Australian Government
Department of Health and Ageing

SECRETARY

Dr Ian Holland
Committee Secretary
Senate Standing Committee on Community Affairs
PO Box 6100
Parliament House
Canberra ACT 2600

Dear Dr Holland

**Inquiry into the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013**

I refer to the response provided to the Committee by Ms Flanagan, as Acting Secretary, on 27 May 2013 to a number of questions posed by the Senate Community Affairs Legislation Committee in relation to its Inquiry into the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013. I understand that the Committee is now seeking a response to the question why the regulation-making power in section 18 of the *Therapeutic Goods Act 1989* is not sufficient to resolve concerns that proposed section 7AA that is included in the Bill is designed to address.

Please find attached the Department's written response addressing that issue.

Yours sincerely

Jane Halton PSM
Secretary

14 June 2013

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Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

# Response to Issue Raised by the Senate Community Affairs Legislation Committee

# Inquiry into the Therapeutic Goods Amendment (2013) Measures No. 1) Bill 2013

**11 May 2013**

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**Introduction**

On 20 March 2013, the Therapeutic Goods Amendment (2013 Measures No. 1) Bill 2013 (the Bill) was introduced into the House of Representatives. On 21 March 2013, the Senate referred the Bill to the Senate Community Affairs Legislation Committee (the Committee) for inquiry and report.

The Bill contains various amendments to the *Therapeutic Goods Act 1989* (the TG Act). The Department of Health and Ageing (the Department) provided a written submission to the Committee's inquiry on 3 May 2013. The Department's submission has been made available on the Committee's website, as have other submissions.

On 27 May 2013, the Department provided responses to a number of specific questions in relation to the Bill and to concerns about various provisions in the Bill expressed in submissions from Mr Doug Kentwell (submission 7) and from the Complementary Healthcare Council of Australia (submission 8).

The Committee is now seeking advice in relation to the amendment in Schedule 3 of the Bill which would include a new section 7AA in the TG Act. In particular the Committee is asking why the regulation-making power in section 18 of the TG Act is not sufficient to resolve the concerns that proposed section 7AA is designed to address.

**Response**

The effect of the making, by regulation, of an exemption under section 18 of the TG Act in relation to therapeutic goods is that such goods are not required to be listed or registered in the Australian Register of Therapeutic Goods (the Register) in order to be imported, exported, supplied or manufactured (see for instance subparagraph 19B(1)(b)(ii) of the TG Act).

However the exemption only operates in relation to "this Part" ie Part 3-2 of the TG Act (which includes the provisions for listing and registration). Thus the goods will still be subject to other requirements in the Act that apply to therapeutic goods of that kind (ie those that would otherwise need to be listed or registered). This would include, for instance:

- the requirements in Part 3-3 of the TG Act for the goods if manufactured in Australia to be manufactured by a licensed manufacturer in compliance with Good Manufacturing Principles
- compliance with any standards made under section 10 of the Act that would apply to the goods, and
- compliance with the advertising provisions in Part 5-1 of the Act and the provisions in Part 5-2 and 5-3 of the Act about counterfeit therapeutic goods and product tampering.

While it is possible to exempt therapeutic goods from the operation of Part 3-3 by regulation (see section 34 of the TG Act) and for a sponsor to seek an exemption from various standards that would otherwise apply under section 10 of the TG Act (and possibly all standards), it is **not** possible to exempt therapeutic goods from the advertising, counterfeit and product tampering provisions.

Regulation 12 of the Therapeutic Goods Regulations 1990 has been made in reliance on section 18 (which applies to therapeutic goods that would otherwise be registered or listed) and section 32CA (which is the equivalent provision for biologicals). Therapeutic

goods that are exempt by reason of regulations made under these sections are set out in Schedules 5 and 5A of the Regulations.

There is a similar regulation-making power in section 41HA of the Act for medical devices (see Regulation 7.1 and Schedule 4 of the Therapeutic Goods (Medical Devices) Regulations 2002). Medical devices that are, by reason of regulations made for the purposes of that section, exempt from the operation of Division 3 of Part 4-11 of the TG Act (which would otherwise require them to be included in the Register in order to be imported, exported, supplied or manufactured) are also still subject to the advertising, counterfeit and product tampering provisions.

Exempting goods by the making of regulations under these provisions has been considered by the TGA as an option in the context of the Secretary making a declaration under section 7 of the TG Act (through the inclusion of goods in an Excluded Goods Order). For the reasons set out above, this cannot achieve the intended outcome that proposed section 7AA is designed to achieve ie completely removing goods from regulation under the Act.

Proposed section 7AA on the other hand, would allow the Minister to do so in appropriate cases by the making of a legislative instrument.