

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 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.

Section 26BB of the Act relevantly provides that the Minister of Health may, by legislative instrument, make a determination specifying ingredients and, for some or all of those ingredients, requirements in relation to those ingredients being contained in a medicine. Under subsections 26BB(2), (2A) and (3) of the Act, such requirements may relate to particular ingredients not being contained in particular medicines or being contained in particular medicines only in specified circumstances, or to permitted concentrations or total amounts of an ingredient in a medicine.

Legislative instruments made under section 26BB of the Act are designed to specify those ingredients that may be contained in a medicine that is listed in the Australian Register of Therapeutic Goods (“the Register”) under section 26A or 26AE of the Act, and to specify requirements in relation to the inclusion of those ingredients in such medicines.

Section 26BC of the Act provides that the Minister may, on his or her own initiative and by legislative instrument, vary a determination made under section 26BB of the Act, and the *Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 2019* (“the Amendment Determination”) is a determination made by a delegate of the Minister under section 26BC of the Act.

The purpose of the Amendment Determination is to amend the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2019* (“the Principal Determination”), which commenced on 3 July 2019, mainly to better address the risks posed by overuse of the ingredient caffeine and other ingredients that contain the chemical caffeine as a component, and to make a small number of other amendments including to introduce new ingredients for use in listed and assessed listed medicines.

Background

Medicines that are listed in the Register under section 26A of the Act are considered to be low risk and are not individually evaluated before those medicines are listed. Medicines that are listed in the Register under section 26AE of the Act are also considered to be low risk, but are evaluated in relation to whether the efficacy of the medicine for the purposes for which it is to be used has been satisfactorily established (these purposes are specific efficacy claims for which the sponsor of the medicine holds supporting evidence). When listed under section 26AE, these listed medicines are commonly referred to as ‘assessed listed medicines’.

As the safety and quality of medicines listed under sections 26A and 26AE are not evaluated by the TGA before being given marketing approval, the Act contains mechanisms to help ensure that those medicines are of appropriate quality and able to be used safely by consumers. In particular, medicines listed under section 26A and 26AE may only contain ingredients from an approved list of ingredients that have been evaluated in relation to their quality and safety and suitability for use in such medicines. Sponsors of such medicines may also only use indications (statements of therapeutic use) from a list of pre-approved low level indications to ensure that these products do not overstate their therapeutic benefits.

Under paragraphs 26A(2)(ca) and (cb) of the Act, persons applying to list a medicine in the Register under section 26A of the Act must certify that the medicine does not contain an ingredient that is not specified in a determination under paragraph 26BB(1)(a) of the Act; and does not contravene a requirement in relation to such an ingredient that is specified in such a determination. Paragraphs 26AB(2)(d) and (e) contain equivalent certification requirements for applicants seeking marketing approval in relation to assessed listed medicines. A listed (or assessed listed) medicine may be cancelled from the Register if it appears to the Secretary that such a certification is incorrect.

Separately, items 3, 4A, 5, 7 and 8 of Schedule 4 to the *Therapeutic Goods Regulations 1990*, which identifies those therapeutic goods that are eligible for listing in the Register, require that, in order for the goods mentioned in each of those items to be eligible for listing, the goods must only contain ingredients that are specified in a determination under paragraph 26BB(1)(a) of the Act and must not contravene a requirement in such a determination.

As such, determinations under section 26BB are designed to provide a comprehensive list of ingredients which have been assessed or otherwise considered to be safe for use in listed medicines (including assessed listed medicines), and associated requirements to be followed when using particular ingredients in such products. These requirements may relate to a range of matters including, for example, how an ingredient may be used in a medicine or the inclusion of relevant safety information on product labels.

The Amendment Determination amends the Principal Determination to make a number of safety related changes to entries in the Principal Determination for the ingredient ‘caffeine’ and other ingredients that contain the chemical caffeine as a component, principally in order to mitigate concerns in relation to unintentional overuse.

Caffeine occurs naturally in certain plants, nuts and seeds and has a long history of use as a stimulant. Adverse effects may occur in people who consume caffeine depending on a number of factors, including how much a person consumes, their general health and whether they are a regular or infrequent user of caffeine.

