EXPLANTORY STATEMENT

Subject: THERAPEUTIC GOODS ORDER NO. 61A – *REPLACEMENT OF TGO 61: CONTRACEPTIVE DEVICES-RUBBER CONDOMS*

(Section 10, Therapeutic Goods Act 1989)

The *Therapeutic Goods Act 1989* (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 or exported from Australia.

Section 10 of the Act provides that the Minister, or Minister's delegate, may, by Order published in the *Commonwealth of Australia Gazette* determine standards for therapeutic goods.

The current Therapeutic Goods Order (TGO) for rubber condoms (TGO 61 *Standard Rubber Condoms*) was gazetted and commenced on 1 April 1998.

The proposed Order revokes TGO 61 *Contraceptive Devices – Rubber Condoms* and adopts ISO 4074: 2002(E) *Natural Latex Rubber Condoms – Requirements and Test Methods*, including *Technical Corrigendum 1* and includes additional labelling requirements for condoms.

Therapeutic Goods Order No. 61A (TGO 61A) was signed by the delegate of the Minister for Health and Ageing on 12 March 2004 and notified in the Australian Government Gazette No. GN 12 of 24 March 2004 and will commence six (6) months from the date it is gazetted.

Background

Changes to TGO 61

The International Organisation of Standardisation has published a 2002 edition of ISO Standard 4074, which supersedes ISO 4074-1:1996(E). Accordingly, the TGA has amended Therapeutic Goods Order No 61 *Contraceptive Devices – Rubber Condoms* to include a reference to ISO 4074:2002(E) *Natural Latex Rubber Condoms – Requirements and Test Methods,* and to remove any reference to the previously published edition of ISO 4074.

The new International Standard specifies the minimum requirements and tests to be used for condoms made from natural rubber latex which are supplied to consumers for contraceptive purposes and to assist in reducing the risk of sexually transmitted infections. With the exception of the tests for stability and shelf life, this International Standard does not require that a manufacturer perform any of the tests. Rather, the Quality System must assure that the products meet the requirements set out in this Standard when tested by a third party using specific test methods.

The new TGO also:

- Introduces requirements for manufacturers to conduct stability tests to estimate the shelf life of any new or modified product and to initiate real-time stability studies before the product is available on the market.

- Includes additional requirements for tensile properties for condoms claiming to have extra strength, including clinical evaluation of the performance or additional labelling information.

- Introduces additional labelling requirements for condoms containing the spermicide nonoxinal-9. These changes are based on recommendations of the Medicines Evaluation Committee made at its February 2003 meeting.

Consultation

Industry stakeholders, including the Medical Industry Association of Australia, Standards Australia and condom sponsors were consulted during the development of the proposed TGO 61A *Replacement of TGO 61: Contraceptive Devices-Rubber Condoms*. This was done in the context of adopting standards under the new system. There was overall support for the adoption of international standard and additional labelling requirements.

The Therapeutic Goods Committee (TGC), which advises the Minister on matters relating to standards for therapeutic goods, agreed at its 17 December 2003 meeting that a new standard for rubber condoms should be adopted as a Therapeutic Goods Order to include the latest revisions of the International Standard for Condoms International Standard ISO 4074:2002(E) *Natural Latex Rubber Condoms-Requirements and Test Methods.*

Regulation Impact Statement

The new TGO will only apply to those sponsors whose products were entered on the ARTG prior to the introduction of the new regulatory system for medical devices. Furthermore, will only continue to apply until either the sponsor seeks inclusion of the product on the ARTG under the new system or October 2007, when the transition period ends.

As most sponsors and manufacturers have been complying with the 2002 ISO Standard for *Natural Latex Rubber Condoms-Requirements and Test Methods*, there should be minimal change required of sponsors and manufacturers when the adopted standard for these products comes into force. Key stakeholders, including sponsors, the Medical Industry Association of Australia and Standards Australia have been consulted during the development of the proposed TGO 61A. There was overall support for the adoption of the proposed Order.

Under the new system, sponsors of new products for entry onto the ARTG can apply ISO 4074:2002 (E) to demonstrate compliance with the Essential Principles for quality, safety and performance. As medical device standards are voluntary under the new regulatory system, the adoption of the Standard is considered not to be prohibitive either in terms of costs or time delays.

Further Background

Impact on the new regulation for medical devices implemented October 2002

Rubber condoms are regulated as medical devices under the Act. Since the introduction of the new medical devices framework in Australia, rubber condoms, like all medical devices have been subject to transitional requirements. Condoms entered onto the ARTG prior to

4 October 2002 are required to meet mandatory standards, such as TGO 61A, and will have to continue doing so until either the sponsor seeks inclusion of the product on the ARTG under the new system or October 2007, when the transition period ends.

Under the new medical device regulatory system introduced on 4 October 2002 compliance with applicable medical device standards is not mandatory, but it is the preferred way to establish compliance with the Essential Principles for quality, safety and performance, if a standard exists. While not mandatory, ISO 4074:2002(E) can be used by manufacturers of rubber condoms to demonstrate compliance with the Essential Principles.

In time ISO 4074: 2002(E) will be gazetted as a Medical Device Standards Order under the new system. If a manufacturer chooses to apply the relevant Medical Device Standard, and this is applied correctly, the device is presumed to comply with the parts of the Essential Principles set out in the Order (section 41BH of the Act).