EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Amendment (Excluded Goods) Determination (No. 2) 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 Commonwealth Department of Health.

Subsection 7AA(1) of the Act provides that the Minister may, by legislative instrument, determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act. Subsection 7AA(2) of the Act provides that the Minster may, by legislative instrument determine that specified goods (other than goods declared to be therapeutic goods under an order in force under section 7 of the Act) are excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner.

The *Therapeutic Goods (Excluded Goods) Determination 2018* ("the Principal Determination") is made under subsections 7AA(1) and 7AA(2) of the Act. The Principal Determination determines specified goods to be excluded goods for the purposes of the Act; and specified goods to be excluded goods for the purposes of the Act when used, advertised or presented for supply in a specified manner.

The *Therapeutic Goods Amendment (Excluded Goods) Determination (No. 2) 2019* ("the Amendment Determination") is made under subsection 7AA(1) of the Act. The purpose of the Amendment Determination is to amend the Principal Determination to specify fluoridated reticulated drinking water to be excluded goods for the purposes of the Act. The effect of this provision is to exclude fluoridated reticulated drinking water from the operation of the Act.

Water fluoridation is the process of adjusting the amount of fluoride in drinking water to levels which the NHMRC supports Australian states and territories to provide. Fluoride is a chemical ion of the element fluorine and is a *naturally occurring* component of mineral salts found in rocks, soil, natural water resources, plants and animals. That water is not only used for drinking – primarily to satisfy thirst – it is also used in washing, bathing, flushing the toilet and bathing.

Reticulated drinking water is used in its commonly understood sense in the Australian community, drinking water that is distributed by pipes whether that is a network of pipes or a single pipeline (as opposed, for example, to well water).

The Amendment Determination confirms that the regulation of fluoridated reticulated drinking water is a matter for the states and territories.

Before making a determination under subsection 7AA(1) or subsection 7AA(2), the Minister or his delegate must have regard to certain matters specified in subsection 7AA(3). Those matters are:

(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.

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In addition, the Minister may have regard to any other matter that the Minister or his delegate considers relevant (subsection 7AA(4) refers). In making this Amendment Determination, the delegate considered each of the matters specified in subsection 7AA(3) of the Act.

The Public Statement on water fluoridation of the National Health and Medical Research Council (NHMRC), Australia's leading expert body promoting the development and maintenance of public health and clinical standards and responsible for providing the Australian community with health advice based on the best available science, is clear evidence that it is not likely that fluoridated reticulated drinking water will harm members of the public if not regulated as a therapeutic good.

First, the NHMRC includes in that statement its conclusion that there is reliable evidence that there is *no* association between the specified goods with cancer, Down Syndrome, cognitive dysfunction, lowered intelligence or hip fracture.

Second, the NHMRC also found that there is *no* reliable evidence of an association between the specified goods and other health conditions such as chronic kidney disease, kidney stones, hardening of the arteries, high blood pressure, low birth weight, all-cause mortality, musculoskeletal pain, osteoporosis, skeletal fluorosis, thyroid problems or self-reported ailments such as gastric discomfort, headache and insomnia. The NHMRC notes that it uses the term 'no reliable evidence' when there is a lack of confidence that the evidence reviewed is relevant to Australia or valid to accept any association between community water fluoridation and human health outcomes. Confidence in the body of evidence can be affected by several issues including the small number of studies, the study designs, the low quality of the studies and the lack of control for possible confounding factors, Confounding factors can include lack of consideration of fluoride from sources, socioeconomic status and exposure to other chemicals such as iodine or lead.

As also explained by the NHMRC, state and territory water authorities add fluoride to community water supplies using strict controls typically set out in the current regulatory frameworks used in each Australian state and territory (see table 2 of the *Water Fluoridation and Human Health in Australia: Questions and Answers* published by the NHMRC). This includes controls on the quality and purity of chemicals used in accordance with *Australian Drinking Water Guidelines*. The controls in place under the relevant state and territory regulatory schemes regarding the fluoridation of water are appropriate. It follows that it is not appropriate to apply the national system of controls established by the Act to regulate fluoridated reticulated drinking water.

These considerations are consistent with the statement on the TGA's website published in 2014. Consistent with the delegate's conclusion in the previous paragraph, the TGA's statement recognises that water fluoridation is a matter to be regulated by the states and territories.

