

**GENERAL AGREEMENT
ON TARIFFS AND TRADE**

RESTRICTED
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16 December 1993
Special Distribution

(93-2192)

Committee on Technical Barriers to Trade

NOTIFICATION

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

1.	Party to Agreement notifying: <u>JAPAN</u>
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. ICS numbers may be provided in addition, where applicable): Medical devices (HS: 30, 34, 37, 40, 90 and 94)
5.	Title and number of pages of the notified document: Amendment to the Pharmaceutical Affairs Law. (Available in Japanese, 4 pages)
6.	Description of content: 1. To clarify that computer software used for medical devices are involved in the category of "medical devices" defined in the Pharmaceutical Affairs Law. 2. To enable those other than medical devices manufacturers who have enough knowledge and technical capacity to engage in medical devices repairing business. 3. In order to ensure quality, effectiveness, and safety of medical devices; to add, as requirements for getting a manufacturing licence, manufacturing control and quality control conditions, to establish a medical devices tracking system and to introduce a re-examination system of new medical devices and re-evaluation system of medical devices. 4. In order to simplify the business for approval of medical devices; to transfer the competence of granting licences of manufacture (import) products to prefectural governors, in principle, to entrust certain third-party (public body) designated by the Minister with examination business for approval etc.
7.	Objective and rationale: To review the regulations concerning medical devices in order to improve quality of public health and medical care, taking into account characteristics of medical devices.

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: From April 1995 gradually
10.	Final date for comments: 15 February 1994
11.	Texts available from: National enquiry point [X] or address and telefax number of other body: