EXPLANATORY STATEMENT

Select Legislative Instrument 2009 No. 140

Therapeutic Goods Act 1989

Therapeutic Goods Amendment Regulations 2009 (No. 2)

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) 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. Subject to certain limitations, paragraph 57(1)(c) of the Act allows the Minister for Health and Ageing (the Minister) or the Secretary of the Department of Health and Ageing (the Secretary), by signed instrument, to delegate all or any of his or her powers under the Act, to a person occupying or acting in an office, or holding an appointment, declared by the regulations to be an office or appointment, the occupant or the holder of which may be a delegate under section 57.

The Regulations amend the *Therapeutic Goods Regulations 1990* (the Principal Regulations) to allow the Secretary or the Minister to delegate all or any of his or her powers to a person employed by a national therapeutic goods regulatory authority of another country but who has been seconded to a position in the TGA.

The Regulations also amend the Principal Regulations to allow the Australian Register of Therapeutic Goods (the Register) to be amended when a person, in relation to whom a kind of medical device is included in the Register, transfers or assigns his or her business or interest to another person.

An overview of the Regulations is at Attachment A, and details of the Regulations are set out in Attachment B.

Interested parties were consulted on a number of changes to the current regulatory framework held in Parliament House during late July and early August 2008. This amendment was part of that consultation.

A regulatory impact statement was not prepared in relation to this matter because these changes will have no impact on industry. The amendment allowing for the change in name of the person in relation to whom a kind of medical device is included in the Register complements other similar provisions for the change of name of the sponsor of the medical device included in the Register and address the current limitation of regulation 10F.

The Act specifies no conditions that need to be met before the power to make the Regulations may be exercised.

The Regulations are a legislative instrument for the purposes of the *Legislative Instruments Act 2003.*

The Regulations commence on the day after they are registered on the Federal Register of Legislative Instruments.

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

ATTACHMENT A

SUBSECTION 57(1) OF THE *THERAPEUTIC GOODS AMENDMENT REGULATIONS 2009 (No. 2)*

Delegations

Subsection 57(1)(c) of the Act enables the Secretary or the Minister to delegate any of their powers under the Act to an officer of the Department of Health and Ageing, of the TGA or a person occupying or acting in an office, or holding an appointment, declared by the regulations. This permits regulations to be made to allow, for example, a person appointed under contract or other arrangements to the TGA, which is a division of the Department, to implement the Act and its regulations as a delegate of the Secretary or the Minister. The current regulation 46A of the Principal Regulation provides that the appointment of National Manager, Therapeutic Goods Administration is declared for the purposes of paragraph 57(1)(c) of the Act to be an appointment, the holder of which may be a delegate of the Minister or the Secretary under section 57 of the Act. No other appointments are currently declared.

The granting of marketing approval of therapeutic goods through registration, listing or inclusion of medical devices in the Register requires a level of assessment of the quality, safety, efficacy and/or intended purpose of the therapeutic goods that is proportionate to the risk that the goods pose to public health and safety. Similarly, post-marketing activities and assessment of goods supplied in Australia relating to safety and quality are also carried out by the TGA. Many decisions in relation to the granting of marketing approval and post-marketing activities require scientific assessments by persons who are appropriately qualified and have the relevant scientific and regulatory background.

It is therefore important that relevant staff in the TGA have the appropriate scientific qualifications and experience necessary for implementing and maintaining the effective regulation of particular therapeutic goods. The TGA employs highly qualified medical officers, pharmacists, biomedical engineers, chemists and other professionals. There are instances where the TGA had experienced difficulties in recruiting relevantly qualified staff.

In this context, and in the context of a global market for therapeutic goods, the TGA has always maintained close relations with therapeutic goods regulators in other countries. This measure enables the TGA and other regulators to work more closely by exchanging staff thereby consolidating expertise among participating regulators.

The TGA has explored work sharing opportunities and exchanges of officers with other national therapeutic goods regulatory authorities to enable it to appoint person who have the relevant expertise and are highly qualified in a relevant scientific field by secondment to a position in the TGA. Exchanges by secondment to a relevant position in a national regulatory authority provide significant benefits for both the TGA and the relevant national regulatory authority, enabling them to draw on each other's staff resources. This kind of opportunity is therefore welcomed by the TGA. Enabling seconded persons to have delegations under the Act and regulations allows those persons to contribute by applying their skills and expertise and making appropriate decisions required under the Act and regulations.

Change of name of person in relation to whom a medical device is included in the Register under Chapter 4 of the Act

Chapter 4 of the Act relates to the regulation of medical devices. Regulation 10F of the Principal Regulations allows the change of name of persons in relation to whom a kind of medical device is included in the Register under Chapter 4 in specified circumstances. The current circumstances covered by regulation 10F include those where that person:
(a) dies;
(b) becomes bankrupt;
(c) is a body corporate and the body corporate is wound up;
(d) changes his or her, or its name;
(e) being a corporation, amalgamates with another corporation under a name that is different from the name entered in the Register.

Regulation 10F of the Principal Regulations does not currently provide for a change of name where a person for whom a kind of medical device is included in the Register transfers or assigns, in whole or in part, the business to which the kind of medical device relates, or the person's interest in the kind of medical device, to another person. The inclusion of new subregulation 10F(4A) addresses this limitation.

ATTACHMENT B

DETAILS OF THE *THERAPEUTIC GOODS AMENDMENT REGULATIONS 2009 (NO. 2)*

Regulation 1 names the Regulations as the *Therapeutic Goods Amendment Regulations 2009 (No. 2)*.

Regulation 2 provides that the Regulations commence on the day after they are registered.

Regulation 3 provides that the Regulations amend the *Therapeutic Good Regulations 1990* as provided in Schedule 1.

SCHEDULE 1 –Amendments

Item [1]

Item 1 inserts a new subregulation 10F(4A). Subregulation 10F(4A) provides that if a person in relation to whom a kind of medical device is included in the Register under Chapter 4 of the Act transfers or assigns his or her business to which the kind of medical device relates, or his or her interest in the kind of medical device, the person to whom the business or interest is transferred or assigned is taken to be the person in relation to whom the kind of medical device is included in the Register under Chapter 4 of the Act. The latter person be required to notify the Secretary in writing of the assignment or transfer within 3 months of that assignment or transfer.

Item [2]

Item 2 is a consequential amendment and has the effect of adding a reference to new paragraph 4A(b) to subregulation 10F(5). Subregulation 10F(5) provides that if a person notifies the Secretary of an event under paragraph 10F(1)(b), 2(b), 3(b) or 4A(b), or a change of name under subregulation 10F(4), the person is required to provide the Secretary sufficient documentary evidence to establish the matter asserted in the notification under those provisions.

Item [3]

Item 3 substitutes regulations 46A with a new regulation 46A. The current regulation 46A declares the National Manager of the Therapeutic Goods Administration may be given delegation by the Minister or the Secretary under section 57 of the Act.

The new regulation 46A includes the National Manager, as well as the appointment by secondment of a person employed by a national therapeutic goods regulatory authority of another country to a position in the Therapeutic Goods Administration.