EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Declared Goods) Order 2019

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 3(1) of the Act relevantly provides that 'therapeutic goods' means 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. That definition relevantly 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* (paragraph (e) of the definition of therapeutic goods refers).

Subsection 7(1) of the Act confers on the Secretary of the Department a power to declare, by order published in the *Gazette* or on the Department's website, 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 be satisfied that the goods are or are not in fact therapeutic goods as defined in the Act. In short, subsection 7(1) provides a mechanism for clarifying whether particular goods or classes of goods are or are not therapeutic goods, and therefore whether or not those goods are subject to the regulatory scheme established by the Act.

In determining whether particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are therapeutic goods, subsection 7(1A) of the Act provides that the Secretary must disregard paragraphs (e) and (f) of the definition of 'therapeutic goods' in subsection 3(1). As mentioned above, paragraph (e) refers to goods for which there is a standard under subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*, with the effect that those goods are excluded from the definition of 'therapeutic goods'. Similarly, paragraph (f) refers to goods which have a tradition of use as foods for humans in the form in which they are presented, with the effect of excluding goods which have a tradition of use as foods from 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 may bring certain goods within the scope of the Act, notwithstanding any food standard that may otherwise apply to those goods, or whether those goods have a tradition of use as foods.

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 Amendment (Declared Goods) Order 2019* ("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 containing folate substances ("the relevant goods") 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 clarifies that the relevant goods are indeed therapeutic goods as defined by the Act and therefore subject to the national system of controls established by the Act. This measure addresses uncertainty about the proper characterisation of the relevant goods as a consequence of the *Australia New Zealand Food Standards Code* – Standard 2.9.5 – Food for special medical purposes

("Food Standard 2.9.5"). The effect of the Amendment Order is to confirm that the relevant goods are therapeutic goods for the purposes of the Act, irrespective of any view regarding the application of Food Standard 2.9.5 to the relevant goods prior to the making of this Amendment Order.

The power to declare in subsection 7(1) is a discretionary power to be exercised having regard to the objects of the Act (section 4 of the Act refers). In this case, the exercise of that power is particularly useful in resolving uncertainty or differences of opinion regarding the proper characterisation of certain goods at the food medicine interface. The power to declare therefore provides an appropriate mechanism to address regulatory uncertainty by enabling the Secretary to declare particular goods to be therapeutic goods, irrespective of whether or not those goods are goods for which there is a food standard.

Background

An understanding of the regulatory frameworks for therapeutic goods and foods, as follows, necessarily informs the background for making the Amendment Order.

Regulation of therapeutic goods in Australia

The regulation of therapeutic goods in Australia is the principal responsibility of the Australian Government. The purpose of the Act is to provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods. The controls relate to a range of measures that Parliament has considered appropriate in regulating therapeutic goods, including requirements relating to the lawful supply and advertisement of medicines.

Therapeutic goods are relevantly defined in subsection 3(1) of the Act to mean 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. The definition does not include goods that come within paragraphs (e) and (f) of the definition, unless those goods are declared to be therapeutic goods under an order in force under section 7 of the Act.

In making an order under section 7 of the Act, subsection 7(1A) provides that the Secretary must disregard paragraphs (e) and (f) of the definition in deciding whether particular goods or classes of goods are therapeutic goods, either generally or when used, advertised or presented for supply in a particular way.

Therapeutic use is defined in subsection 3(1) of the Act, amongst other things, to include use in or in connection with preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons, or use in or in connection with influencing, inhibiting or modifying a physiological process.

Regulation of foods in Australia

The regulation of food in Australia is a joint responsibility of the Commonwealth and the states and territories. Food Standards Australia New Zealand ("FSANZ") is responsible for the Australia New Zealand Food Standards Code ("the Food Standards Code"), a set of national standards for food under the *Food Standards Australia New Zealand Act 1991*.

