

WORLD TRADE ORGANIZATION

G/TBT/N/AUS/21
24 September 2003

(03-5056)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1.	Member to Agreement notifying: <u>AUSTRALIA</u> If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Department of Health and Ageing, Therapeutic Goods Administration Name and address (including telephone and fax numbers, e-mail and web-site addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Rubber Condoms
5.	Title, number of pages and language(s) of the notified document: Therapeutic Goods Order No 61A – Replacement of TGO 61: Contraceptive Device – Rubber Condoms
6.	Description of content: Describes mandatory standards for Rubber Condoms based on ISO Standard Specifications. The proposal seeks to amend Therapeutic Goods Order No. 61 to include the reference to ISO 4074:2002(E) <i>Natural Latex Rubber Condoms – Requirements and Test Methods</i> and to include additional labelling requirements for condoms and condoms containing nonoxinol 9. Any references to the previously published ISO Standard 4074-1:1996(E) <i>Rubber Condoms</i> will be removed.
7.	Objective and rationale, including the nature of urgent problems where applicable: To have a national regulatory requirement and to ensure the safety, quality and efficacy of rubber condoms in Australia. The proposed amendment to TGO 61 <i>Contraceptive Devices – Rubber Condoms</i> will update the standard to include a reference to the new ISO Standard for rubber condoms which supersedes the previously published standard ISO 4074-1:1996(E) <i>Rubber Condoms</i> .
8.	Relevant documents: ISO 4074:2002(E) <i>Natural Latex Rubber Condoms – Requirements and Test Methods</i> – Specification.
9.	Proposed date of adoption: To be determined Proposed date of entry into force: The Order shall commence six months from the day it is gazetted in the Commonwealth Gazette.
10.	Final date for comments: 21 November 2003

11. Texts available from: National enquiry point [] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:

A copy of the draft Therapeutic Goods Order No 61A – “Replacement of TGO 61: Contraceptive Devices-Rubber Condoms” from the Policy & Regulatory Liaison Section, Office of Devices, Blood & Tissues, Therapeutic Goods Administration:

Fax No: +61 2 6232 8687.

The text is also available at: <http://www.tga.gov.au/devices/devices.htm>

A copy of the ISO Standard is available from:
International Organisation for Standardisation,
Case Postale 56,
CH-1211 GENEVE 20,
SWITZERLAND

Email: central@iso.ch