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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 [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 the Blood Grouping and Typing Serums (available in Japanese, 21 pages)
6.	Description of content: This Amendment includes the following:  (1) To change the title "The Minimum Requirements for the Blood Grouping and Typing Serums" into the title "The Minimum Requirements for the Blood Grouping and Typing Reagents".  (2) To establish "General Notices", "General Rules for Blood Grouping and Typing Reagents" and "General Testing Methods".  (3) To unify the mutually-related monographs.  (4) To arrange the contents and testing items of monographs taking into account international harmonization.
7.	Objective and rationale: To establish the manufacturing process, properties, quality, storage, etc., of drugs to which special attention must be paid for attaining public health and sanitation (the Blood Grouping and Typing Serums).

8.	Relevant documents: The basic law is the Pharmaceutical Affairs Law.
9.	Proposed date of adoption and entry into force: April 1994
10.	Final date for comments: 8 December 1993
11.	Texts available from: National enquiry point <input checked="" type="checkbox"/> or address of other body: