

COMMONWEALTH OF AUSTRALIA

Therapeutic Goods Act 1989

THERAPEUTIC GOODS ORDER NO. 61A

Replacement of TGO 61: Contraceptive Devices - Rubber Condoms

I, Terry Slater, delegate of the Minister for Health and Ageing for the purposes of section 10 of the *Therapeutic Goods Act 1989* and acting under that section, having consulted with the Therapeutic Goods Committee in accordance with subsection 10(4) of the said Act, **HEREBY:**

REVOKE Therapeutic Goods Order No. 61 *Contraceptive Device - Rubber Condoms* (TGO 61) signed by the delegate on 20 March 1998; and

DETERMINE that the matters specified in International Standard "ISO 4074:2002(E) *Natural Latex Rubber Condoms - Requirements and Test Methods, including Technical Corrigendum 1*" shall constitute the standard for rubber condoms, subject to the modifications set out below:

1) Insert after paragraph 11.2.3.2 the following paragraph:

"11.2.3.3 Labelling of condoms

The following claims may be included on either the outside consumer package or a leaflet contained within the consumer package:

- i. condoms can help reduce the risk of pregnancy;
- ii. condom use may help reduce the risk of transmission of HIV/AIDS and other sexually transmitted infections (STIs)

2) Insert after paragraph 11.2.3.3 the following paragraph:

"11.2.3.4 Labelling of condoms containing nonoxinol 9

In relation to the labelling of, and package inserts for, condoms containing nonoxinol 9:

- (a) Claims implying that the addition of nonoxinol 9 helps reduce or prevent HIV/AIDS or sexually transmitted infections (STIs) shall not be included.
- (b) Any claim for "added protection" shall specify that this claim is limited only to added protection against pregnancy.
- (c) The label or package insert shall bear the following information:

"The presence of nonoxinol 9 has not been shown to reduce the risk of transmission of HIV/AIDS or other sexually transmitted infections (STIs)."

This Order shall commence six months from the day it is gazetted in the Commonwealth Gazette.

Dated this 12th day of March 2004

Terry Slater
Delegate of the Minister for Health and Ageing