

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods (Excluded Goods) Determination 2018

The *Therapeutic Goods Act 1989* (“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.

Section 7AA of the Act confers a power on the Minister for Health to determine specified goods to be excluded goods for the purposes of the Act. The effect of this provision is to exclude specified goods from the operation of the Act.

Specifically, subsection 7AA(1) provides that the Minister may determine that specified goods are excluded goods for the purposes of the Act. Further, subsection 7AA(2) provides that the Minister may determine that specified goods are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified way.

A determination made under subsections 7AA(1) and 7AA(2) must be made by legislative instrument and, in accordance with subsection 13(3) of the *Legislation Act 2003*, may be made with reference to a class or classes of goods.

Before making a determination under section 7AA, the Minister is required to have regard to certain matters specified in subsection 7AA(3). In addition, the Minister may have regard to any other matter that the Minister considers relevant (subsection 7AA(4) refers).

The matters that the Minister must have regard to before making a determination are as follows:

- (a) whether it is likely that the specified goods might harm the health of members of the public if not regulated under the Act;
- (b) whether it is appropriate in all the circumstances to apply the national system of controls established by the Act (as mentioned above) to regulate the specified goods; and
- (c) whether the kinds of risks that members of the public might be exposed to from the specified goods could be more appropriately dealt with under another regulatory scheme.

The *Therapeutic (Excluded Goods) Determination 2018* (“Determination”) is a new determination under section 7AA of the Act. The purpose of the Determination is to exclude the following specified goods from the operation of the Act:

- ear candles and low risk antiperspirant preparations (“the first measure”);
- certain goods, which are presently declared not to be therapeutic goods in the existing *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011* (“EGO”) (“the second measure”); and
- low risk cosmetic therapeutic goods, which are also declared not to be therapeutic goods in the EGO and are currently subject to requirements set out in the *Cosmetics Standard 2007* (“Cosmetics Standard”) (“the third measure”).

The first measure implements changes considered as part of the review into low risk products, *Consultation: Options for the future regulation of “low risk” products* (March 2017). That review was undertaken as a consequence of recommendations 14, 23 and 48 in the Expert Panel Review of Medicines and Medical Devices Regulation (“MMDR Review”).

The purpose of the first measure is to confirm that such goods are consumer goods and need not be further regulated under the Act as therapeutic goods. A consequence of this measure is to enable

valuable resources of the Department of Health to be appropriately directed towards the regulation of other therapeutic goods, such as prescription medicines and high-risk medical devices.

The effect of this measure will be to ensure that ear candles and certain low risk antiperspirants are regulated solely under Australian Consumer Law, in the absence of any additional regulation by the Therapeutic Goods Administration (“TGA”). The reference to low risk antiperspirant preparations is limited to those that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only.

The second measure is intended to clarify the characterisation and regulation of fifteen specified goods. This measure will not have any regulatory impact on affected stakeholders, as the goods are presently considered not to be therapeutic goods and are therefore not subject to the operation of the Act. The purpose of this measure is to remove any ambiguity associated with the regulation of these goods and clarify the mechanism under which the Act does not apply to them.

The third measure relates to the second measure to the extent that it concerns eight low risk cosmetic therapeutic goods, which are also declared not to be therapeutic goods under the current EGO (section 6 of that order refers). The purpose of this measure is intended to clarify the characterisation and regulation of the eight low risk cosmetic therapeutic goods, and (as explained above) to remove any ambiguity associated with the regulation of these goods.

In addition, the third measure reproduces the content of the Cosmetics Standard, which will be allowed to sunset on 1 October 2018. That standard, made under section 81 of the *Industrial Chemicals (Notification and Assessment) Act 1989*, remains the responsibility of the National Industrial Chemicals Notification and Assessment Scheme (“NICNAS”) until its sunsetting. It specifies minimum requirements for the eight low risk cosmetic therapeutic goods in question that meet the definition of therapeutic goods but are excluded from therapeutic goods legislation as a consequence of the current EGO.

In reproducing the content of the *Cosmetics Standard 2007* in the Determination, the intention is to maintain continuity with respect to the quality of these goods and, where applicable, the particular manner in which they may be advertised or presented for supply. This measure will not change or impose any additional regulatory burden on industry. Rather, it is intended to make sure that the quality standards that apply with respect to these goods are maintained in order for those goods to remain outside the operation of the Act. As a consequence, this measure will maintain the regulatory status quo.

In summary, the first measure will result in, and the second and third measures will continue, the regulation of the specified goods as consumer goods by the Australian Competition and Consumer Commission. In the event of a safety issue or false and misleading statements in advertising for these products, provisions of the Australian Consumer Law would continue to afford protection to the Australian public. Further, in the event that these goods are exported, imported or supplied in a manner that is not consistent with the terms of their exclusion under the Determination, then those goods (to the extent that they are therapeutic goods) will be captured by the operation of the Act.

Background

The MMDR Review was undertaken to identify unnecessary or ineffective regulation and propose opportunities to enhance the regulatory framework so that Australia continues to be well-positioned to respond effectively to global trends in the development, manufacture, marketing and regulation of therapeutic goods. The Government’s response to that review was released in September 2016.

The Australian Government accepted recommendations 14, 23 and 48 of the MMDR Review, to undertake further reviews in relation to the regulation of ‘low risk’ products. The Government charged the TGA with examining whether the regulatory oversight applied to a range of low risk products, which represent a negligible safety risk to consumers, was consistent with the principles

of best practice regulation; and further, whether there were any opportunities for streamlining or simplifying current regulatory requirements in relation to these products.

The Determination implements two proposals for the regulation of low risk products that have been endorsed by the Government following that review, including ear candles and antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only. The benefit of this measure is to align the regulation of these goods with other comparable overseas regulators and to remove any perception, specifically in relation to ear candles, that those products have a legitimate therapeutic use within the meaning of the Act.

Consultation

The Office of Best Practice Regulation advised that a regulation impact statement was not required in relation to the making of this Determination, as the three measures implemented are likely to have minor impacts on businesses, individuals or not-for-profits, remove ambiguity, or are machinery in nature (OBPR ID24223). In addition, the Determination is not expected to have any financial impact.

Prior to the making of this Determination, the TGA undertook a series of targeted stakeholder consultations over the last two years in relation to the first measure, being the regulation of ear candles and low risk antiperspirant preparations. In particular, public consultation on potential options to streamline the regulation of low risk therapeutic goods was conducted between March and May 2017. During that process, key stakeholders, including peak industry bodies and health professional interest groups, were expressly invited to comment.

In response, the TGA received over 1,000 written submissions from numerous interested parties, including major industry groups, sponsors, manufacturers, healthcare professional bodies and individuals with a significant interest in the product types discussed in the consultation paper. The proposed options for reform ranged from retaining the status quo to exemption and exclusion from the therapeutic goods regulatory framework.

Following an analysis of the submissions, the Government endorsed a range of reform activities, including the first measure of this Determination to exclude ear candles and low risk antiperspirants from the operation of the Act. These outcomes were communicated to the public in a statement dated 21 June 2018, which is published on the TGA website.

In relation to the second and third measures, the TGA considered that consultation was not necessary, as the exclusion of the specified goods in question is minor and machinery in nature. It clarifies the mechanism in the Act under which those goods are not subject to the operation of the Act. Importantly, these measures do not alter the existing regulatory arrangements in relation to the goods.

