GENERAL AGREEMENT ON TARIFFS AND TRADE

RESTRICTED

TBT/Notif.92.388
11 December 1992

Special Distribution

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.4.

1. Party to Agreement notifying: JAPAN
2. Agency responsible: Ministry of Health and Welfare
3. Notified under Article 2.5.2 [], 2.6.1 [], 7.3.2 [X], 7.4.1 [], other:
4. Products covered (HS or CCCN where applicable, otherwise national tariff heading): Drugs, quasi-drugs, cosmetics and medical devices (HS: 05, 12, 13, 29, 30, 34, 35, 37, 38, 39, 40, 90 and 94)
5. Title and number of pages of the notified document: Amendment to the Pharmaceutical Affairs Law and the Adverse Drug Reaction Sufferings Relief and Research Promotion Fund Law (available in Japanese, 3 pages)
6. Description of content: (1) To introduce exceptions in the taxation system and development subsidy for researcher and developer of orphan drugs and orphan devices which are designated by the Minister for Health and Welfare. (2) To expand the scope of the types of drugs and quasi-drugs which are exempted from the application for approval. With regard to drugs, quasi-drugs and cosmetics, the following measures will be taken: - to give competence such as granting license to manufacture (import) products with the exception of certain products to prefectural governors; - to entrust to the Adverse Drug Reaction Sufferings Relief and Research Promotion Fund which is an independent and semi-governmental organization with examination of business for approval etc.; - to add regulations of manufacturing control and quality control to conditions of license; (3) Orphan drugs and etc. if applicable, may be given priority in an examination for approval, and their re-examination period may be extended.

7. Objective and rationale: To facilitate the development of orphan drugs and to ensure the supply of drugs necessary for public health.
8. Relevant documents: The basic laws are the Pharmaceutical Affairs Law and the Adverse Drug Reaction Sufferings Relief and Research Promotion Fund Law. The said amendment will appear in "KAMPO" (Official Government Gazette) when adopted.
9. Proposed date of adoption and entry into force: With regard to 6.(1) on 1 April 1993. With regard to 6.(2) from 1 April 1994 gradually. With regard to 6.(3) on 1 April 1993.
10. Final date for comments: 10 February 1993
11. Texts available from: National enquiry point [X] or address of other body: