EXPLANATORY STATEMENT

Subject: MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR CLINICAL EVIDENCE) 2008

Section 41CB, Therapeutic Goods Act 1989

OUTLINE

Medical Device Standards Order (Standards for Clinical Evidence) 2008 (MDSO 2008) is an Order made by the delegate of the Minister for Health and Ageing under section 41CB of the *Therapeutic Goods Act 1989* (the Act). Section 41CB of the Act authorises the Minister, or her delegate, to determine appropriate medical standards that are applicable to kinds of medical devices and to determine that medical devices that comply with those standards are to be treated as complying with those parts of the essential principles specified in the standards.

MDSO 2008 revokes and replaces Medical Device Standards Order No. 1 – Medical Device Standards for Clinical Evidence (MDSO 1 of 2003) that was made on 20 February 2003 and commenced upon its *gazettal* on 5 March 2003. MDSO 1 of 2003 specified particular standards relevant to medical devices that require clinical evidence in order to demonstrate compliance with essential principles.

MDSO 2008 introduces new and updated standards (or parts of these standards) published by standards organisations that are relevant to medical devices for humans that require clinical evidence in order to demonstrate compliance with essential principles. The standards set out in MDSO 2008 are the following:

- **AS ISO 14155-1: 2004 -** *Clinical investigation of medical devices for human subjects – General requirements*;
- **ISO 14155-1: 2003 -** *Clinical investigation of medical devices for human subjects – General requirements (which is identical to* **AS ISO 14155-1: 2004)**
- **AS ISO 14155-2: 2004** *Clinical investigation of medical devices for human subjects – Clinical investigation plans*
- **ISO 14155-2: 2003** *Clinical investigation of medical devices for human subjects – Clinical investigation plans* (which is identical to **AS ISO 14155-2: 2004)** *;*
- **ISO 5840: 2005** *Cardiovascular implants – Cardiac valve prostheses;* and
- **ISO 11979-7: 2006** *Ophthalmic implants – Intraocular lenses – Part 7: Clinical investigations.*

Electronic or hard copies of these standards can be purchased on-line from SAI Global Limited, which is accessible at the following website: http://www.saiglobal.com.

The Order was signed by the delegate to the Minister on 19 May 2008 and commenced on the day after it was registered on the Federal Register of Legislative Instruments.

BACKGROUND

The Act provides for the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy of therapeutic goods that are used in Australia (whether manufactured in Australia or elsewhere) or exported from Australia.

Section 41CB of the Act authorises the Minister, or the Minister's delegate, by order, to determine medical device standards for kinds of medical devices identified in that determination and to also determine that medical devices that comply with these standards are to be treated as complying with those parts of the essential principles specified in that determination. That determination is made in the form of an order.

The essential principles set out the requirements relating to the safety and performance characteristics of medical devices that must be complied with before a device can be imported, supplied or exported. Compliance with applicable medical device standards is not required, but it is one way to establish compliance with the essential principles. If a manufacturer chooses to apply a specified medical device standard, and this is applied correctly to a device, the device is presumed to comply with the parts of the essential principles set out in MDSO 2008 (section 41BH of the Act).

MDSO 2008 applies to all medical devices for which clinical evidence is required to demonstrate compliance to the essential principles.

Items 1 and 2 of the Schedule to MDSO 2008 specify parts 1 and 2 of **AS ISO 14155: 2004** and parts 1 and 2 of **ISO 14155-1: 2003** as those medical device standards that could be used to establish compliance with essential principle 14 in Schedule 1 to the Therapeutic Goods (Medical Devices) Regulations 2002 (the Regulations). Essential principle 14 provides that every medical device requires clinical evidence, appropriate for the use of and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles. **AS ISO 14155: 2004** and **ISO 14155: 2003** provide a method for the generation of clinical evidence. These standards provide guidance in determining "how" to conduct clinical investigations that form part of the clinical data required to address one or more of the essential principles (ie. general requirements, methodology, documentation, clinical investigation plan, role of the sponsor, role of the clinical investigator, presentation of results, etc.). However these standards do not specify the "type" of clinical data required to address the essential principles.

Items 3 and 4 of the Schedule to MDSO 2008 specify clause 7.4 of **ISO 5840: 2005** and part 7 of **ISO 11979: 2006** as medical device standards applying to cardiac valve prostheses and intra-ocular lenses, respectively, that could be used to establish compliance with essential principle 1(a) in Schedule 1 to the Regulations. Essential principle 1(a) provides that a medical device is to be designed and produced in a way that ensures that the device will not compromise the clinical condition or safety of the patient, or the safety and health of the user or any other person, when the device is used on a patient under the conditions and for the purposes for which the device was intended and, if applicable, by a user with appropriate technical knowledge, experience, education or training. In general these medical device standards determine the "type" of clinical data required for particular kinds of devices. Future amendments to this Order may include insertion of new items related to other particular kinds of devices.

The application of the medical device standards set out in Items 1 and 2 to establish compliance with essential principle 14, does not remove the need to comply with the particular requirements set out in the *Therapeutic Goods (Medical Devices) Regulations 2002* with regard to clinical evidence. Clinical trials in Australia must be conducted in accordance with these requirements, which include the ethical standards set out in the National Health

and Medical Research Council's *National Statement on Ethical Conduct in Research Involving Humans, July 1999.* Clinical trials conducted overseas must be in accordance with the principles of the Declaration of Helsinki.

CHANGES TO STANDARDS

International 'ISO' and 'EN' device standards are living documents that are developed and constantly being updated by groups of international experts. Australian representatives are involved in some of these committees. There is extensive consultation on the ISO and EN standards during their development and subsequent review. With both industry and the TGA seeking to optimise Australia's position in the global device market, it is imperative that Australia's standards do not fall out of step with the international market.

Updates to international device standards reflect changes to international best practice as well as the emergence of new technologies and new manufacturing procedures. Where relevant the latest international standards are adopted by leading regulators including Australia, Europe, the USA and Canada.

Australia will very quickly fall behind if it fails to adopt the latest international standards. In the longer term not keeping up with changes to the relevant international standards will lead to a unique regulatory system in Australia, making regulatory compliance more difficult and costly for importers and/or exporters of medical devices into Australia.

Due to the cost of international standards a number of 'ISO' and 'EN' standards have been adopted by Standards Australia as Australian 'AS ISO' or 'AS EN' standards to provide a cheaper alternative for Australian industry. The updated standards referenced in MDSO 2008 reflect the current relevant international standards for clinical investigation.

CONSULTATION

Key industry stakeholders including the Medical Industry Association of Australia (now the Medical Technology Association of Australia), the Australian Dental Industry Association and AusBiotech were consulted on the adoption of an updated version of MDSO 1 of 2003 during April-June 2007 in preparation for the move to a joint regulatory scheme under the proposed Australia New Zealand Therapeutic Products Authority (ANZTPA). Industry groups supported the adoption of these standards.

With the postponement of ANZTPA the drafts used during the ANZTPA consultation have been amended so that they reference the current Therapeutic Goods (Medical Devices) Regulations 2002 instead of the draft ANZTPA Medical Devices Rule 2007. There was a further round of stakeholder consultation on MDSO 2008 from 21 December 2007 to 15 February 2008. Industry groups supported the adoption of the Order which references the latest international standards for clinical evidence.

REGULATION IMPACT STATEMENT

Compliance with the proposed medical device standards is voluntary and members of industry may choose alternative means to demonstrate compliance with the Essential Principles. All stakeholders, including industry and Standards Australia have been consulted during the development of the proposed new regulatory system for medical devices. There

was overall support for the adoption of international standards. The Office of Regulation Review assessed the proposal for voluntary standards and, as it is not prohibitive either in terms of costs or time delays, the proposal is considered to be non-regulatory and as such a Regulatory Impact Statement is not required.

APPLICATION OF THE *LEGISLATIVE INSTRUMENTS ACT 2003* (THE LIA)

Under paragraph 6(d)(i) of the LIA, an instrument is a legislative instrument for the purposes of section 5 of the LIA if it is declared to be a disallowable instrument under legislation in force before the commencement of the LIA. This determination is a legislative instrument and it is subject to tabling and disallowance in the Parliament under sections 38 and 42 of the LIA, respectively.