EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Declared Goods) Amendment (Sports Supplements) Order 2020

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.

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. 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 the 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 a standard within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991* ("food standard"). 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 would be 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).

The exercise of the Secretary's power under section 7 of the Act is particularly useful in providing certainty or resolving differences of opinion regarding the proper characterisation of certain goods. Depending on the circumstances, it is reasonable and appropriate to exercise that power in relation to goods that are represented as being foods but are properly characterised, and more appropriately regulated, as therapeutic goods, notwithstanding the possible application of a food standard. A declaration therefore provides an appropriate mechanism to address regulatory uncertainty by enabling the Secretary to specify particular goods to be therapeutic goods, irrespective of whether or not those goods are goods for which there is an applicable food standard.

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.

Purpose

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.

The *Therapeutic Goods (Declared Goods) Amendment (Sports Supplements) Order 2020* ("the Amendment Order") is made under section 7 of the Act, read together with subsection 33(3) of the *Acts Interpretation Act 1901*. The Amendment Order amends the Principal Order by declaring certain 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 (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 Amendment Order does not declare all 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. Rather, the Amendment Order is concerned with declaring a specific class of sports supplements to be therapeutic goods ("the relevant sports supplements"), being those sports supplements that are supplied in the dosage form of a tablet, capsule or pill (other than those goods containing glucose only) or sports supplements that contain:

- a substance included in a schedule to the current Poisons Standard; or

- a substance expressly identified on *The World Anti-Doping Code International Standard Prohibited List* (January 2020) published by the World Anti-Doping Agency ("the Prohibited List") that is added as an ingredient to the sports supplements; or

- a relevant substance that is added as an ingredient to the sports supplements ('relevant substance' is defined in item 2 of Schedule 1 to the Amendment Order); or

- a substance with equivalent pharmacological action to a substance mentioned above.

Importantly, sports supplements that contain relevant substances and substances expressly identified on the Prohibited List only fall within the terms of the Amendment Order where those substances are specifically added as ingredients. This is to ensure that sports supplements that contain relevant substances or substances expressly identified on the Prohibited List are not captured by the terms of

the Amendment Order in circumstances where those substances are naturally occurring components of legitimate food ingredients added to the sports supplements.

However, sports supplements containing a substance included in a schedule to the current Poisons Standard fall within the terms of the Amendment Order, whether or not those substances are added as ingredients to the sports supplements. This is because, as explained below, the classification and scheduling of substances under the current Poisons Standard occurs by reference to (among other matters) minimum concentrations for those substances, and does not generally differentiate between substances prepared from natural sources or otherwise (subsection 1(2) of the current Poisons Standard refers).

In accordance with paragraphs 1(2)(i) and (j) of the current Poisons Standard, a reference to a substance in a schedule to the current Poisons Standard does not include a substance below the minimum concentration provided in respect of that substance in Appendix G or, for other substances included in Schedules 1 to 6 that are not also included in Schedules 7 or 8, a minimum concentration of 10 mg per litre or kilogram. This interpretation applies unless a contrary intention appears including, for example, where a minimum concentration is expressly provided for a particular substance within a schedule. Given the high degree of control recommended to be exercised over the availability of substances included in Schedules 7 and 8, the minimum concentration of general application under paragraph 1(2)(j) does not apply in relation to those substances.

The Amendment Order clarifies that the relevant sports supplements, 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, are indeed therapeutic goods as defined by the Act and therefore subject to the national system of controls established by the Act. In so doing, the Amendment Order addresses both uncertainty about the proper characterisation of the relevant sports supplements as therapeutic goods as a consequence of the *Australia New Zealand Food Standards Code* – Standard 2.9.4 – Formulated supplementary sports foods ("Food Standard 2.9.4") as well as legitimate safety concerns with the purported regulation of the relevant sports supplements as foods. The effect of the Amendment Order is to confirm that the relevant sports supplements (when used, advertised, or presented for supply in the manner specified in the Amendment Order) are therapeutic goods for the purposes of the Act, irrespective of any view regarding the application of Food Standard 2.9.4 to the relevant sports supplements prior to the making of the Amendment Order.

