

Committee on Technical Barriers to Trade

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: Therapeutic Goods Administration (TGA) Agency or authority designated to handle comments regarding the notification can 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): Tablets, pills and capsules
5.	Title, number of pages and language(s) of the notified document: General Standard for Tablets, Pills and Capsules (21 pages)
6.	Description of content: The TGA is issuing a new Therapeutic Goods Order (TGO) entitled "General Standard for Tablets, Pills and Capsules" under the Therapeutic Goods Act. The proposed TGO will revoke and replace two current TGOs - TGO 35 "General Standard for Tablets and Pills" and TGO 36 "General Standard for Capsules". The new TGO will adopt the requirements in the General Monographs of the British Pharmacopeia (BP) for Tablets and Capsules and will also specify general limits for content of active ingredient for those tablets, pills or capsules which are not the subject of a specific monograph of the BP.
7.	Objective and rationale: This action is being taken as a move towards international harmonization of standards for tablets, pills and capsules and to minimise barriers to international trade in these products.
8.	Relevant documents: Therapeutic Goods Act 1989
9.	Proposed date of adoption: } Proposed date of entry into force: } 1 January 1997
10.	Final date for comments: 5 August 1996
11.	Texts available from: National enquiry point [ ] or address and telefax number of other body: Conformity Assessment Branch Therapeutic Goods Administration PO Box 100 WODEN ACT 2606 AUSTRALIA Telefax No. + 61 6 232 8659