**EXPLANATORY STATEMENT**

*Therapeutic Goods Act 1989*

*Therapeutic Goods (Declared Goods) Amendment (Prohibited List) Order 2023*

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy, and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health and Aged Care.

Subsection 7(1) of the Act relevantly provides that the Secretary may declare that particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods for the purposes of the Act. The exercise of the Secretary’s power under subsection 7(1) of the Act may provide clarity regarding the proper characterisation of certain goods as therapeutic goods, for example where the relevant goods sit at the interface between the therapeutic goods framework and food standards.

The *Therapeutic Goods (Declared Goods) Order 2019* (“the Principal Order”) is made under section 7 of the Act. The Principal Order declares particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, to be therapeutic goods, or not to be therapeutic goods, for the purposes of the Act. Relevantly, it declares certain 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 (commonly known as “sports supplements”) to be therapeutic goods when used, advertised, or presented for supply for therapeutic use, or in a way that is likely to be taken to be for therapeutic use.

The *Therapeutic Goods (Declared Goods) Amendment (Prohibited List) Order 2023* (“the Amendment Order”) amends the Principal Order to update the definition of ’Prohibited List’ to refer to the *World Anti-Doping Code International Standard Prohibited List* *2023* (“the 2023 WADA Prohibited List”), which is the most recent version of the *World Anti-Doping Code International Standard Prohibited List* (“the International Standard Prohibited List”) published by the World Anti-Doping Agency.

**Legislative framework**

In making a declaration under section 7 of the Act that goods are or are not therapeutic goods, the Secretary must first be satisfied that the goods are or are not in fact therapeutic goods as defined in subsection 3(1) of the Act (subsection 7(1A) of the Act refers). As such, it is a precondition to the exercise of the Secretary’s power under section 7 that the Secretary first be satisfied in relation to the threshold question of whether particular goods or classes of goods under consideration fall within the definition of ‘therapeutic goods’ provided by the Act.

Subsection 3(1) of the Act defines ‘therapeutic goods’ as goods 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 for therapeutic use. Paragraph (e) of the definition of ‘therapeutic goods’ excludes goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is an applicable food standard under the *Food Standards Australia New Zealand Act 1991* (“the FSANZ Act”). Similarly, paragraph (f) of the definition of ‘therapeutic goods’ excludes goods (other than goods declared to be therapeutic goods under an order in force under section 7) which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.

Subsection 7(1A) of the Act provides that in deciding whether particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are therapeutic goods, the Secretary must disregard paragraphs (e) and (f) of the definition of ‘therapeutic goods’. Accordingly, subsection 7(1A) has the purpose and effect of ensuring that an order declaring goods to be therapeutic goods under section 7 of the Act brings those goods within the scope of the Act, irrespective of any food standard that may otherwise apply to those goods, or whether those goods have a tradition of use as foods. The Supplementary Explanatory Memorandum to the *Therapeutic Goods Amendment (2010 Measures No. 1) Act 2010* explains that subsection 7(1A) clarifies the powers of the Secretary in section 7 to ensure that goods, despite being covered by a food standard, or despite having a tradition of use as food for humans in the form presented in either Australia or New Zealand, may be regulated as therapeutic goods in appropriate cases.

Where the Secretary is satisfied in relation to the threshold question of whether particular goods or classes of goods are or are not therapeutic goods (disregarding paragraphs (e) and (f) of the definition of ‘therapeutic goods’), it is open to the Secretary to exercise the discretion conferred by section 7 of the Act to declare that those goods are or are not therapeutic goods for the purposes of the Act. The exercise of the Secretary’s discretionary power under section 7 must be reasonable and appropriate in the circumstances. In short, the exercise of the Secretary’s power in making an order under section 7 of the Act is twofold:

* first, the Secretary must be satisfied that the goods or classes of goods covered by the proposed order are therapeutic goods, or are therapeutic goods when used, advertised, or presented for supply in a particular way (disregarding paragraphs (e) and (f) of the definition of ‘therapeutic goods’ in subsection 3(1) of the Act); and
* second, the Secretary must be satisfied that it is reasonable and appropriate to make the order in the circumstances (having regard to the objects of the Act, specifically whether the national system of controls should apply to the relevant goods).

