

## **EXPLANATORY STATEMENT**

Minute No. 29 of 2019 – Minister for Health

Subject - *Therapeutic Goods Act 1989*

*Therapeutic Goods Amendment (Approval of Advertisements) Regulations 2019*

The object of the *Therapeutic Goods Act 1989* (the Act) is to establish and maintain a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia. The Therapeutic Goods Administration (the TGA), which is part of the Department of Health, is responsible for administering the Act.

Subsection 63(1) of the Act provides that the Governor-General may make regulations, not inconsistent with the Act, prescribing matters required or permitted to be prescribed by the Act or necessary or convenient to be prescribed for carrying out or giving effect to the Act. Amongst other matters, the regulations may prescribe fees in respect of matters under the Act or regulations made under it, and provide for the refund, reduction or waiving of such fees.

The principal purpose of the *Therapeutic Goods Amendment (Approval of Advertisements) Regulations 2019* (the Regulations) is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations), to enable the Secretary to delegate the power to approve certain advertisements about therapeutic goods (being advertisements for which pre-approval is required under section 42BAA of the Act) to the Australian Self Medication Industry Limited (ASMI).

The advertisements concerned are advertisements for complementary medicines that are made in the mainstream media, cinematograph films or displays about goods (including posters) in shopping malls (except inside shops), in or on public transport or on billboards.

Under regulation 5G of the TG Regulations, if a person applies to the Secretary for the approval of such an advertisement and pays the prescribed fee for such an application, the Secretary must approve the advertisement if the Secretary is satisfied of a number of specified matters. In particular, these include that the proposed advertisement complies with the Therapeutic Goods Advertising Code (a legislative instrument made by the Minister under section 42BAA of the Act setting out critical requirements for the advertising of therapeutic goods).

In practice, the approval of these kinds of advertisements is conducted at arms-length from the TGA in order to preserve the integrity of post-market monitoring of such advertisements and to avoid any inherent conflict of interest that might otherwise arise if the regulator were to make decisions about whether or not to take action in relation to an advertisement that it had itself approved.

Accordingly, subregulation 5Q(3) of the TG Regulations currently allows the Secretary to delegate the Secretary's power in regulation 5G to the Complementary Healthcare Council of Australia (CHCA), the industry representative body for complementary medicines in Australia.

However, CHCA is expected to shortly cease this role, in anticipation of the removal of the requirement for advertisements for therapeutic goods to be pre-approved when Part 2 of Schedule 6 of the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* commences on 1 July 2020.

ASMI has agreed to assume this role in the interim (that is until 1 July 2020), and amendments are therefore needed to reflect this and to minimise any gap that might otherwise be created between the cessation of CHCA's role and when measures are in place to allow ASMI to commence these approvals.

Details of the Regulations are set out in Attachment A.

The Act specifies no conditions that need to be satisfied before the power to make the Regulations may be exercised. The Regulations are a legislative instrument for the purposes of the *Legislation Act 2003*.

The Regulations commence on the day after they are registered.

### **Consultation**

In terms of consultation, the possibility of ASMI undertaking this role was raised with ASMI in early 2019 as part of the consideration of options, and canvassed again in a meeting in July 2019, when ASMI confirmed their willingness to take on the role, based on their existing experience with this function.

Authority: Subsection 63(1) of the  
*Therapeutic Goods Act 1989*

**Details of the *Therapeutic Goods Amendment (Approval of Advertisements) Regulations 2019***

**Section 1 – Name**

This section provides for the Regulations to be referred to as the *Therapeutic Goods Amendment (Approval of Advertisements) Regulations 2019* (the Regulations).

**Section 2 – Commencement**

This section provides for the commencement of the Regulations on the day after the Regulations are registered.

**Section 3 – Authority**

This section provides that the Regulations are made under the *Therapeutic Goods Act 1989* (the Act).

**Section 4 – Schedules**

This section provides that each instrument that is specified in a Schedule to this instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Regulations has effect according to its terms.

**Schedule 1 – Amendments**

***Therapeutic Goods Regulations 1990***

**Item 1 – Regulation 2 (definition of *NFAA*)**

This item makes a minor amendment to repeal a spent and redundant definition from regulation 2 of the TG Regulations.