State and territory government food authorities and local councils enforce the Food Standards Code through their respective legislation, and deal with complaints regarding food and investigate food safety issues. The Department of Agriculture enforces food laws at Australia's borders in relation to imported food.

Foods are permitted to be supplied to consumers without prior regulatory approval by state and territory food authorities. Therefore, goods may be brought to market as foods without prior regulatory assessment as to whether those goods are indeed foods or therapeutic goods under law.

Goods at the interface of the food and medicines frameworks

Goods at the interface of the food and medicines frameworks give rise to uncertainty, or potential uncertainty, as to which of the regulatory frameworks applies in relation to those goods. This stems, in part, from the interplay between the definitions of *therapeutic goods* and *therapeutic use* in the Act; and the presentation and health claims made in relation to some foods, for which permission may or may not be provided in the relevant food standards.

Goods that are, or are likely to be taken to be, for use in preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons, or modifying a physiological process, are therapeutic goods, unless—in the absence of a relevant order under section 7 of the Act—there is an existing food standard applying in relation to those goods.

Food Standard 2.9.5 – Foods for special medical purposes

Food Standard 2.9.5 applies to foods for special medical purposes. A food for special medical purposes ("FSMP") is defined to mean a food that, amongst other requirements, is specially formulated for the dietary management of individuals, by way of exclusive or partial feeding, in relation to whom there are special medically determined nutrient requirements or whose capacity is limited or impaired to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients in ordinary food – and whose dietary management cannot be completely achieved without the use of the food. Other requirements include that the food is represented as being a food for special medical purposes, or for the dietary management of a disease, disorder or medical condition.

Food Standard 2.9.5 distinguishes between representations related to food for special medical purposes or dietary management, which are permitted for goods in relation to which the standard applies, from those related to therapeutic use, which is not permitted in relation to foods for special medical purposes. This is consistent with there being separate regulatory regimes in Australia relating to foods and therapeutic goods. In particular, a claim in relation to an FSMP must not refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition, or the modification of a physiological process. Nor must a claim compare the food with a good that is represented in any way to be for therapeutic use, or likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason (section 2.9.5–4 of Food Standard 2.9.5 refers).

Characterisation of foods for special medical purposes

Some goods that are purported to be FSMPs are marketed and supplied to consumers in circumstances where those goods are represented as being, or likely to be taken to be, for therapeutic use. This situation may arise due to a misunderstanding regarding the interpretation of the definition of an FSMP in Food Standard 2.9.5 and the definition of therapeutic goods in the Act. Some products are mistaken for foods because it is assumed that Food Standard 2.9.5 applies. In any case, the application of Food Standard 2.9.5 is irrelevant for the purposes of making an order under section 7 of the Act.

Considerations

In exercising the power under subsection 7(1) to declare certain goods, the Secretary must be satisfied that the goods are therapeutic goods within the meaning of the Act. Whether or not there is a food standard applying in relation to the goods is irrelevant to the exercise of the power (subsection 7(1A) refers). Ultimately, it is a matter for the Secretary or her delegate to determine whether such goods

should be declared to be therapeutic goods under subsection 7(1) because those goods are, in the Secretary's reasonable opinion, therapeutic goods within the meaning of the Act.

In determining whether goods are therapeutic goods, the Secretary must be satisfied that the definition for 'therapeutic goods' in subsection 3(1) applies. Therapeutic goods are defined with reference to therapeutic use. Most relevantly, therapeutic goods are 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.

For present purposes, the principal aspect of the definition for therapeutic use is use in or in connection with preventing, diagnosing, curing or *alleviating* a disease, *ailment*, defect or injury in persons (emphasis added) (paragraph (a) of the definition for 'therapeutic use' refers). Accordingly, the assessment as to the proper characterisation of the relevant goods is predicated on a reasonable assessment of whether or not the goods 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, specifically the alleviation of an ailment.

In the alternative, the assessment therapeutic use may also extend to whether or not the relevant goods 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 modify a physiological process in persons (paragraph (b) of the definition for 'therapeutic use' refers).

In light of the above, the following matters were considered and necessarily found in making the Amendment Order.

Depression is an ailment in persons

The ordinary meaning of depression, as defined in the Macquarie Dictionary, is 'a mental disorder characterised by unresponsiveness to stimuli, self-depreciation, delusions of inadequacy and hopelessness'. Depression is characterised as a disorder that 'specifically affect[s] the individual's capacity to function.'[1] As such, it is appropriate to conclude that depression is an ailment in persons.

Folate deficiency is an ailment in persons

Folate substances encompass the substance folic acid and its derivatives with similar biological activity. These substances are metabolised in the body to derivatives that are essential co-factors for enzymes involved in nucleic acid (DNA and RNA) synthesis, and are substrates in amino acid synthesis and metabolism, processes that are essential for human life. Folate substances are particularly important for developmental phases and physiological processes that involve rapid cell replication, such as foetal and red blood cell development. Therefore, deficiency in folate is associated with and mechanistically linked to a variety of ailments and defects in persons. Folate deficiency can result from an inborn error of metabolism, or a deficiency for another reason, such as insufficient dietary intake. Folate deficiency is considered to be an ailment in persons.

There is an association and plausible causal relationship between folate deficiency and depression

The level of folate substances in red blood cells, serum and/or cerebrospinal fluid has been found to be significantly altered in a substantial yet variable proportion of patients with major depressive disorder ("MDD") compared to control individuals.[2,3] Folate plays a role in processes that are linked

[1] *Diagnostic and Statistical Manual of Mental Disorders DSM-5* (American Psychiatric Association, 5th ed, 2013).
[2] Simon Gilbody, Tracy Lightfoot and Trevor Sheldon, 'Is low folate a risk factor for depression? A meta-analysis and exploration of heterogeneity' (2007) 61 *Journal of Epidemiology and Community Health* 631.

to the synthesis of neurotransmitters, the dysregulation of which is linked to depression. This means that there is a biologically plausible molecular mechanism by which folate deficiency in persons (evidenced by reduced levels of folate substances in cells, serum and/or cerebrospinal fluid) dysregulates cellular processes in the central nervous system, thereby causing or exacerbating the incidence or severity of mental illnesses, including depression.[4,5]

Folate deficiency in persons can result from an inborn error of folate metabolism

The methylenetetrahydrofolate reductase ("MTHFR") gene encodes the cognate protein that is involved in the *in vivo* metabolism of dietary folate. In some persons, the MTHFR gene is mutated at a single base pair and those persons are therefore said to carry an MTHFR C677T polymorphism, which impairs MTHFR activity. It follows that persons, who are considered to have a genetic (inborn) error of folate metabolism, have a defect in normal folate metabolism, which can lead to a deficiency in folate substances.

There is an association between an inborn error of folate metabolism due to the MTHFR C677T polymorphism and depression

It has been reported in several meta-analyses that individuals with depression are more likely to carry the MTHFR C677T polymorphism than those without.[6] It is reasonable to conclude that there is an association between an inborn error of folate metabolism as a consequence of the MTHFR C677T polymorphism and depression.

There is a plausible causal relationship between an inborn error of folate metabolism, depression, and other ailments or defects in persons

An inborn error of folate metabolism can lead to folate deficiency in persons, which in turn can cause ailments or defects in persons such as abnormal foetal development or depression for the reasons stated above. As such, the association between the MTHFR C677T polymorphism and depression suggests that folate deficiency secondary to the inborn error of folate metabolism is involved in the pathogenesis of depression.[7] The plausible causal relationship between an inborn error of folate metabolism and depression gives rise to the possibility that consumption of folate substances may alleviate depression in persons with folate deficiency.

Conclusions

Noting the above, it is appropriate that the relevant goods are characterised as therapeutic goods for the following reasons.

