

WORLD TRADE ORGANIZATION

G/TBT/N/AUS/4
23 July 2001

(01-3658)

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): Dental Materials
5.	Title, number of pages and language(s) of the notified document: Therapeutic Goods Order No 67A – Standard for Dental Materials
6.	Description of content: Describes mandatory standards for Dental Materials based on ISO Standard Specifications. The proposal seeks to amend Therapeutic Goods Order No. 67 to include the reference to ISO 4049:2000 <i>Dentistry – Polymer-based filling, restoration and luting materials</i> and remove any references to the previously published ISO Standard 4049:1988 <i>Dentistry-Resin-based filling, materials</i> .
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 dental materials in Australia. The proposed amendment to TGO 67 <i>Dental Materials</i> will update the standard for dental materials to include a reference to the new ISO Standard for polymer-based filling restoration and luting materials which supersedes the previously published standard ISO 4049:1988 <i>Dentistry-resin-based filling materials</i> .
8.	Relevant documents: ISO 4049:2000 <i>Dentistry – Polymer-based filling, restoration and luting materials – Specification</i> .
9.	Proposed date of adoption: Proposed date of entry into force: } To be determined
10.	Final date for comments: 13 September 2001

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 67A – “Dental Materials” from the Policy & International Liaison Section, Conformity Assessment Branch, Therapeutic Goods Administration: 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 Standard is available from:

International Organisation for Standardisation,
Case Postale 56,
CH-1211 GENEVE 20,
SWITZERLAND
Email: central@iso.ch