These frameworks were in place as early as 1957, all before the Act was enacted. There is no indication in the Act's terms that it was intended to apply to the specified goods. It is difficult to imagine that the Parliament intended to bring such fundamentally important and widely used goods as fluoridated reticulated drinking water within the scope of the Act. It is not consistent with the objects of the Act for a good with several uses additional to drinking for it to be regulated as a therapeutic good.

Despite this position, noting recent conflicting external views on the matter, it is apparent that there is clear public benefit in this Amendment Determination expressly excluding fluoridated reticulated drinking water from being regulated under the Act. The Amendment Determination provides necessary certainty that fluoridated reticulated drinking water is excluded from being regulated as a therapeutic good.

Consistent with subsection 13(3) of the *Legislation Act 2003*, a determination made under section 7AA of the Act may be made with reference to a class or classes of goods. For the purpose of the Amendment Determination, the class of specified goods is characterised as fluoridated reticulated drinking water. This expression is intended to have broad application, and applies in relation to

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drinking water that contains fluoride, whether or not the fluoride is present as a consequence of manufacture or natural occurrence and subsequently tested, treated or modified accordingly.

The specified goods are described with reference to reticulation in general terms, on account of such water being reticulated within each of the states and territories for the purposes of testing, treatment and, otherwise, supply. Fluoridated reticulated drinking water may or may not also be the subject of further storage or transportation prior to being supplied to the consumer.

Consultation

The Office of Best Practice Regulation (OBPR) advised that a regulation impact statement was not required in relation to the Amendment Determination, and would not be required unless the measure reflected in this instrument changed significantly (OBPR reference: 25295).

The TGA consulted the Environmental Health Standing Committee ("enHealth"), and the relevant subcommittee known as the Water Quality Expert Reference Panel, regarding the proposal for the Minister or his delegate to determine under subsection 7AA(1) of the Act that fluoridated reticulated drinking water are excluded goods for the purposes of the Act. The committees comprise members of the Commonwealth, state and territory governments with responsibility for environmental health and water quality matters. The committees provided their support for the measure.

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

The Amendment 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 Amendment Determination is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on the day after it is registered on the Federal Register of Legislation.

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Attachment A

Details of the *Therapeutic Goods Amendment (Excluded Goods) Determination (No. 2) 2019*

Section 1 – Name

This section provides that the name of the instrument is the *Therapeutic Goods Amendment (Excluded Goods) Determination (No. 2) 2019* ("the Amendment Determination").

Section 2 – Commencement

This section provides that the Amendment Determination 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 Determination is subsection 7AA(1) 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 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 (Excluded Goods) Determination 2018* ("the Principal Determination").

Item 1 of Schedule 1 inserts a new item 7A into the table in Schedule 1 to the Principal Determination specifying fluoridated reticulated drinking water. The effect of this insertion is that those goods are determined to be excluded goods for the purposes of the Act.

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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 (Excluded Goods) Determination (No. 2) 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 (Excluded Goods) Determination (No. 2) 2019* ("the amendment instrument") is made under subsection 7AA(1) of the *Therapeutic Goods Act 1989* ("the Act"). The purpose of the instrument is to amend the *Therapeutic Goods (Excluded Goods) Determination 2018* ("the principal instrument") by specifying fluoridated reticulated drinking water to be excluded goods for the purposes of the Act. The effect of this provision is to exclude fluoridated reticulated drinking water from the operation of the Act.

The amendment instrument underscores the long-standing position of the Therapeutic Goods Administration ("TGA") on the regulation of fluoridated reticulated drinking water, and confirms that the regulation of fluoridated reticulated drinking water is a matter for the states and territories.

Indeed, the relevant state and territory regulatory schemes regarding the fluoridation of water are appropriate in the circumstances. The national system of controls established by the Act to regulate therapeutic goods does not apply, and should not apply, in relation fluoridated reticulated drinking water. Further, consistent with the current National Health and Medical Research Council Public Statement on water fluoridation, there is no reliable evidence that the specified goods pose any health risks to the public.

These considerations are consistent with the statement on the TGA's website published in 2014. Consistent with the delegate's conclusion in the previous paragraph, the TGA's statement recognises that water fluoridation is a matter to be regulated by the states and territories.

As such, the amendment instrument simply clarifies that the regulation of fluoridated reticulated drinking water is a matter for the states and territories.

Human rights implications

As the instrument does not introduce any changes to the principal instrument other than to implement the clarifying measure outlined above, it would not appear to engage any of the applicable rights or freedoms.

Conclusion

The instrument is compatible with human rights because it does not raise any human rights issues.

John Skerritt, delegate of the Minister for Health

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