The relationship between an inborn error of folate metabolism and folate deficiency, together with the plausible causal relationship between folate deficiency and depression, means that folate is or is likely to be taken to be for therapeutic use in or in connection with preventing, curing or alleviating the ailment of folate deficiency or depression, or alternatively modifying a physiological process.

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[3] Ansley Bender, Kelsey Hagan and Neal Kingston, 'The association of folate and depression: A meta-analysis' (2017) 95 *Journal of Psychiatric Research* 9.
[4] Marshal Folstein et al, 'The Homocysteine Hypothesis of Depression' (2007) 164(6) *American Journal of Psychiatry* 861.
[5] Alan L Miller, 'The Methylation, Neurotransmitter, and Antioxidant Connections Between Folate and Depression' (2008) 13(3) *Alternative Medicine Review* 216.
[6] Vandana Rai, 'Association of C677T polymorphism (rs1801133) in MTHFR gene with depression' (2017) 63(6) *Cellular and Molecular Biology* 60.
[7] Gilbody, Lightfoot and Sheldon, above n 2.

The consumption of goods containing folate can increase folate levels in persons, meaning that those goods may be used in or in connection with preventing, curing or alleviating the ailment of folate deficiency or curing or alleviating an inborn error folate metabolism; and such use is therapeutic use within the meaning of the Act.

Folate substances are likely to be taken to be for use in or in connection with alleviating the ailment of depression and such use is therapeutic use within the meaning of the Act. A review of meta-analyses of clinical trials in persons concludes that the administration of folate substances is beneficial in the treatment of depression.[8]

Whether or not such goods may be characterised as FSMPs within the meaning of Food Standard 2.9.5 (including because the relevant goods are represented as being for the dietary management of a disease, disorder or medical condition) is irrelevant to the exercise of the power to declare the relevant goods to be therapeutic goods under section 7 of the Act. In fact, the effect of subsection 7(1A) of the Act expressly obliges the Secretary to disregard whether or not a food standard applies in relation to the goods.

Whether a recommended single dose of the goods contains sufficient macronutrients to feed, either exclusively or partially, the person for whom the dose is intended does not affect the characterisation of whether or not the relevant goods are therapeutic goods.

The fact that the relevant goods contain only folate substances that are found in food (within the ordinary meaning of the word), or that are ordinarily obtained from food, and restore levels of folate that are required for normal function, does not preclude the Secretary from declaring those goods to be therapeutic goods when used, advertised or presented for supply for therapeutic use or in a particular way that is likely to be taken to be for therapeutic use.

The power to declare goods to be therapeutic goods does not require an assessment as to whether or not those goods pose an unacceptable risk to human health if regulated as foods. However, the effect of the Amendment Order necessarily ensures that the relevant goods will be regulated under the Act as therapeutic goods – principally medicines, that may be required to be registered or listed in accordance with the Act and instruments made thereunder, having regard to the relevant risk. This ultimately depends on the amount of folate in the goods and the associated therapeutic claims.

The fact that such goods may be used as adjunct therapies for conditions such as depression (working in conjunction with prescription medicines), and containing substances ordinarily consumed from diet, does not mean that these goods are not themselves medicines. Indeed, it is appropriate in the circumstances that the relevant goods are subject to the national system of controls relating to therapeutic goods which may be described as complementary medicines.

Consultation

The TGA undertook public consultation in September 2019 regarding the proposal to make an order under subsection 7(1) of the Act to declare a particular class of goods containing folate substances to be therapeutic goods. As part of the public consultation, the TGA published the proposed declaration, which is in largely similar terms to the Amendment Order. Twenty-five submissions were received from a range of respondents including investors, consumers, academics, health professionals, health-related organisations and persons associated with corporate entities that may be affected by the proposed declaration, including manufacturers and suppliers.

[8] Joesph Firth et al, 'The efficacy and safety of nutrient supplements in the treatment of mental disorders: a meta-review of meta-analyses of randomized controlled trials' (2019) 18 *World Psychiatry* 308.

Following the public consultation, the TGA provided further relevant information in October 2019 to the persons who had made submissions to the public consultation (being information before the TGA, including information provided by other parties) and invited supplementary comment.

A number of submissions objected to the terms of the proposed declaration on the basis of the anticipated financial and other impacts that the proposed declaration would have on a particular entity, including its investors and staff. That entity is presently supplying goods that would appear to fall within the terms of the declaration; and the impacts would therefore include the practical requirements for registering or listing the goods on the Australian Register of Therapeutic Goods ("the Register").

A related issue raised by some respondents was the potential loss of access by consumers of the affected goods, which have been manufactured and supplied as if those goods were not subject to the therapeutic goods framework but, following the making of the declaration, would clearly be so regulated. These respondents made submissions regarding the consequent hardship on consumers if the proposed declaration were to be made. A number of respondents were concerned that relevant schemes under the Act relating to alternative access (that is, the Authorised Prescriber Scheme and the Special Access Scheme) would not be effective.

The relevant goods affected by the declaration may continue to be supplied to consumers under the alternative access schemes until such time as those goods are registered or listed on the Register. The alternative access schemes are means by which the impact on affected entities currently supplying goods within the terms of the declaration and consumers using those goods may be managed. The schemes involve health practitioners facilitating access to goods which are not presently approved for general marketing in Australia. This is reasonable in the circumstances given that the goods 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.

Another issue raised in submissions received in response to the public consultation was that the declaration would preclude dietary management of patients with inborn errors of metabolism. That is, that dietary requirements in this regard would no longer be able to be addressed by FSMPs. However, the possibility of dietary management, including of a disease, disorder or medical condition, would remain if goods containing folate substances are not used, advertised or presented for supply in any way that is likely to be taken to be for therapeutic use. This was recognised in one of the submissions. For example, in individuals whose capacity to take folate substances from ordinary food is impaired due to a disorder that precludes the consumption of foods containing normal dietary sources of folate, then the dietary management of those individuals may require use of goods containing folate substances (folate being an essential vitamin in persons).

A number of submissions questioned the need for, and the scope of, the declaration. The view of some respondents was that Food Standard 2.9.5 deals with goods that are within the scope of the declaration adequately. This view appeared to be on the basis that goods containing only substances ordinarily consumed from the diet (which is the case for some folate substances) are appropriately characterised FSMPs. Further, a number of respondents considered there was no indication that folate should be considered a therapeutic treatment, or no evidence of safety or efficacy issues with products that may be affected by the declaration. These respondents also indicated that, if the declaration was to be made, it could be narrowed or made clearer.

It is evident from the consultation that there are differing views as to whether affected products are to be seen as FSMPs or therapeutic goods. The evidence for the association between folate and therapeutic use has been referred to above. While affected goods may simply be an adjunct therapy for conditions such as depression (working in conjunction with any prescription medicines), and contain substances ordinarily consumed from the diet, as mentioned above, this does not mean those goods are not themselves medicines. Indeed, goods captured by the declaration would be regulated as complementary medicines, whether or not those goods may fall to be registered or listed on the Register. To narrow the scope of the declaration would detract from the purpose of ensuring relevant

goods are regulated by the most appropriate regulatory scheme. It is appropriate that the declaration therefore provide clarification at the interface of the food and medicine frameworks in relation to these goods.

There was also a specific concern raised in two submissions that the general reference to 'inborn error of metabolism' in paragraph (d) of column 3 of the proposed declaration would be interpreted too broadly, and should therefore be specified with reference to folate metabolism. These submissions resulted in an amendment being made to the proposed declaration (now reflected in this Amendment Order) duly referencing folate metabolism.

Further, one of these submissions, although raising some issues about the scope of the proposed declaration discussed above, supported the clarifying intent that when goods claiming to be food for special medical purposes, are presented for therapeutic use, those goods should be regulated as therapeutic goods with the appropriate quality, safety and efficacy controls.

On balance, it is appropriate that the power under subsection 7(1) of the Act is exercised to provide clarity and certainty regarding the regulation of goods within the terms of the Amendment Order. These goods, when represented in any way to be, or 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, are appropriately characterised as therapeutic goods, and should therefore be subject to the national system of controls under the Act for therapeutic goods.

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 2003* ("Legislation Act") and commences on the day after it is registered on the Federal Register of Legislation. Under subsection 56(1) of the Legislation Act, the requirement for the Amendment Order to be published in the *Gazette* under section 7 of the Act, is satisfied by registration of the Amendment Order as a legislative instrument.

Attachment A

Details of the *Therapeutic Goods Amendment (Declared Goods) Order 2019*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Declared Goods) Order 2019* ("the Amendment Order").

Section 2 – Commencement

This section provides that the Amendment Order commences on the day after it is registered on the Federal Register of Legislation.

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 instrument 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 inserts a new item 1A into the table in Part 2 of Schedule 1 to the Principal Order. The effect of this amendment is to declare certain goods containing folate substances that are represented as being food for special medical purposes, or being for the dietary management of a disease, disorder or medical condition to be therapeutic goods when used, advertised, or presented for supply 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 Amendment (Declared Goods) Order 2019

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 Amendment (Declared Goods) Order 2019* ("the instrument") is made under section 7 of the *Therapeutic Goods Act 1989* ("the Act").

Subsection 7(1) of the Act confers on the Secretary of the Department a power to declare, by order published in the *Gazette* or on the Department's website, 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 be satisfied that the goods are or are not in fact therapeutic goods as defined in the Act. In short, subsection 7(1) provides a mechanism for clarifying whether particular goods or classes of goods are or are not therapeutic goods, and therefore whether or not those goods are subject to the regulatory scheme established by the Act.

In determining whether particular goods or classes of goods, or those goods when used, advertised, or presented for supply in a particular way, are therapeutic goods, subsection 7(1A) of the Act provides that the Secretary must disregard paragraphs (e) and (f) of the definition of 'therapeutic goods' in subsection 3(1). Paragraph (e) refers to goods for which there is a standard under subsection 4(1) of the *Food Standards Australia New Zealand Act 1991*, with the effect that those goods are excluded from the definition of therapeutic goods for the purposes of the Act. Similarly, paragraph (f) refers to goods which have a tradition of use as foods for humans in the form in which they are presented, with the effect of excluding goods which have a tradition of use as foods from the definition of therapeutic goods for the purposes of the Act. 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 may bring certain goods within the scope of the Act, notwithstanding any food standard that may otherwise apply to those goods, or whether those goods have a tradition of use as foods.

The instrument amends the *Therapeutic Goods (Declared Goods) Order 2019* by declaring certain goods containing folate substances ("the relevant goods") 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 instrument clarifies that the relevant goods are therapeutic goods as defined by the Act and therefore subject to the national system of controls established by the Act. This measure addresses uncertainty about the proper characterisation of the relevant goods as a consequence of the *Australia New Zealand Food Standards Code* – Standard 2.9.5 – Food for special medical purposes ("Food Standard 2.9.5"). The effect of the instrument is to confirm that the relevant goods are therapeutic goods for the purposes of the Act, irrespective of any view regarding the application of Food Standard 2.9.5 to the relevant goods prior to the making of this 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 clarifying that the relevant goods are indeed therapeutic goods appropriately regulated under the Act. As a consequence, the instrument promotes public health and safety by ensuring the relevant goods are subject to the national system of controls provided under the Act relating to the quality, safety, and efficacy of therapeutic goods.

Conclusion

This 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.

Dr Jane Cook, delegate of the Secretary of the Department of Health