOMESEARCHHELPFAQS

User Type
Select

Sport
Select

Nation of Purchase
Australia

Search for

Search

Top 5 Searches

- VENTOLIN CFC-FREE INHALER
- ENDONE TABLETS
- PARACETAMOL
- IBUPROFEN
- STANOZOLOL


**MEDICATION
PROHIBITED?**
**CLICK HERE
FOR TUE
INFORMATION**

**SUPPLEMENTS
WHAT ARE
YOUR NEEDS?
WHAT ARE
THE RISKS?**

Contact

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Phone: 13 000 27232 or +61 2 6222 4200 if overseas
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LIVE POLL

Today's speakers are currently reading over your submitted questions.

We'll be back shortly for **Q&A**

We appreciate your participation to complete our live poll.



Question time



Contact us

Complementary & OTC
Medicines Branch

Complementary.Medicines@health.gov.au

Website and link references

Changes to the regulation of sports supplements in Australia

<https://www.tga.gov.au/changes-regulation-sports-supplements-australia>

Frequently asked questions: Sports supplements section 7 declaration

<https://www.tga.gov.au/frequently-asked-questions-sports-supplements-section-7-declaration>

Is my Sports Supplement a Therapeutic Good? decision tree

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

TGA Advertising hub

www.tga.gov.au/advertising-hub

More information



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