

WORLD TRADE ORGANIZATION

G/TBT/Notif.00/351
8 August 2000

(00-3244)

Committee on Technical Barriers to Trade

NOTIFICATION

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

1.	Member to Agreement notifying: JAPAN If applicable, name of local government involved (Articles 3.2 and 7.2):
2.	Agency responsible: Ministry of Health and Welfare Agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [], 2.10.1 [], 5.6.2 [X], 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): Pharmaceuticals (HS 30.01, 30.02, 30.03, 30.04, 30.05, 30.06)
5.	Title, number of pages and language(s) of the notified document: Revision of Pharmaceuticals' Post-Marketing Safety Measures (5 pages, available in Japanese)
6.	Description of content: To introduce "Early Post-Marketing Phase Vigilance for New Drug" (EPPV) and Reconsider the Post-Marketing Study Requirements for Re-examination Application
7.	Objective and rationale, including the nature of urgent problems where applicable: Further safety assurance of new drugs at the early phase of post-marketing.
8.	Relevant documents: <ol style="list-style-type: none">1. Pharmaceutical Affairs Law (Law No. 145 issued in 1960)2. Good Post-Marketing Surveillance Practice (MHW Notification No. 10 issued in 1997)3. The post-marketing study guideline (MHW PAB/SD Notification No. 34 issued on 27 March 1997)
9.	Proposed date of adoption: 31 December 2000 Proposed date of entry into force: 1 July 2001
10.	Final date for comments: 13 October 2000
11.	Texts available from: National enquiry point [X] or address, e-mail and telefax number of the other body: Safety Division Pharmaceutical and Medical Safety Bureau Ministry of Health and Welfare Kasumigaseki 1-2-2, Chiyoda-ku Tokyo 100-8045 Japan Tel: +81-3-3503-1711 (Ext. 2750) Fax: +81-3-3508-4364