The Amendment Order provides transitional arrangements with respect to the declaration of sports supplements that are supplied in the dosage form of a tablet, capsule or pill. Specifically, the relevant provision of the Amendment Order relating to tablets, capsules and pills (paragraph (b) in column 2 of new table item 1A inserted by the Amendment Order) applies from 30 November 2023 onwards.

Background

Sports supplements in Australia

Many sports supplements are appropriately supplied in Australia as foods, commensurate with their low risk profile. These sports supplements include, for example, a number of meal replacement shakes and nutritional bars that contain food ingredients only and are presented in a way that is appropriate for food. However, there is a growing body of reports and studies (as detailed in the Regulation Impact Statement at **Attachment C**) in relation to the concerning rate of intentional or unintentional adulteration of certain sports supplements often with substances such as stimulants and anabolic steroids, and the adverse effects related to the use of those sports supplements.

One study suggests that up to 19 per cent of sports supplements in Australia contain substances that are banned in sport. Moreover, a number of serious adverse events, including events that have led to death, involving the use of certain sports supplements have occurred in Australia and internationally. Case studies report instances of renal failure and exercise related rhabdomyolysis (damage and

subsequent breakdown of skeletal muscle); liver damage and failure; lupus-like syndrome (an auto-immune syndrome with joint and muscle pain, fatigue and inflammation to the lining of the heart and lungs); interstitial nephritis (hindering the ability of the kidneys to work properly); cardiac toxicities; compartment syndrome (muscle pressure build up resulting in severe pain and weakness); and haemorrhagic stroke among other sequelae.

In general, the sports supplements associated with serious adverse events contain ingredients that are not appropriate for food, such as substances included in Schedule 4 to the current Poisons Standard, the supply of which should only be available on prescription. Adverse events have occurred in otherwise healthy, predominantly younger persons, where there is usually no medical reason for taking the sports supplements. Although the frequency of serious adverse events and deaths may be low (for example, the NSW Poisons Information Centre reports 4 people have died in Australia from 'fat shredder' supplements in the last 5 years), the cost associated with just one mortality is very high (the Value of Statistical Life in 2019 dollars is $4.9 million) and far outweighs the regulatory impact of the Amendment Order.

Further, the NSW Ministry of Health estimates the hospital costs of a liver transplant procedure to be $153,200 based on 2014-15 data. This amount does not take into consideration other costs such as medication, pathology, ongoing monitoring, the costs of a potential organ rejection or the personal costs to the individuals and their families.

Online sales of vitamins and supplements in Australia amounted to $159.2 million in 2019 (as detailed in the Regulation Impact Statement at **Attachment C**). Sports and nutrition supplements comprised 24.5% and fitness and weight loss products 11% of this figure. It is predicted that industry revenue in Australia for vitamins and supplements in 2020 will be $1.9 billion (although the actual 2020 figures are likely to be affected by the COVID-19 pandemic).

The predicted continued growth of the Australian sports supplement industry is supported by the growing consumer demand for these products, particularly by younger generations. Australian gym memberships in the last five years have increased due to personal wellbeing trends and an increasing number of consumers participating in fitness classes and weight training (as detailed in the Regulation Impact Statement at **Attachment C**). This trend supports growing sales in sports supplements to support intensive training routines.

Food regulation in Australia and Food Standard 2.9.4

The regulation of foods in Australia is the joint responsibility of the Commonwealth and the states and territories. The *Food Standards Australia New Zealand Act 1991* ("FSANZ Act") establishes the joint body known as Food Standards Australia New Zealand ("FSANZ"). FSANZ is responsible for developing and reviewing the bi-national standards for food under the FSANZ Act, which constitute the Australia New Zealand Food Standards Code ("the Code").

State and territory government food authorities and local councils enforce the Code, deal with complaints about food and investigate food safety issues through their respective legislation. The Department of Agriculture, Water and the Environment administers the *Imported Food Control Act 1992* and enforces food laws at Australia's border.

Goods for which there is a standard under the FSANZ Act are not therapeutic goods, unless those goods are declared to be therapeutic goods by an order under section 7 of the Act (definition of 'therapeutic goods' in subsection 3(1) of the Act refers). In the absence of an applicable order under section 7 of the Act, the question of whether or not particular goods are therapeutic goods may turn on the application (or purported application) of a relevant food standard. For this reason, the application of food standards have the potential to give rise to uncertainty as to the appropriate regulatory framework that applies in relation to goods that would otherwise be characterised as therapeutic goods. These goods occupy what is commonly referred to as the food-medicine interface.

Food Standard 2.9.4 is a food standard in relation to 'formulated supplementary sports food', which is defined in the standard as '*a product that is specifically formulated to assist sports people in achieving specific nutritional or performance goals*'. Formulated supplementary sports food within the meaning of the standard comprises a class of products within the broader class of sports supplements. Sports supplements that would otherwise be characterised as therapeutic goods have been taken to be regulated as food as a consequence of Food Standard 2.9.4 and views claiming that those goods fall within the definition of 'formulated supplementary sports food'. These views are advanced in circumstances including, for example, where sports supplements, which make representations in connection with therapeutic use, contain substances that are included in a schedule to the current Poisons Standard. This is of particular concern considering that the current Poisons Standard places access controls and restrictions over scheduled substances in the interests of public health and safety, principally to minimise risks of poisoning from, and misuse or abuse of, those substances.

Goods declared by the Amendment Order are therapeutic goods

The Amendment Order applies in relation to the class of goods described above as relevant sports supplements, when those goods are used, advertised, or presented for supply for therapeutic use, or in a way that is likely to be taken to be for therapeutic use. Relevantly, subsection 3(1) of the Act defines 'therapeutic use' as (among other things) '*use in or in connection with… (b) influencing, inhibiting or modifying a physiological process in persons; or… (f) the replacement or modification of parts of the anatomy in persons*'.

Considering the definition of 'therapeutic goods' in the Act (disregarding paragraphs (e) and (f) of that definition) together with the definition of 'therapeutic use', the relevant sports supplements specified in column 2 of new table item 1A inserted by the Amendment Order are clearly therapeutic goods when used, advertised or presented for supply in the circumstances described by column 3 of that item. Indeed, any goods that are, or are likely to be taken to be (whether because of the way in which the goods are presented or for any other reason), for therapeutic use as defined by the Act, are therapeutic goods for the purposes of the Act.

In particular, the uses described in paragraphs (c) to (j) in column 3 (namely, gaining muscle, increasing mental focus, metabolism, or stamina, modifying hormone levels, losing weight or fat, preparing for workout, and recovering from workout) are therapeutic uses because those uses may be characterised as uses in or in connection with influencing, inhibiting or modifying a physiological process in persons. Moreover, gaining muscle may also be characterised as a use in or in connection with modifying parts of the human anatomy.

In practice, when considering the application of the Amendment Order to individual goods, the connection between the goods and the therapeutic use of those goods is strengthened by the fact that the relevant sports supplements as described in column 2 of new table item 1A, contain substances or are in dosage forms that are ordinarily associated with therapeutic uses as defined in subsection 3(1) of the Act. Therefore, the relevant sports supplements would, because of those characteristics, be even more likely to be taken to be for therapeutic use because of the way in which the goods might be used, advertised, or presented for supply.

Discretion exercised to make the Amendment Order

It is reasonable and appropriate to exercise the discretion under subsection 7(1) of the Act to declare the relevant sports supplements to be therapeutic goods when used, advertised or presented for supply in the manner specified in the Amendment Order. In exercising the power, it is appropriate to have regard to the objects in section 4 of the Act, principally, the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy of therapeutic goods.

The goods specified in column 2 of new table item 1A are therapeutic goods when those goods are used, advertised or presented for supply for therapeutic use, or in a way that is likely to be taken to be for therapeutic use as specified in column 3 of that item. In accordance with subsection 7(1A) of the Act, the application of Food Standard 2.9.4 is not relevant to the threshold question of whether the goods are or are not therapeutic goods. However, the existence of the standard is relevant to the consideration as to whether to exercise the discretion to declare the relevant sports supplements to be therapeutic goods when used, advertised or presented for supply in the manner specified in the Amendment Order.

As mentioned above, the Amendment Order applies only in relation to a class of goods within the broader class of sports supplements. Two considerations have principally informed the exercise of the discretion to declare relevant sports supplements to be therapeutic goods. These are articulated as follows and discussed further below in the context of each material aspect of the Amendment Order as specified in column 2 of new table item 1A:

(a) the relevant sports supplements (when used, advertised or presented for supply in the manner specified in the Amendment Order) pose an unacceptable risk to public health and safety; and should therefore be regulated as therapeutic goods to ensure that the national system of controls applies in relation to them;

(b) the differences of opinion regarding the application of Food Standard 2.9.4 (in light of the definition of formulated supplementary sports food) has resulted in a lack of regulatory certainty regarding the proper characterisation of the relevant sports supplements at the food medicine interface; and the power to declare those goods under subsection 7(1) of the Act to be therapeutic goods provides an appropriate mechanism to resolve this uncertainty and should therefore be exercised in the present circumstances.

Substances included in the current Poisons Standard

The current Poisons Standard imposes restrictions on access to substances that are poisons in the interests of public health and safety. All substances mentioned in the current Poisons Standard are classified with reference to the schedules in which those substances are included. The inclusion of a substance in a schedule is based in practice on the degree of control recommended to be exercised regarding its availability to the public. Poisons for therapeutic use are generally included in Schedules 2, 3, 4 and 8 with progression through these schedules signifying increasing regulatory controls.

It is appropriate that sports supplements containing substances for which access is restricted by the current Poisons Standard are regulated accordingly. Substances mentioned in the current Poisons Standard, for example, substances included in Schedule 4 (prescription only medicines), are frequently detected in sports supplements. The consumption of these substances requires appropriate medical management and monitoring. Selective Androgen Receptor Modulators (SARMs), for instance, are included in Schedule 4 to the current Poisons Standard and may only be accessed with a prescription from a medical practitioner. SARMs are associated with serious safety concerns, including liver toxicity and increased risk of heart attack and stroke.

Relevantly, goods containing Schedule 2 or 3 substances may only be supplied in pharmacies or by pharmacists respectively. Goods containing Schedule 4 substances may only be supplied by a pharmacy on prescription by persons permitted by state or territory legislation to prescribe. Goods containing Schedule 8 substances are controlled drugs which require restrictions regarding manufacture, supply, distribution, possession and use of those goods in order to reduce abuse, misuse or physical and psychological dependence. Goods containing Schedule 9 substances are prohibited by law except when required for medical or scientific research or for analytical, teaching or training purposes with approval of Commonwealth or state or territory health authorities.

While regulatory enforcement activity may be taken regarding the supply of sports supplements containing scheduled substances, current legal uncertainty as to the proper characterisation of the relevant sports supplements as foods or therapeutic goods (when used, advertised or presented for supply in the manner specified in the Amendment Order) creates regulatory confusion and significantly hinders timely enforcement action. The Amendment Order is intended to deal with this uncertainty and delay by ensuring the relevant sports supplements are appropriately regulated as therapeutic goods, irrespective of whether Food Standard 2.9.4 applies.

Prohibited List substances

Many substances included in the 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). Other substances in the Prohibited List that are not included in a schedule to the current Poisons Standard continue to pose an actual or potential health risk to the public. It is arguable that some substances in the Prohibited List are likely candidates for scheduling but not yet the subject of a scheduling decision.

The high correlation between substances included in the Prohibited List and those in a schedule to the current Poisons Standard, combined with the resulting increased risk posed by these substances to athletes and other consumers, supports the conclusion that the relevant sports supplements containing Prohibited List substances (when used, advertised or presented for supply in the manner specified in the Amendment Order) should be subject to an appropriate level of regulatory control to ensure their quality, safety and efficacy.

Relevant substances

The list of relevant substances as defined by the Amendment Order contains two substances that the delegate of the Secretary considers to have a risk profile that warrants regulation as therapeutic goods (as opposed to food) but which are not already included in the current Poisons Standard or the Prohibited List.

Inclusion of Dendrobium (*Dendrobium nobile*) in sports supplements is often correlated with promotion as a stimulant for sports performance. The European Union has placed the herb in the Novel Food catalogue, stating that the use of the ingredient as a food is unknown, and therefore requires a safety assessment under the Novel Food Regulation before it may be placed on the EU market as a food or food ingredient. The inclusion of dendrobium in the relevant substances list provides legal clarity that sports supplements containing this ingredient are indeed therapeutic goods.

Methylliberine was considered by the Advisory Committee for Novel Foods (ACNF) in 2018. The ACNF raised concerns that methylliberine performs as a psychoactive stimulant, has no nutritional value, does not appear to fit under a food standard and has no tradition of use as a food in the form in which it is presented. In addition, there is currently a lack of robust safety assessment data on methylliberine, its effects on the human body and its synergistic effect on the action of other stimulants, such as caffeine. The inclusion of methylliberine in the relevant substances list provides legal clarity that sports supplements containing this ingredient are indeed therapeutic goods.

In addition to dendrobium and methylliberine, β-methylphenylethylamine and N-phenethyl dimethylamine were also included in the public consultation for inclusion in the relevant substances list. The World Anti-Doping Agency separately advised that it would not be necessary to specify β-methylphenylethylamine and N-phenethyl dimethylamine as a relevant substance as those substances would be covered by the express identification of 'phenethylamine and its derivatives' in the Prohibited List.

Substances with equivalent pharmacological action

Subparagraph (iv) of column 2 of new table item 1A inserted by the Amendment Order ensures that sports supplements containing a substance with equivalent pharmacological action to substances included in a schedule to the current Poisons Standard, a substance expressly identified on the Prohibited List that is added as an ingredient, or a relevant substance that is added as an ingredient, fall within the remit of the Amendment Order. This provision is principally designed to address circumstances where new active principles or derivatives providing an equivalent pharmacological action of those other substances are developed as a means of circumventing the intent of the Amendment Order. The inclusion of this provision is also consistent with the general approach taken in the current Poisons Standard (subsection 1(2) of the current Poisons Standard refers).

Tablets, capsules and pills

A sports supplement with therapeutic claims that is presented as a tablet, capsule or pill is likely to be taken to be for therapeutic use and, would therefore meet the definition of 'therapeutic good' under the Act. A reasonable consumer would assume that a sports supplement presented as a tablet, capsule or pill and making therapeutic claims is a medicine and is subject to an appropriate level of regulatory oversight to ensure its quality, safety and efficacy.

Tablets, capsules and pills generally provide ingredients at higher concentrations than dosage forms traditionally aligned with foods, such as powders and bars. The manufacturing requirements for foods are not as stringent as for therapeutic goods (the latter being required to be made in accordance with good manufacturing principles). Products manufactured as foods have lower sample testing requirements than products manufactured as therapeutic goods. This means that there is a potential for food products with an active ingredient to be variable between batches. Sports supplements in the form of a tablet, capsule or pill are generally formulated to deliver a specific concentration of a substance that is safe and efficacious. Such goods should therefore be regulated as therapeutic goods to ensure consistent manufacturing processes with respect to the concentration of the substance, the variation of which may otherwise be deleterious to consumer health.

