

GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.92.388/Corr.2
10 February 1993

Special Distribution

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

Corrigendum

This document supersedes TBT/Notif.92.388/Corr.1.

The following communication by Japan is being circulated in accordance with Article 10.4.

Under item 9, Proposed date of adoption and entry into force, the information should be replaced by the following:

- (1) - Assistance, advice and guidance in developing orphan drugs
- Extension of the re-examination period
- Priority examination

effective from October, 1993.

- (2) - Delegation of licensing authority

effective from April, 1995.

- (3) Others

- Incorporation of Good Manufacturing Practice (GMP) programme as a prerequisite for license
- Setting up of new fees for licenses of additional items
- Entrusting the Adverse Drug Reaction Sufferings Relief and Research Promotion Fund with business other than orphan drugs related business

effective from April, 1994.