An order made under section 7 of the Act is a disallowable legislative instrument within the meaning of subsection 8(4) of the *Legislation Act 2003* (“the Legislation Act”). In accordance with subsection 56(1) of the Legislation Act, the requirement for an instrument made under section 7 of the Act to be published in the *Gazette* is satisfied by registration of the instrument as a legislative instrument.

**Background**

Table item 1A in Part 2 of Schedule 1 to the Principal Order declares certain 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, to be therapeutic goods when used, advertised, or presented for supply for therapeutic use, or in a way that is likely they be taken to be for therapeutic use (“the relevant sports supplements”). Currently, the relevant sports supplements include those that contain, or are represented to contain, a substance included in a schedule to the current Poisons Standard, or a substance expressly identified in the ‘Prohibited List’, defined in section 4 of the Principal Order as *The World Anti-Doping Code International Standard Prohibited List* (January 2020) (“the 2020 WADA Prohibited List”), that is added as an ingredient to the sports supplement.

The International Standard Prohibited List is one of six International Standards that work in conjunction with the World Anti-Doping Code, and together aim to harmonise anti-doping policies, rules, and regulations within sport organisations and among public authorities around the world. The International Standard Prohibited List identifies the substances and methods that are prohibited both in and out of competition, and in particular sports. The substances and methods are classified by different categories, including for example, steroids, stimulants, and gene doping.

Australia is a State Party to the United Nations Educational, Scientific and Cultural Organization (“UNESCO”) International Convention against Doping in Sport (“the Convention”). Australia’s anti-doping obligations derive from the Convention, which requires governments to adopt appropriate measures at the national and international levels, consistent with the principles of the World Anti-Doping Code. The Convention places obligations on State Parties to limit the availability of prohibited substances and methods in order to restrict their use in sport (Article 8 refers) and, to encourage producers and distributors of nutritional supplements to establish best practices in the marketing and distribution of nutritional supplements, including information about their composition and quality assurance (Article 10 refers).

The International Standard Prohibited List forms part of the Convention at Annexure 1. Australia formally recognises annual updates to Annexure 1 as a minor treaty action through the Joint Standing Committee on Treaties (JSCOT).

In accordance with paragraph 14(1)(b) of the Legislation Act, the definition of ‘Prohibited List’ in the Principal Order incorporates by reference the 2020 WADA Prohibited List as in force or existing at 30 November 2020, being the date the Principal Order was amended by the *Therapeutic Goods (Declared Goods) Amendment (Sports Supplements) Order 2020*.

The most recent version is the 2023 WADA Prohibited List, that came into effect on 1 January 2023. It contains 31 substances that were not included in the 2020 WADA Prohibited List.

**Purpose**

Section 4 of the Principal Order defines ‘Prohibited List’ as “*The World Anti-Doping Code International Standard Prohibited List* (January 2020) published by the World Anti-Doping Agency, as in force or existing at 30 November 2020”. The Amendment Order amends the Principal Order by repealing this definition and substituting it with a new definition referencing “the *World Anti-Doping Code International Standard Prohibited List* 2023 published by the World Anti-Doping Agency, as in force or existing on 1 March 2023”.

Many substances included in the International Standard Prohibited List are already included in a schedule to the current Poisons Standard, either explicitly or under scheduled drug classes, such as ‘androgenic steroidal agents’ (Schedule 4) or ‘alkoxyamfetamines’ (Schedule 9). While this is the case with many of the substances that have been added since the 2020 WADA Prohibited List, some substances (such as voxelotor and solriamfetol) are not currently included in a schedule to the current Poisons Standard, but are nevertheless considered to be for a therapeutic use. The Amendment Order ensures that substances of this nature fall within the purview of table item 1A in Part 2 of Schedule 1 to the Principal Order.

*Incorporation by reference*

The 2023 WADA Prohibited List is incorporated as in force or existing on 1 March 2023, in accordance with paragraph 14(1)(b) of the Legislation Act. The 2023 WADA Prohibited List is published by the World Anti-Doping Agency and is available for free at www.wada-ama.org.