An analysis of the presentation of sports supplement products in Australia by Noetic (as detailed in the Regulation Impact Statement at **Attachment C**) shows that the product category known as 'fat burners' represents the largest portion of products being presented as tablets, capsules or pills. The significance of the above information is that, not only is the product category of 'fat burners' the most common sports supplement product category presented as tablets, capsules and pills, the category has also been linked to serious adverse events in Australia. In 2018, the NSW Ministry of Health advised of significant adverse events from the category of products known as 'fat burners' or 'shredders' and urged the public to avoid any product from an unverified source being promoted as a weight-loss agent.

Given these safety concerns, sports supplements that are supplied in the dosage form of tablets, capsules and pills, 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, should be regulated as therapeutic goods in order to ensure their safe and effective use with the exception discussed below. These dosage forms are generally administered to deliver concentrated amounts of active ingredients, which (combined with therapeutic use claims) would more closely align with regulation under the therapeutic goods framework to ensure their quality, safety and efficacy, and otherwise to protect public health.

In making the Amendment Order, consideration was given to specific food substances in the dosage form of tablets, capsules or pills that should not be covered by the Amendment Order. Food substances, such as apple cider vinegar, enzymes, fermented soy and lecithin, are generally not represented (expressly or by implication) as being for the improvement or maintenance of physical or mental performance in sport, exercise or recreational activity; and, as a consequence, would not be covered by new item 1A. Other food substances, such as branch chain amino acids that are presented

in the dosage form of tablets, capsules or pills with sports related therapeutic claims, would be covered by new item 1A and therefore appropriately regulated as therapeutic goods. However, branch chain amino acids presented in traditional food forms, such as nutrition bars, would not be covered, unless the product also contains a substance mentioned in paragraph (a) of column 2 of the item.

It should be noted that paragraph (b) of column 2 of new item 1A does not cover tablets, capsules or pills containing glucose only. Glucose tablets are commonly represented as enhancing energy levels for active people; and presentation of this ingredient in the dosage form of a tablet, capsule or pill may be regarded as a traditional food form in the same manner as lollies or sweets. These goods would have been covered by new item 1A but have been expressly excluded so that tablets, capsules or pills containing glucose only may continue to be appropriately regulated as foods.

Incorporation by reference

The Amendment Order incorporates by reference:

- the *Therapeutic Goods (Standard for Tablets, Capsules and Pills) (TGO 101) Order 2019* ("TGO 101")*;* and

- *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, being the commencement of the Amendment Order ("the Prohibited List").

TGO 101 is a legislative instrument, which constitutes a ministerial standard for the purposes of section 10 of the Act. TGO 101 applies principally to therapeutic goods that are intended for oral administration and are manufactured in the dosage form of a tablet, capsule or pill, and specifies the minimum requirements for the safety and quality of these therapeutic goods. TGO 101 is incorporated as in force from time to time, in accordance with paragraph 14(1)(a) of the *Legislation Act 2003*. TGO 101 is available for free from the Federal Register of Legislation and may be accessed on the internet at www.legislation.gov.au.

The 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 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 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). The Prohibited List is incorporated as in force or existing at 30 November 2020, in accordance with paragraph 14(1)(b) of the Legislation Act. The Prohibited List is published by the World Anti-Doping Agency and is available for free on the internet at www.wada-ama.org.

Consultation

Extensive consultation was conducted in relation to the preparation of the Amendment Order. In August 2018, on the initiative of the Minister for Health, the Department of Health convened a round table discussion in relation to the regulation of sports supplements. The round table was convened on behalf of the Food Regulation Standing Committee, the subcommittee of the Australia and New Zealand Ministerial Forum on Food Regulation responsible for coordinating policy advice and ensuring a nationally consistent approach to the implementation and enforcement of food standards. Participation at the round table included senior officials from relevant Australian and New Zealand Government agencies, state and territory agencies, public health organisations and industry representatives.

