

EXPLANATORY STATEMENT

THERAPEUTIC GOODS ORDER NUMBER 54B

DISINFECTANTS AND STERILANTS

(Section 10, Therapeutic Goods Act 1989)

The Therapeutic Goods Act 1989 (the Act), 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.

Part 2 of the Act, in sections 10-15, contains provisions dealing with how and what standards may be made in relation to therapeutic goods.

Subsection 10(1) of the Act provides: "The Minister may, by order published in the *Gazette*, determine that matters specified in the order constitute 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 that the document *Standard For Disinfectants And Sterilants* should be adopted as the standard for disinfectants and sterilants. The Therapeutic Goods Order (TGO 54) adopting the standard was signed by the delegate of the Minister on 25 October 1996.

The Senate Standing Committee for Regulations and Ordinances recommended changes to TGO 54 to remove what were considered to be technical legislative flaws. These changes together with two minor modifications to TGO 54 that were requested by industry were effected by TGO 54A on 26 March 1997.

The present Order, "No. 54B - Amendment to the standard for disinfectants and sterilants", was made on 23 September 1999 after the Senate Standing Committee for Regulations and Ordinances noted cross referencing errors between TGO 54 and TGO 54A. TGO 54B corrects those errors. It also clarifies the requirements for embossing of batch and expiry particulars on labels by deleting subclause 5(14) and replacing it with a simpler subclause 5(13).