GENERAL AGREEMENT ON TARIFFS AND TRADE

RESTRICTED

TBT/Notif.83.90
5 May 1983

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, Ministry of Agriculture, Forestry and Fisheries

3. Notified under Article 2.5.2 [ ], 2.6.1 [ ], 7.3.2 [x], 7.4.1 [ ], Other:

4. Products covered (CCCN where applicable, otherwise national tariff heading):
Pharmaceuticals, cosmetics, medical devices, quasi-drugs

5. Title: Amendment to the Pharmaceutical Affairs Law

6. Description of content:

(1) The Minister of Health and Welfare will be able to give the manufacture-approval of each product on the basis of the application of the foreign manufacturer who intends to manufacture the pharmaceuticals, quasi-drugs, cosmetics or medical devices for the purpose of export to Japan. In that case, the applicant will have to designate an agent who can take measures in Japan to prevent hazards on the public health which may be caused by the use of the said product.

(2) The importer who intends to import the pharmaceutical, etc., for which the foreign manufacturer has already obtained the manufacture-approval will not be required to obtain the import-approval of that product.

(3) The Minister of Health and Welfare will be able to make the agent provide necessary information such as information on adverse reactions, make his officials conduct on-site inspection or order the agent to take measures to prevent the occurrence or spreading of hazards on the public health.

(4) The foreign recipient of the manufacture-approval or the agent will have to provide the information concerning the approval and other necessary information for proper dealing with the pharmaceutical, etc., to the importer who intends to import the related pharmaceutical, etc.

7. Objective and rationale: To ensure in terms of legal systems that there be no discrimination between nationals and non-nationals in certification procedures.

8. Relevant documents: Basic document is the Pharmaceutical Affairs Law.

9. Proposed dates of adoption and entry into force: Not yet determined

10. Final date for comments: The purpose of this amendment is to proceed further with the opening of the Japanese market by ensuring in terms of legal systems that there be no discrimination between nationals and non-nationals in certification procedures, in the light of the views and requests presented by Japan's trading partners.

Given the urgent nature of this legislation, it has been decided by the Cabinet to present the legislation promptly to the current session of the Diet. Such being the case, there will be no comment period for this legislation.

11. Texts available from: National enquiry point [x] or address of other body: