

EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ORDER NUMBER 54A
AMENDMENT TO THE STANDARD FOR DISINFECTANTS AND
STERILANTS

(section 10, Therapeutic Goods Act 1989)

The Therapeutic Goods Act 1989 (the Act), which was enacted on 17 January 1990, regulates the establishment and maintenance of a national system of controls relating to the quality, safety and efficacy of therapeutic goods which are used in humans. The Act came into effect on 15 February 1991.

Section 10 of the Act empowers the Minister, or an Officer of the Commonwealth with the appropriate delegation, by Order published in the *Commonwealth of Australia Gazette* to determine, as required, standards for therapeutic goods.

Part 2 of the Act, in sections 10-15, contains provisions dealing with the standards which may be applied to therapeutic goods. This Part covers matters such as the determination of standards (s. 10), date of effect of standards (s.11), special standards (s.14) and consent being subject to conditions etc.... in certain circumstances (s.15).

Section 10(1) of the Act states that "The Minister may, by order published in the Commonwealth of Australia Gazette, determine that matters specified in the order specify a standard for therapeutic goods or a class of therapeutic goods identified in the order (whether or not those goods are the subject of a monograph in the British Pharmacopoeia or the British Pharmacopoeia (Veterinary))".

The Therapeutic Goods Committee (TGC), which is the committee that advises the Minister on matters relating to standards for therapeutic goods agreed at their 19 April 1996 meeting, that the document entitled *Standard for Disinfectants and Sterilants* should be adopted as a Therapeutic Goods Order (TGO). This Order was signed by the delegate of the Minister on 25 October 1996.

The present Order, "No. 54A – Amendment to the standard for disinfectants and sterilants", was made on 26 March 1997 to effect changes recommended by the Senate Standing Committee for Regulations and Ordinances in their letter of 28 November 1996 from the Committee Chairman (Bill O'Chee) to the Minister for Health and Family Services (Michael Wooldridge). This Order removes the technical legislative flaws present in TGO No.54 namely:

that documents not referenced in the parent Act, were described as however, "published from time to time"; and

that a discretion conferred upon the Secretary in TGO 54 would not have been subject to merits review.

TGO No.54A also includes two minor clarifications that were subsequently requested by industry and gives the start date for the labelling provisions.