**Item 2 – Regulation 5B (definition *withdraw*)**

This item amends the definition of ‘withdraw’ in regulation 5B, to reflect the changes that would be introduced by item 3 below.

**Item 3 – Subregulation 5Q(3)**

Under regulation 5G of the TG Regulations, if an application for approval of an advertisement for therapeutic goods for which approval is needed is made, and the prescribed fee is paid, the Secretary must approve the advertisement if satisfied of the matters listed in paragraphs 5G(1)(a)-(e) in relation to the advertisement (including, for example, that the advertisement complies with the Therapeutic Goods Advertising Code).

Under subregulation 5Q(3), the Secretary may delegate the Secretary’s power under regulation 5G to the Complementary Healthcare Council of Australia (CHCA) in relation to an advertisement about therapeutic goods that are complementary medicines if the advertisement is made in the mainstream media, cinematograph films or displays about goods (including posters) in shopping malls (except inside shops), in or on public transport and on billboards.

However, as part of measures to prepare for the removal of the need for pre-approval for advertisements for therapeutic goods from 1 July 2020 (when Part 2 of Schedule 6 to the

*Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* commences), CHCA is expected to cease this role towards the end of 2019.

There is therefore a need for another organisation to undertake the approval of the advertisements mentioned in subregulation 5Q(3), and the Australian Self Medication Industry Limited (ASMI) has agreed to take over this role.

As such, this item amends subregulation 5Q(3) of the TG Regulations to include a reference to ASMI in that regard.

## Statement of Compatibility with Human Rights

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

### ***Therapeutic Goods Amendment (Approval of Advertisements) Regulations 2019***

The *Therapeutic Goods Amendment (Approval of Advertisements) Regulations 2019* (the Regulations) are 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 Regulations are made under subsection 63(1) of the *Therapeutic Goods Act 1989* (the Act). The principal purpose of the Regulations is to amend the *Therapeutic Goods Regulations 1990* (the TG Regulations), to enable the Secretary to delegate the power to approve certain advertisements about therapeutic goods (being advertisements for which pre-approval is required under section 42BA of the Act) to the Australian Self Medication Industry Limited (ASMI).

The advertisements concerned are advertisements for complementary medicines that are made in the mainstream media, cinematograph films or displays about goods (including posters) in shopping malls (except inside shops), in or on public transport or on billboards.

Under regulation 5G of the TG Regulations, if a person applies to the Secretary for the approval of such an advertisement and pays the prescribed fee for such an application, the Secretary must approve the advertisement if the Secretary is satisfied of a number of specified matters. In particular, these include that the proposed advertisement complies with the Therapeutic Goods Advertising Code (a legislative instrument made by the Minister under section 42BAA of the Act setting out critical requirements for the advertising of therapeutic goods).

Subregulation 5Q(3) of the TG Regulations currently provides that the Secretary may delegate the Secretary's power in regulation 5G to the Complementary Healthcare Council of Australia (CHCA), the industry representative body for complementary medicines in Australia. However, CHCA is expected to shortly cease this role, in anticipation of the removal of the requirement for advertisements for therapeutic goods to be pre-approved when Part 2 of Schedule 6 of the *Therapeutic Goods Amendment (2017 Measures No.1) Act 2018* commences on 1 July 2020.

ASMI has agreed to assume this role in the interim (i.e. until 1 July 2020), and amendments to the TG Regulations are therefore needed to reflect this and to minimise any gap that might otherwise be created between the cessation of CHCA's role and when measures are in place to allow ASMI to commence these approvals.

#### **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 Regulations take positive steps to promote the right to health by ensuring that the TG Regulations continue to protect and promote the health of all Australians and continue to effectively regulate the advertising of therapeutic goods so that the benefits, uses and effects of therapeutic goods are accurately promoted.

### **Conclusion**

These Regulations are compatible with human rights because they maintain and support the right to health in Article 12 of the ICESCR as outlined above, and does not raise any other human rights issues.

**Greg Hunt, Minister for Health**