

WORLD TRADE ORGANIZATION

G/TBT/N/AUS/2
23 May 2001

(01-2624)

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 Aged Care, 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): Tampons, menstrual
5. Title, number of pages and language(s) of the notified document: Therapeutic Goods Order No. 64A Tampons - Menstrual
6. Description of content: The proposal is to amend the current Therapeutic Goods order No. 64 Tampons – Menstrual, which sets the minimum requirements for tampons, to include an additional advisory statement in relation to the sterility of tampons and Toxic Shock Syndrome (TSS), for tampon package inserts or patient information leaflets.
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 menstrual tampons in Australia. The proposed advisory statement for tampon package inserts or patient information leaflets supplements the minimum requirements for tampon information leaflets specified in the Australian/New Zealand Standard AS/NZS 2869:1998 <i>Tampons – Menstrual – Specification</i> .
8. Relevant documents: To be determined.
9. Proposed date of adoption: } Proposed date of entry into force: } 17 July 2001
10. Final date for comments: To be determined.

- 11. Texts available from: National enquiry point [X] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:** A copy of the draft "Therapeutic Good Order No. 64A – Standard for Tampons – Menstrual" from the Policy & International Liaison Section, Conformity Assessment Branch, Therapeutic Goods Administration, PO Box 100, Woden, ACT 2606.

Fax No. +61 2 6232 8687

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

A copy of the Australian/New Zealand Standard is available from Standards Australia, PO Box 1055, Strathfield NSW 2135