

# WORLD TRADE ORGANIZATION

G/TBT/N/AUS/22  
24 September 2003

(03-5064)

Committee on Technical Barriers to Trade

Original: English

## NOTIFICATION

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

1.	<b>Member to Agreement notifying:</b> AUSTRALIA <b>If applicable, name of local government involved (Articles 3.2 and 7.2):</b>
2.	<b>Agency responsible:</b> Department of Health and Ageing, Therapeutic Goods Administration <b>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:</b>
3.	<b>Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], other:</b>
4.	<b>Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Therapeutic goods
5.	<b>Title, number of pages and language(s) of the notified document:</b> Therapeutic Goods Order No. 71 <i>Tamper-Evident Packaging of Therapeutic Goods</i> (2 pages, in English)
6.	<b>Description of content:</b> The proposal seeks to adopt the document <i>Code of Practice for the Tamper-Evident Packaging (TEP) of Therapeutic Goods</i> (Edition 1, June 2003), published by the Therapeutic Goods Administration on behalf of the Industry Government Crisis Management Committee, as a mandatory packaging standard for therapeutic goods in Australia.  Compliance with this packaging standard will be required for those therapeutic goods described under <i>Scope</i> in the Code of Practice, namely those therapeutic goods (medicines and medical devices) that are available for general sale to the public without restriction, or for sale in pharmacies without prescription.
7.	<b>Objective and rationale, including the nature of urgent problems where applicable:</b> Protection of human health and safety, through improving the security of therapeutic goods supplied in Australia and increasing the likelihood that consumers will discover if a product has been tampered with.
8.	<b>Relevant documents:</b> Publication in which the notification is published when adopted: Commonwealth of Australia Gazette.  Referenced document: <i>Code of Practice for the Tamper-Evident Packaging (TEP) of Therapeutic Goods</i> (Edition 1, June 2003), published by the Therapeutic Goods Administration on behalf of the Industry Government Crisis Management Committee, available at <a href="http://www.health.gov.au/tga/docs/html/tepguide.htm#pdf">http://www.health.gov.au/tga/docs/html/tepguide.htm#pdf</a> .

<b>9.</b>	<b>Proposed date of adoption:</b> <b>Proposed date of entry into force:</b>	<b>}</b> 1 January 2004
<b>10.</b>	<b>Final date for comments:</b> 1 November 2003	
<b>11.</b>	<b>Texts available from: National enquiry point [ ] or address, telephone and fax numbers, e-mail and web-site addresses, if available of the other body:</b>  A copy of the draft Therapeutic Goods Order No. 71 <i>Tamper-Evident Packaging of Therapeutic Goods</i> is available from the Recalls & Secretariat Section, Therapeutic Goods Administration, PO Box 100 Woden ACT 2606  Telephone No. +61 2 6232 8661, Fax No. +61 2 6232 8687.  The text is also available at: <a href="http://www.health.gov.au/tga/docs/html/tgo/tgo71dr.htm">http://www.health.gov.au/tga/docs/html/tgo/tgo71dr.htm</a> .	