**Consultation**

The TGA published notification of the proposed amendment to the definition of ‘Prohibited List' in the Principal Order on 17 February 2023. Feedback was not specifically invited from stakeholders as the 31 substances that have been added to the International Standard Prohibited List since the 2020 WADA Prohibited List was published are already likely to be taken to be for a therapeutic use and most are already included in the current Poisons Standard. Accordingly, such substances, or goods that contain such substances, are already subject to the therapeutic goods legislative framework, and in this respect, the amendment made by the Amendment Order is in effect clarificatory in nature only.

The Office of Impact Analysis has advised that the preparation of a policy impact analysis is not required in relation to the Amendment Order as it is unlikely to have more than a minor regulatory impact (OBPR23-03920).

Details of the Amendment Order are set out in **Attachment A**.

The Amendment Order is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Order is a disallowable legislative instrument for the purposes of the Legislation Act and commences on 1 March 2023.

**Attachment A**

**Details of the *Therapeutic Goods (Declared Goods) Amendment (Prohibited List) Order 2023***

**Section 1 – Name**

This section provides that the name of the instrument is the *Therapeutic Goods (Declared Goods) Amendment (Prohibited List) Order 2023* (“the Amendment Order”).

**Section 2 – Commencement**

This section provides that the Amendment Order commences on 1 March 2023.

**Section 3 – Authority**

This section provides that the legislative authority for making the Amendment Order is section 7 of the *Therapeutic Goods Act 1989* (“the Act”)*.*

Subsection 33(3) of the *Acts Interpretation Act 1901* relevantly provides that, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character, the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument. This instrument is made in accordance with that provision.

**Section 4 – Schedules**

This section provides that each instrument that is specified in a Schedule to the Amendment Order is amended or repealed as set out in the applicable items in the Schedule concerned, and that any other item in a Schedule to the Amendment Order has effect according to its terms.

**Schedule 1 – Amendments**

This Schedule amends the *Therapeutic Goods (Declared Goods) Order 2019* (“the Principal Order”).

Item 1 of this Schedule repeals the definition of ‘Prohibited List’ in section 4 of the Principal Order (not including the note) and substitutes it with a new definition that references to “*The World Anti-Doping Code International Prohibited List* (January 2023) published by the World Anti-Doping Agency, as in force or existing on 1 March 2023”.

**Attachment B**

**Statement of Compatibility with Human Rights**

*Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011*

***Therapeutic Goods (Declared Goods) Amendment (Prohibited List) Order 2023***

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

**Overview of legislative instrument**

Subsection 7(1) of the Act relevantly provides that the Secretary may declare that particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods for the purposes of the Act. The exercise of the Secretary’s power under subsection 7(1) of the Act may provide clarity regarding the proper characterisation of certain goods as therapeutic goods, for example where the relevant goods sit at the interface between the therapeutic goods framework and food standards.

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In making a declaration that goods are or are not therapeutic goods, the Secretary must first be satisfied that the goods are or are not in fact therapeutic goods as defined in subsection 3(1) of the Act (subsection 7(1A) of the Act refers). As such, it is a precondition to the exercise of the Secretary’s power under section 7 that the Secretary first be satisfied in relation to the threshold question of whether particular goods or classes of goods under consideration fall within the definition of ‘therapeutic goods’ provided by the Act.

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**Human rights implications**

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights (“the ICESCR”).

Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standards of physical and mental health. In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The instrument takes positive steps to promote the right to health by ensuring that the Principal Order is current and aligns with the most recent version of the International Standard Prohibited List that has been prepared by the World Anti-Doping Agency. As a consequence, relevant sports supplements that contain, or are represented to contain (as an ingredient), a substance that has been added to the International Standard Prohibited List since the 2020 WADA Prohibited List, are appropriately regulated as therapeutic goods. As such, these products would have to meet the regulatory requirements applying to therapeutic goods that are designed to ensure the safety and efficacy of therapeutic goods, thereby promoting public health and safety.

**Conclusion**

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and otherwise does not raise any other human rights issues.