EXPLANATORY STATEMENT

Subject: THERAPEUTIC GOODS ORDER NUMBER 54
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).

The document was developed as a result of extensive discussion with industry, health care professionals, scientists and other interested parties and all have advised their acceptance. Disinfectants and sterilants are constantly used in clinical situations where exposure to infection with viruses such as HIV and Hepatitis is high. Both health care professionals and patients have the expectation that disinfectants and sterilants will destroy infective agents as claimed as they are specifically sold and used for the prevention of the spread of infection. Like condoms and medical gloves the efficacy of disinfection and sterilising products and procedures is considered a critical aspect of the National Aids program and infection control procedures in all health care facilities. There are well known cases of the transmission of infection, including HIV and Hepatitis, from patient to patient via instruments and there is a strong expectation among health workers and patients that disinfectants and sterilants are of sufficiently high quality to protect them.

Adoption of the Standard as an order introduces mandatory controls over disinfectants and sterilants covering performance requirements, packaging and labelling.

The Order was signed by the delegate of the Minister on 25 October 1996.