EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Information (Exemptions from Annual Charges) Specification 2016

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

Section 61 of the Act lists a number of circumstances in which the Secretary of the Department of Health (the Secretary) can release specified kinds of therapeutic goods information to the public, including information relating to any decision under the Act. Section 61 also allows the Minister for Health to make a legislative instrument setting out other circumstances in which the Secretary can release therapeutic goods information to the public under that section.

The Therapeutic Goods Information (Exemptions from Annual Charges) Specification 2016 (the Specification) is made by a delegate of the Minister under subsection 61(5D) of the Act, and specifies the kinds of therapeutic goods information that may be released to the public by the Secretary under subsection 61(5C) of the Act. The Specification has the effect of permitting the Secretary to release therapeutic goods information of a kind mentioned in the Specification to the public.

Therapeutic goods information in this context is defined in subsection 61(1) of the Act as information in relation to therapeutic goods that is held by the Department and which relates to the performance of the Department's functions.

The Specification commenced on the day after it was registered on the Federal Register of Legislative Instruments.

BACKGROUND

The Act provides for the collection of annual charges payable for maintaining the registration, listing or inclusion of therapeutic goods in the Australian Register of Therapeutic Goods (the Register). The Act also specifies when payment of annual charges must be made, and provides for regulations to be made to exempt persons in relation to whom therapeutic goods are on the Register (sponsors) from liability to pay annual charges if the turnover of their goods is of "low value". Generally, annual charges for therapeutic goods are levied in order to support post-market monitoring of the goods for so long as they remain in the Register.

Under the revised exemption scheme that came into effect on 1 July 2015 under the Therapeutic Goods Regulations 1990 (the Regulations), sponsors of therapeutic goods coming onto the Register are automatically exempt from the requirement to pay annual charges in relation to those goods, provided the sponsor submits a declaration by 22 July in the next financial year that they had no ($0) turnover in relation to their goods (there were also arrangements for existing sponsors whose goods are already in the Register as at 1 July 2015).

A sponsor with no ($0) turnover for particular goods who misses this 22 July deadline for the immediately preceding financial year is still able to submit a late declaration of no turnover for

those goods by the following 15 September. Provided the prescribed fee for such a declaration is paid, the sponsor's exemption can continue.

If, under the new scheme, a sponsor declares that they had no ($0) turnover of their goods for a financial year but the Secretary becomes aware that the sponsor's turnover for that financial year was not $0, the Secretary must notify the sponsor that they were not exempt from annual charges for that financial year, or for any subsequent financial years since the year for which they may have made a declaration, and must notify the sponsor of the relevant charge(s) that are therefore payable (regulation 43AAG of the Regulations refers).

Sponsors who, because they have some turnover, do not qualify for the exemption can apply to the Secretary for a waiver of their annual charge for a financial year in certain circumstances. The Secretary may grant a waiver if satisfied that it would be in the interests of public health for the goods to remain on the Register, and that it would be financially unviable for the goods to remain on the Register if the charge were payable.

To complement these new arrangements, the TGA will publish, on its website (www.tga.gov.au), information about the therapeutic goods in relation to which sponsors were exempt for a particular financial year, starting with the 2015-16 financial year.

The information for a particular financial year will be published after the 22 July deadline for sponsors to make their no turnover declarations – e.g. after 22 July 2016, for financial year 2015-16. This will be updated following the 15 September deadline for late declarations made in accordance with regulation 43AAE of the Regulations. The information to be published in relation to each financial years will include the name of the sponsor and the name and Register number of the therapeutic goods to which the exemption related in that financial year.

The TGA will also publish information about sponsors who declared that they had no turnover for a financial year but who the Secretary has later notified did have turnover for that year (meaning that they were not exempt from paying an annual charge for that year, or for any subsequent year, under the new arrangements). The information to be published will include the relevant year, the name of the sponsor and the name and Register number of the therapeutic goods in that year and the fact that the TGA has notified the sponsor under regulation 43AAG that it must pay the annual charge for that year.

The publication of this information is expected to support the overall transparency of the exemption scheme and encourage the provision of declarations by sponsors only where it is justified. The TGA will also publish information about the granting of waivers. Because the grant of a waiver requires a decision by the Secretary under the Regulations (regulation 43AAH refers), particulars of such a grant can be published by the Secretary under subsection 61(5A) of the Act.

The kinds of therapeutic goods information that the Secretary will be able to release to the public under the Specification are set out at Schedule 1 to the Specification.

CONSULTATION

Publishing the particulars of exempt sponsors, as part of the new annual charges exemption arrangements, was discussed with industry representative bodies during bilateral meetings with industry in March 2015. Industry bodies accepted the proposal to publish such information in relation to the new arrangements and no objections were raised to it (though the Australian Dental Industry Association did object to the overall proposal to introduce the new scheme).

The Specification is a legislative instrument for the purposes of the *Legislation Act 2003*.

Statement of Compatibility with Human Rights for a legislative instrument that does not raise any human rights issues

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

Therapeutic Goods Information (Exemptions from Annual Charges) Specification 2016

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 Information (Exemptions from Annual Charges) Specification 2016* is made under subsection 61(5D) of the *Therapeutic Goods Act 1989* (the Act) by a delegate of the Minister for Health. It permits the Secretary of the Department of Health to release to the public, under subsection 61(5C) of the Act, specified kinds of therapeutic goods information held by the Therapeutic Goods Administration (TGA) about sponsors of therapeutic goods who are exempt from the requirement to pay annual charges in relation to those goods under the Therapeutic Goods Regulations 1990 (the Regulations), and also about sponsors who have declared that they had no turnover for their therapeutic goods for a particular financial year but who are later identified by the Secretary as having had turnover for that year.

The kinds of information to be released in relation to the former in relation to a particular financial include the name of the sponsor and the name and Register number of the therapeutic goods to which the exemption related in that financial year. The kinds of information to be released in relation to the latter include the name of the sponsor, Register number of the relevant therapeutic goods and the financial years in relation to which the Secretary has notified the sponsor under regulation 43AAG of the Regulations that annual charges are payable for that financial year.

Human rights implications

As this instrument does not include any measures other than providing for the release to the public of information outlined above, it does not engage any of the applicable rights or freedoms.

Conclusion

This legislative instrument is compatible with human rights as it does not raise any human rights issues.

Larry Kelly, delegate of the Minister for Health