

GENERAL AGREEMENT ON

TARIFFS AND TRADE

RESTRICTED

TBT/Notif.93.102

31 March 1993

Special Distribution

Committee on Technical Barriers to Trade

NOTIFICATION

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

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| 1. Party to Agreement notifying: <u>JAPAN</u> |
| 2. Agency responsible: Ministry of Health and Welfare |
| 3. Notified under Article 2.5.2 [X], 2.6.1 [], 7.3.2 [], 7.4.1 [], other: |
| 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading): Drugs (HS:30) |
| 5. Title and number of pages of the notified document: Amendment to the Minimum Requirements for Biological Products (available in Japanese, 3 pages) |
| 6. Description of content: The minimum requirements for biological products will be amended for the purposes of simplifying the control tests, up-dating the testing methods and harmonizing the minimum requirement with Japanese Pharmacopoeia, the WHO standards and United States Pharmacopoeia etc. |
| 7. Objective and rationale: To establish the minimum requirements for the manufacturing process, properties, quality, storage, etc. of drugs with a view to attaining public health and sanitation (biological products). |
| 8. Relevant documents: The basic law is the Pharmaceutical Affairs Law. The said amendment will appear in "KAMPO" (Official Government Gazette) when adopted. |
| 9. Proposed date of adoption and entry into force: July 1993 |
| 10. Final date for comments: 4 June 1993 |
| 11. Texts available from: National enquiry point [X] or address of other body: |