EXPLANATORY STATEMENT

Subject: MEDICAL DEVICE STANDARDS ORDER (STANDARDS FOR BIOLOGICAL SAFETY OF MEDICAL DEVICES) 2008

Section 41CB, Therapeutic Goods Act 1989

OUTLINE

Medical Device Standards Order (Standards for Biological Safety of Medical Devices) 2008 (MDSO (Biological Safety) 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, by written Order, 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 (Biological Safety) 2008 introduces standards (or parts of these standards) published by standards organisations that are relevant to biological safety of medical devices in order to demonstrate compliance with essential principle 7.1(b). The standards set out in MDSO (Biological Safety) 2008 are Parts 1, 3, 4, 5, 6, 7, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18 of ISO 10993 *Biological evaluation of medical devices*.

Electronic or hard copies of this standard can be purchased on-line from SAI Global Limited at the following website: http://www.saiglobal.com.

MDSO (Biological Safety) 2008 was signed by the delegate of the Minister on 14 November 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 written instrument called an Order, to determine medical device standards for kinds of medical devices set out in the Order and to determine that medical devices of those kinds that comply with the standard are to be treated as complying with those parts of the essential principles specified in the standard.

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 medical device standard set out in the Order, and this is applied correctly to a device, the device is presumed to comply with the parts of the essential principles set out in the Order (section 41BH of the Act).

MDSO (Biological Safety) 2008 determines medical device standards, which set methods for risk analysis and risk management in order to demonstrate compliance of medical devices with the essential principles.

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. The updated standards referenced in MDSO (Biological Safety) 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 MDSO (Biological Safety) 2008 during July-August 2008. Industry groups supported the adoption of these standards.

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 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.