In July 2019, an early draft proposal to declare certain sports supplements to be therapeutic goods under section 7 of the Act was presented to and discussed at the Implementation Subcommittee for Food Regulation (a subcommittee of the Food Regulation Standing Committee). Participants at the meeting included senior officials from New Zealand and Australian state and territory food regulators, the Australian Local Government Association, and representatives from relevant Australian Government agencies, including the Food Standards Australia New Zealand and Sports Integrity Australia (the then Australian Sports Anti-Doping Authority).

In September 2019, the TGA held a workshop with relevant national regulatory agencies as well as state and territory agencies responsible for regulating food. The workshop was aimed at further developing and generating technical input in relation to the specific parameters of the draft proposal to declare certain sports supplements to be therapeutic goods under section 7 of the Act.

In October 2019, the TGA published a consultation paper, *Consultation: Sports supplements – Proposed clarification that certain sports supplements are therapeutic goods* seeking submissions and public comment in relation to the proposal. The consultation paper outlined the regulatory complexities associated with regulation of foods and therapeutic goods at the food-medicine interface. The consultation paper also included an exposure draft of the proposed order under section 7 of the Act.

In response to the consultation, the TGA received:

- 43 written submissions from a range of stakeholders including consumers, manufacturers and retailers, industry representatives, regulatory affairs consultants, government bodies, professional bodies, healthcare professionals and health professional associations;

- 5,300 responses to an online survey primarily from consumers; and

- over 14,000 signatories to an industry-initiated campaign called ‘Save Aussie Supplements’.

Submissions received from healthcare professional, government bodies, regulatory bodies, athletes and sports associations strongly favoured the proposal outlined in the consultation paper, while submissions received from the sports supplements industry were primarily opposed to the proposal. Consumers were mixed in their responses. Regular users of sports supplements were generally opposed to the proposal, while other consumers were generally in favour of the proposal.

Almost no opposition was received in relation to aspects of the proposal concerning goods containing substances included in a schedule to the current Poisons Standard. Most respondents understood that these goods should be appropriately characterised as therapeutic goods as opposed to foods. Indeed, several submissions from consumers and consumer representative groups, industry, and healthcare professionals called for broadening aspects of the proposal concerning the dosage form of goods in order to capture other dosage forms such as gels and wafers.

The 'Save Aussie Supplements' campaign claimed that the proposal would restrict the supply of a large number of products in Australia and lead to job losses. These claims appear to have largely been based on a misperception in relation to the scope of sports supplements that would be affected by the proposal. Separately, a number of submissions raised concerns that legitimate foods might be captured by the aspects of the proposal concerning goods containing substances or ingredients in excess of the limits provided in the *Australia New Zealand Food Standards Code* – Schedule 29 – Special purpose foods, or limits specified in the Permissible Ingredients Determination made under section 26BB of the Act. Having regard to these submissions, it was decided that the aspects of the proposal relating to Schedule 29 and the Permissible Ingredients Determination should be removed.

In February 2020, further consultation was undertaken in the form of targeted stakeholder workshops in Sydney and Melbourne. Participants at the workshops included consumer representative groups, contract manufacturers, relevant government agencies, healthcare professional representative groups, industry representative groups, manufacturers, regulatory consultants, major retailers and distributors, sporting bodies and associations, and an independent sports supplements testing facility. The consultation was conducted on the basis of a revised proposal that took into account feedback received from the public consultation process. The revised proposal was generally supported and considered an improvement of the initial proposal. However, some concerns remained about aspects of the proposal relating to goods containing substances in the Prohibited List and goods in the dosage form of tablets, capsules and pills.

In addition to the consultation outlined above, the TGA has also engaged in communication with the Department of Industry, Science, Energy and Resources, the Department of Foreign Affairs and Trade, and the Australian Small Business and Family Enterprise Ombudsman in relation to the domestic and international trade implications of the proposal.

In July 2020, in accordance with Australia's international obligations under the World Trade Organization Agreement on Technical Barriers to Trade, the TGA notified other member states of the World Trade Organization about the proposal. Member states did not raise any concerns in relation to the proposal.

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**.

A Regulation Impact Statement ("RIS") was prepared in relation to the development of the Amendment Order, taking into account the feedback received from stakeholders and the Australian public through the extensive consultation process. The Office of Best Practice Regulation assessed the RIS and determined that the analysis in the RIS was consistent with good practice and that the RIS met Australian Government best practice regulation requirements (OBPR ID 25664). The RIS is set out in full at **Attachment C**.

The Amendment Order is a disallowable legislative instrument for the purposes of the Legislation Act and commences on 30 November 2020.

Attachment A

Details of the *Therapeutic Goods (Declared Goods) Amendment (Sports Supplements) Order 2020*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods (Declared Goods) Amendment (Sports Supplements) Order 2020* ("the Amendment Order").

Section 2 – Commencement

This section provides that the Amendment Order commences on 30 November 2020.

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 substitutes the note at the beginning of section 4 of the Principal Order to include a reference to 'current Poisons Standard', and to remove the reference to 'therapeutic device' which is no longer defined by the Act.

Item 2 of this Schedule inserts a number of definitions in the Principal Order, including 'Prohibited List', 'relevant substance', and 'TGO 101'.

Item 3 of this Schedule inserts a new item 1A in the table in Part 2 of Schedule 1 to the Principal Order. The effect of this amendment is to declare certain 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 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.

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 (Sports Supplements) Order 2020

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

The *Therapeutic Goods (Declared Goods) Amendment (Sports Supplements) Order 2020* ("the instrument") is a legislative instrument made under section 7 of the *Therapeutic Goods Act 1989* ("the Act). 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.

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' in subsection 3(1) of the Act. 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 a standard within the meaning of subsection 4(1) of the *Food Standards Australia New Zealand Act 1991* ("food standard"). 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.

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. 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).

The instrument amends the *Therapeutic Goods (Declared Goods) Order 2019* by declaring certain 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 (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.

Importantly, however, the instrument does not declare all sports supplements to be therapeutic goods when used, advertised, or presented for supply for therapeutic use. Rather, the instrument is

concerned with declaring a specific class of sports supplements to be therapeutic goods ("the relevant sports supplements"), being those sports supplements that are supplied in the dosage form of a tablet capsule or pill (other than those goods containing glucose only) or sports supplements that contain:

- a substance included in a schedule to the current Poisons Standard; or

- a substance expressly identified on *The World Anti-Doping Code International Standard Prohibited List* (January 2020) published by the World Anti-Doping Agency ("the Prohibited List") that is added as an ingredient to the sports supplements; or

- a relevant substance that is added as an ingredient to the sports supplements ('relevant substance' is defined in item 2 of Schedule 1 to the instrument); or

- a substance with equivalent pharmacological action to a substance mentioned above.

The instrument clarifies that the relevant sports supplements, 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, are indeed therapeutic goods as defined by the Act and therefore subject to the national system of controls established by the Act. In so doing, the instrument addresses both uncertainty about the proper characterisation of the relevant sports supplements as therapeutic goods as a consequence of the *Australia New Zealand Food Standards Code* – Standard 2.9.4 – Formulated supplementary sports foods ("Food Standard 2.9.4") as well as legitimate safety concerns with the purported regulation in Australia of the relevant sports supplements as food. The effect of the instrument is to confirm that the relevant sports supplements are therapeutic goods for the purposes of the Act, irrespective of any view regarding the application of Food Standard 2.9.4 to the relevant sports supplements prior to the making of the instrument.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural rights ("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 declaring the relevant sports supplements when used, advertised or presented for supply in the manner specified in the instrument, to be therapeutic goods appropriately regulated under the Act and therefore subject to the national system of controls relating to the quality, safety and efficacy of therapeutic goods established by the Act. As a consequence, the instrument promotes public health and safety by addressing any uncertainty in relation to the regulatory status of the relevant sports supplements as well as legitimate safety concerns and risks with the regulation in Australia of the relevant sports supplements as foods.

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.

Attachment C

Regulation Impact Statement

[please see supporting material]