Documents incorporated by reference

The Determination specifies goods in Schedules 1 and 2 by reference to certain matters contained in the following documents:

- *Australian Standard: Medical gas systems – Installation and testing of non-flammable medical gas pipeline systems (AS 2896–2011)*, prepared by Committee HE-017 (Medical Gas Systems), approved on behalf of the Council of Standards Australia on 13 January 2011, and published by SAI Global Limited under licence from Standards Australia on 8 May 2011 (AS 2896–2011);
- *Australian/New Zealand Standard Sunscreen products – Evaluation and classification (AS/NZS 2604:1998)*, prepared by the Joint Technical Committee CS/42 Sunscreen Agents, approved on behalf of the Council of Standards Australia on 31 July 1998 and the Council

of Standards New Zealand on 24 August 1998, and published jointly by Standards Australia and the body known as Standards New Zealand on 5 October 1998 (AS/NZS 2604:1998);

- *Australian/New Zealand Standard Sunscreen products – Evaluation and classification (AS/NZS 2604:2012)*, prepared by the Joint Technical Committee CS-042, Sunscreen Agents, approved on behalf of the Council of Standards Australia on 9 May 2012 and the Council of Standards New Zealand on 9 May 2012, and published by SAI Global Limited under licence from Standards Australia on 30 May 2012 (AS/NSZ 2604:2012); and
- the Poisons Standard made under section 52D of the Act.

AS 2896–2011 sets out requirements for the safety aspects, construction, testing and certification, operation and maintenance of non-flammable medical gas pipeline systems used for patient care, therapeutic, diagnostic and for operating surgical tools. This standard may be purchased from <https://infostore.saiglobal.com>. It is not freely available, as it is subject to copyright. The cost of obtaining the standard is a matter for industry. The TGA has no control over these costs. However, by prior written arrangement with the TGA, a copy of the standard may be made available for viewing free of charge at the TGA office in Symonston, ACT.

Both AS/NZS 2604:1998 and AS/NSZ 2604:2012 set out procedures for determining the performance of sunscreen products in terms of their mean protection factors. These standards may be purchased from <https://infostore.saiglobal.com>. As above, these documents are not freely available, as they are subject to copyright. The cost of obtaining them is a matter for industry. The TGA has no control over these costs. However, by prior written arrangement with the TGA, a copy of the standards may be made available for viewing free of charge at the TGA office in Symonston, ACT.

The Poisons Standard comprises decisions of the Secretary or her delegate regarding the classification of poisons into the different Schedules, signifying the degree of control recommended to be exercised over their availability to the public. The Poisons Standard is a legislative instrument and is freely available from the Federal Register of Legislation at <https://www.legislation.gov.au>.

In accordance with subsection 14(2) of the *Legislation Act 2003*, these documents are incorporated as in force or existing immediately before the commencement of this Determination. This means that any subsequent changes to these documents will not be automatically applied under the Determination.

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

The Determination 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 Determination is a disallowable legislative instrument and commences on 1 October 2018.

Details of the *Therapeutic Goods (Excluded Goods) Determination 2018*

Section 1 – Name

This section provides that the name of the Determination is the *Therapeutic Goods (Excluded Goods) Determination 2018*.

Section 2 – Commencement

This section provides that the Determination commences on 1 October 2018. This date corresponds with the date on which the *Cosmetics Standard 2007* (“Cosmetics Standard”) will be allowed to sunset in accordance with the provisions of the *Legislation Act 2003*.

Section 3 – Authority

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

Section 4 – Definitions

This section provides the definitions of certain terms used in the Determination. The section notes that a number of terms have the same meaning as in the Act, including advertise, label and supply. It also provides definitions in relation to instruments that are referenced in the Determination.

Section 5 – Excluded goods

This section is made pursuant to subsection 7AA(1) of the Act, and provides that the goods specified in Schedule 1 to this Determination are excluded goods for the purposes of the Act.

Section 6 – Excluded goods when used, advertised or presented for supply in a particular way

This section is made pursuant to subsection 7AA(2) of the Act, and provides that the goods specified in Schedule 2 to this Determination, when used, advertised, or presented for supply in a way specified in the Schedule, are excluded goods for the purposes of the Act.

Schedule 1 – Specified goods

Schedule 1 specifies 15 goods that are excluded goods for the purposes of the Act.

With the exception of ear candles and antiperspirant preparations that derive their antiperspirant properties from inorganic salts of aluminium, zinc or zirconium only, all items in Schedule 1 of the Determination specify goods that are presently declared not to be therapeutic goods in the current *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011* (“EGO”).

These items include adhesive removers and non-medicated skin cleansers relating to colostomy and ileostomy; dental bleaches and whiteners; devices for measuring alcohol content in bodily fluids or exhaled air; disinfectant and sterile gases; drinking water purification and treatment equipment; hair bleaches and dyes; incontinence and menstrual pads, and mattress overlays and protectors.

As these goods are presently declared not to be therapeutic goods within the meaning of section 3 of the Act (and therefore not subject to its operation), their inclusion in the Determination will have no regulatory impact on industry and does not pose an increased risk to public health.

Item 2 of Schedule 1 expressly excludes certain antiperspirant preparations from the operation of the Act. These products are largely viewed by consumers as toiletries rather than therapeutic goods.

In addition, the exclusion of these goods will align Australia's regulation of these goods with New Zealand and Europe. Accordingly, it is considered appropriate for these goods to be regulated under the Australian Consumer Law and excluded from the operation of the Act.

Item 7 of Schedule 1 specifies ear candles, which prior to this Determination required listing on the Australian Register of Therapeutic Goods ("Register") prior to any lawful exportation, importation, or supply in Australia. However, given that the claims relating to ear candles are generally cosmetic or personal hygiene in nature, it is appropriate that these products are regulated as consumer goods under the Australian Consumer Law to align with community expectations, and also to remove any perception that these goods have a legitimate therapeutic use.

Items 12 and 14 of Schedule 1 specify low risk cosmetic therapeutic goods, which include products intended for application to the lips and tinted bases and foundations, both of which must contain sunscreen and not any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard. These goods are currently declared in the EGO not to be therapeutic goods, subject to compliance with requirements set out in the Cosmetics Standard.

As the Cosmetics Standard will be allowed to sunset on 1 October 2018, the content of that standard has been reproduced in this Determination to maintain continuity of quality standards for low risk cosmetic therapeutic goods, which are by their compliance with those standards not presently subject to the operation of the Act.

Schedule 2 – Specified goods used, advertised or presented for supply in a particular way

Schedule 2 specifies 11 goods that are excluded goods for the purposes of the Act, when used, advertised, or presented for supply in a particular way specified in column 3 of the table in Schedule 2.

All items specified in this Schedule are currently declared not to be therapeutic goods in the EGO, and are therefore not subject to the operation of the Act. The majority of these items are low risk cosmetic therapeutic goods, for which the requirements of the sunseting Cosmetic Standards are reproduced in full.

These items include specified anti-acne, anti-bacterial, moisturising and sunbathing skin care products, which contain sunscreen and do not contain any substance included in Schedules 2, 3, 4 or 8 to the Poisons Standard. These goods are specified with reference to relevant Australian (and New Zealand) Standards, and are contingent on the goods being used, advertised or presented for supply in a particular manner.

In addition to low risk cosmetic therapeutic goods, Schedule 2 also specifies:

- compressed gases when used as a power source for medical devices;
- packs and kits containing medical devices for the prevention of blood borne and sexually transmissible diseases, where each individual therapeutic good contained within the packs or kits is already included in the Register and the packs or kits are advertised or presented for supply as part of a Government endorsed health promotion program;
- piped medical gas systems when installed and used in compliance with AS 2896–2011;
- preparations containing a suncreening substance, if the primary purpose of the preparation is neither protection from solar radiation nor another therapeutic purpose, and the preparation is not advertised or presented for supply with:
 - ✓ a statement of claimed sun protection factor;
 - ✓ a description of a claimed sun protection factor; or
 - ✓ a reference to another therapeutic use in respect of the preparation; and

- therapeutic goods for retaining, cushioning or repairing dentures when advertised or presented for supply to the ultimate consumer.

As these goods are presently declared not to be therapeutic goods in the current EGO, their inclusion in the Determination will have no regulatory impact on industry and does not pose an increased risk to public health.

STATEMENT OF COMPATIBILITY WITH HUMAN RIGHTS

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

Therapeutic Goods (Excluded Goods) Determination 2018

This 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 Act 1989* (“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.

Section 7AA of the Act confers a power on the Minister for Health to determine specified goods to be excluded goods for the purposes of the Act. The effect of this provision is to exclude specified goods from the operation of the Act.

Specifically, subsection 7AA(1) provides that the Minister may determine that specified goods are excluded goods for the purposes of the Act. Further, subsection 7AA(2) provides that the Minister may determine that specified goods are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified way.

A determination made under subsections 7AA(1) and 7AA(2) must be made by legislative instrument and, in accordance with subsection 13(3) of the *Legislation Act 2003*, may be made with reference to a class or classes of goods.

Before making a determination under section 7AA, the Minister is required to have regard to certain matters specified in subsection 7AA(3). In addition, the Minister may have regard to any other matter that the Minister considers relevant (subsection 7AA(4) refers).

The matters that the Minister must have regard to before making a determination are as follows:

- (a) whether it is likely that the specified goods might harm the health of members of the public if not regulated under the Act;
- (b) whether it is appropriate in all the circumstances to apply the national system of controls established by the Act (as mentioned above) to regulate the specified goods; and
- (c) whether the kinds of risks that members of the public might be exposed to from the specified goods could be more appropriately dealt with under another regulatory scheme.

The *Therapeutic (Excluded Goods) Determination 2018* (“Determination”) is a new determination under section 7AA of the Act. The purpose of the Determination is to exclude the following specified goods from the operation of the Act:

- ear candles and low risk antiperspirant preparations (“the first measure”);
- certain goods, which are presently declared not to be therapeutic goods in the existing *Therapeutic Goods (Excluded Goods) Order No. 1 of 2011* (“the EGO”) (“the second measure”); and
- low risk cosmetic therapeutic goods, which are also declared not to be therapeutic goods in the EGO and are currently subject to requirements set out in the *Cosmetics Standard 2007* (“Cosmetics Standard”) (“the third measure”).

Human rights implications

The Determination 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 Determination takes positive steps to promote the right to health by clarifying the regulation of certain specified goods. Indeed, the first measure results in, and the second and third measures necessarily continue, the regulation of the specified goods as consumer goods that need not also be regulated under the Act as therapeutic goods.

As a consequence, the Determination enables valuable resources of the Department of Health to be appropriately directed towards the regulation of other therapeutic goods, in particular, prescription medicines, over-the-counter medicines, complimentary medicines, biologicals and medical devices that require registration, listing or inclusion on the Australian Register of Therapeutic Goods.

Importantly, the exclusion of low risk products from the operation of the Act will promote enhanced regulation of the quality, safety and efficacy of higher risk therapeutic goods available to the Australian public.

Before making this Determination, the Minister or his delegate must consider, among other things, whether it is likely that the specified goods might harm the health of members of the public if not regulated under the Act, and whether the kinds of risks that members of the public might be exposed to from the specified goods could be more appropriately dealt with under another regulatory scheme.

While the goods excluded under this Determination will not be subject to the operation of the Act, those goods will continue to be regulated as consumer goods by the Australian Competition and Consumer Commission under Australian Consumer Law. In the event of a safety issue or false and misleading statements in advertising for these products, provisions of the Australian Consumer Law would continue to afford protection to the Australian public.

Further, in the event that these goods are exported, imported or supplied in a manner that is not consistent with the terms of their exclusion under the Determination, then those goods (to the extent that they are therapeutic goods) will be captured by the operation of the Act.

Conclusion

This 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.

John Skerritt, delegate of the Minister for Health