EXPLANATORY STATEMENT

Subject: CONFORMITY ASSESSMENT STANDARDS ORDER (STANDARD FOR QUALITY MANAGEMENT SYSTEMS AND QUALITY ASSURANCE TECHNIQUES) 2008

Section 41DC, Therapeutic Goods Act 1989

OUTLINE

Conformity Assessment Standards Order (Standard for Quality Management Systems and Quality Assurance Techniques) 2008 (CASO (QMS) 2008) is an Order made by the delegate of the Minister for Health and Ageing under section 41DC of the *Therapeutic Goods Act 1989* (the Act).

CASO (QMS) 2008 revokes and replaces Conformity Assessment Standards Order No. 1 of 2005 – Quality Management Systems and Quality Assurance Techniques that was made on 21 September 2005 (CASO 1 of 2005) and commenced on 29 September 2005, the day after it was registered on the Federal Register of Instruments (FRLI). CASO 1 of 2005 specified particular standards as conformity assessment standards relevant to the implementation of the manufacturer's quality management system and quality assurance techniques.

CASO (QMS) 2008 introduces new conformity assessment standards for quality assurance techniques for the manufacture of kinds of medical devices that are intended by the manufacturer to be supplied in a sterile state. The new standards are based on the following updated standards:

- **EN ISO 11135-1:2007** *Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*;
- **AS/NZS ISO 11137-1:2006** which is identical to ISO 11137-1:2006 *Sterilization of health care products – Radiation – Part 1: Requirements for validation and routine control – Radiation sterilization;*
- **AS/NZS ISO 11137-2:2006** *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose;*
- **AS/NZS ISO 11137-3:2006** *Sterilization of health care products – Radiation – Part 3: Guidance on dosimetric aspects;*
- **EN ISO 17665-1:2006** *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.*
- **ISO 13408-1: 2008** *Aseptic processing of health care products – Part 1: General requirements*
- **ISO 13408-2: 2003** *Aseptic processing of health care products – Part 2: Filtration*
- **ISO 13408-3: 2006** *Aseptic processing of health care products – Part 3: Lyophilization*
- **ISO 13408-4: 2005** *Aseptic processing of health care products – Part 4: Clean-in-place technologies*
- **ISO 13408-5: 2006** *Aseptic processing of health care products – Part 5: Sterilization in place*
- **ISO 13408-6: 2005** *Aseptic processing of health care products – Part 6: Isolator systems*
- **ISO 14937: 2000** *Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development of routine control of a sterilization process for medical devices*

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

CASO (QMS) 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, efficacy and timely availability of therapeutic goods that are used in Australia or exported from Australia.

Section 41DC of the Act authorises the Minister, or the Minister's delegate, by written instrument called an Order, to determine conformity assessment standards for quality management systems for medical devices and to determine that a quality management system that complies with the standard is to be treated as having had applied to it those parts of the conformity assessment procedures specified in the standard.

The requirement for a quality management system has been established in the medical devices framework set out in the Act and the standards referenced in the Order provide a means that industry may use to meet the legislative requirements.

The International Standards Organisation (ISO) describes a quality management system as a set of interrelated or interacting processes and interfaces, whose purpose is to achieve defined objectives, within the constraints of established policy. The system is to direct and control a group of people and facilities, with an arrangement of responsibilities, authorities and relationships. Such controls and arrangements are necessary to ensure that the outputs of the system have a set of predetermined inherent and distinguishing features that fulfil a need or expectation that is stated generally, implied or obligatory.

The *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) sets out requirements relating to the obligations of manufacturers of medical devices known as conformity assessment procedures.

The conformity assessment procedures, specified in the Regulations, set out the requirements relating to the application of quality management systems for the manufacture of medical devices and other requirements relating to the obligations of manufacturers of medical devices. Dealing in medical devices that have not had the conformity assessment procedures applied may be an offence or be the subject of a civil proceedings for the contravention of a civil penalty provision. Conformity with applicable conformity assessment standards determined by an Order under section 41DC of the Act is not mandatory, but it is one way to establish conformity with the conformity assessment procedures set out in the Regulations. If a manufacturer chooses to apply a conformity assessment standard set out in the Order, and this is applied correctly, the manufacturer's quality management system is presumed to comply with the parts of the conformity assessment procedures set out in the Order (section 41BI of the Act).

An Order establishing a conformity assessment standard for a medical device may be specified by reference to, among other things, a standard published by a standards organisation including Standards Australia Limited and the International Organisation for Standardisation (section 41DD of the Act).

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 CASO (QMS) 2008 reflect the current relevant international standards for quality assurance techniques for sterile devices.

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 CASO 1 of 2005 (the updated CASO 1) during January-February 2008. Industry groups supported the adoption of these standards.

The updated CASO 1 referenced ISO 13408-1: 1998 which in June 2008 was updated to ISO 13408-1: 2008 *Aseptic processing of health care products – Part 1: General requirements.* The TGA therefore further updated the standard to also reference ISO 13408-1:2008, with a proposal to phase out ISO 13408-1: 1998, in September 2009, in line with the European timeframes. A further round of consultation on this proposal took place in July-August 2008. Industry groups supported the adoption of the updated standard.

REGULATION IMPACT STATEMENT

Compliance with the proposed conformity assessment standards is voluntary and members of industry may choose alternative means to demonstrate compliance with the conformity assessment procedures in the Regulations. There was overall support from all stakeholders, including industry and Standards Australia who were consulted during the development of the proposed new regulatory system for medical devices. 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.