In mid-June 2019, the TGA was contacted by the Coroner’s Court of New South Wales regarding the death of Mr Lachlan Foote. The TGA understands that Mr Foote’s death was associated with caffeine toxicity, with the caffeine suspected to have been ingested from an unlabelled pure or highly concentrated caffeine powder that contained a far higher concentration of caffeine than would be contained in listed or listed assessed medicines, or in regularly consumed foods that contain caffeine. Further, on 10 July 2019 Minister Colbeck

and Minister Hunt wrote to Food Standards Australia New Zealand (FSANZ) to request a review of the safety of caffeine powders and high caffeine content products. The Ministers also requested that FSANZ engages with TGA to align therapeutic goods regulations with food regulation to the extent possible.

The Amendment Determination is therefore intended to introduce additional requirements for this purpose, by specifying limits on total caffeine concentration in listed and assessed listed medicines. This will ensure that caffeine levels in such medicines, which are available for self-selection by consumers, do not present an undue risk of unintentional caffeine overdose.

The Amendment Determination reflects work undertaken by the TGA since 2017, to review the requirements applying to the use of caffeine and related ingredients in listed and assessed listed medicines, input from industry and the Advisory Committee on Complementary Medicines during 2018, and further TGA review of current toxicology data pertaining to caffeine in 2019. The review highlighted that additional requirements, which consist of warning statements about caffeine intake and maximum dose limits within 3 hour and daily periods, are appropriate to ensure that these products are safe and consistent with the expectation that they are low-risk products appropriate for self-selection by consumers.

The existing requirements in the Principal Determination for the ingredient ‘caffeine’ do not permit the listing of such a pure caffeine product. However, these requirements do not also fully address the safety concerns presented by such highly-concentrated caffeine products, and it is these concerns that are addressed by the changes introduced by the Amendment Determination.

The Amendment Determination also amends the Principal Determination to make a small number of other changes, including in particular to introduce new ingredients 3,7-DIMETHYL-1-OCTEN-3-OL, BACILLUS COAGULANS and POLYGLYCERYL-2 DISTEARATE for use in listed and assessed listed medicines for the first time. This follows the completion of an assessment of the suitability of these ingredients for use in low-risk medicines.

The other changes introduced by the Amendment Determination are designed both to make the applicable requirements for a small number of ingredients less restrictive in relation to their use in listed and assessed listed medicines, and (principally) to better align those requirements with the recommended level of control relating to the use of such ingredients in the Poisons Standard (e.g. BRILLIANT SCARLET 4R, LAVENDER OIL and THYMOL).

Consultation

The TGA contacted affected sponsors and key industry associations, the then Australian Self Medication Industry (now Consumer Healthcare Products Australia – “CHPA”) and Complementary Medicines Australia (“CMA”), in March and May 2018 regarding proposals to amend the requirements for caffeine in listed and assessed listed medicines. CMA supported the responsible use of caffeine recognising that it was occasionally subject to

misuse, and proposed additional warning statements for products with a higher caffeine content, based on requirements for current over the counter medicines, a safety report produced by the European Food Safety Authority and a monograph for such products prepared by Health Canada. CMA also raised concerns that products with only low levels of caffeine should not be affected by the proposed changes, as that would not be consistent with the particular risks being addressed.

The Amendment Determination takes into account this feedback from CMA, by considering the EFSA report and better clarifying the proposed additional warning statements for higher and lower caffeine content products.

In addition to the above consultation, advice on the issue was also sought from the Advisory Committee for Complementary Medicines (ACCM) in November 2018 regarding requirements for caffeine in listed medicines. That advice to the Delegate of the Minister of Health was also considered in developing the Amendment Determination.

The Office of Best Practice Regulation (OBPR) advised that a regulation impact statement was not required for the provisions related to caffeine within the Amendment Determination (OBPR reference 25406).

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

The Amendment Determination is compatible with the 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 Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003*, and commences on 2 September 2019.

Details of the *Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 2019*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 2019* (“the Amendment Determination”).

Section 2 Commencement

This section provides that the Amendment Determination commences on 2 September 2019.

Section 3 Authority

This section provides that the legislative authority for making the Amendment Determination is section 26BC of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4

This section provides that each instrument that is specified in a Schedule to the Amendment Determination 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 (Permissible Ingredients) Determination (No. 2) 2019* (“the Principal Determination”), to repeal and substitute the entry in the Principal Determination for caffeine, and a number of other entries in the Principal Determination for other ingredients that contain the chemical caffeine as a component (e.g. *camellia sinensis*).

The principal effect of these amendments is to replace the requirements that applied under the Principal Determination in relation to the use of caffeine and the other specified ingredients with revised requirements that are designed in particular to address the risks of unintentional caffeine overdose.

The amendments in Schedule 1 also have the effect of introducing 3 new ingredients - 3,7-DIMETHYL-1-OCTEN-3-OL, *Bacillus Coagulans*, and Polyglyceryl-2 Distearate to the Principal Determination to authorise their use in listed and assessed listed medicines, and of making the applicable requirements for a small number of ingredients less restrictive in relation to their use in such products.

Statement of Compatibility with Human Rights

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

Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 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 the Legislative Instrument

The *Therapeutic Goods Amendment (Permissible Ingredients) Determination (No. 1) 2019* (“the amendment instrument”) is made by the Minister under section 26BC of the *Therapeutic Goods Act 1989* (“the Act”).

The purpose of the amendment instrument is to amend the *Therapeutic Goods (Permissible Ingredients) Determination (No. 2) 2019* (“the principal instrument”), which commenced on 3 July 2019, mainly to better address the risks posed by overuse of the ingredient caffeine and other ingredients that contain the chemical caffeine as a component.

Caffeine occurs naturally in certain plants, nuts and seeds and has a long history of use as a stimulant. Adverse effects may occur in people who consume caffeine depending on a number of factors, including how much a person consumes, their general health and whether they are a regular or infrequent user of caffeine.

In mid-June 2019, the TGA was contacted by the Coroner’s Court of New South Wales regarding the death of Mr Lachlan Foote. The TGA understands that Mr Foote’s death was associated with caffeine toxicity, with the caffeine suspected to have been ingested from an unlabelled pure or highly concentrated caffeine powder that contained a far higher concentration of caffeine than would be contained in listed or listed assessed medicines, or in regularly consumed foods that contain caffeine.

The amendment instrument is therefore intended to introduce additional requirements for this purpose, by specifying limits on total caffeine concentration in listed and assessed listed medicines. This will ensure that caffeine levels in such medicines, which are available for self-selection by consumers, do not present an undue risk of unintentional caffeine overdose.

The amendment instrument reflects work undertaken by the TGA since 2017, to review the requirements applying to the use of caffeine and related ingredients in listed and assessed listed medicines. The review highlighted that additional requirements, which consist of warning statements about caffeine intake and maximum dose limits within 3 hour and daily periods, are appropriate to ensure that these products are safe and consistent with the expectation that they are low-risk products appropriate for self-selection by consumers.

The existing requirements in the principal instrument for the ingredient ‘caffeine’ do not permit the listing of such a pure caffeine product. However, these requirements do not also fully address the safety concerns presented by such highly-concentrated caffeine products, and it is these concerns that are addressed by the changes introduced by the amendment instrument.

The amendment instrument also amends the principal instrument to make a small number of other changes, including to introduce new ingredients 3,7-DIMETHYL-1-OCTEN-3-OL, Bacillus Coagulans and Polyglyceryl-2 Distearate to the principal instrument to authorise their use in listed or assessed listed medicines for the first time, and to make minor clarifications to requirements for a small number of other ingredients, to better align the applicable requirements for those ingredients with the level of control recommended in the Poisons Standard for those ingredients (e.g. Brilliant Scarlet 4R, Lavender oil and Thymol).

Human rights implications

The amendment 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 standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right. 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 amendment instrument takes positive steps to promote the right to health by, principally, upgrading the requirements relating to the use of caffeine and other ingredients that contain the chemical caffeine as a component, in order to ensure the safety and quality of listed and assessed listed medicines containing such ingredients.

By introducing targeted requirements relating to the risk of overuse of caffeine, such as requiring the use of warning statements on labels about caffeine intake and maximum dose limits within 3 hour and daily periods, the safety of Australian consumers will be better protected, and they will be better able to make informed decisions about such medicines.

This is particularly important for listed medicines, given that those medicines are not evaluated for safety and quality by the TGA prior to listing in the Australian Register of Therapeutic Goods, and as they are usually available for self-selection by consumers without a requirement to first obtain the advice or prescription of a registered medical doctor, or the advice of a pharmacist.

Conclusion

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

Cheryl McRae, delegate of the Minister for Health