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 [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:

93-0443