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

1. Party to Agreement notifying: JAPAN

2. Agency responsible: Biologies and Antibiotic Division, Pharmaceutical Affairs Bureau, 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 (CCCN where applicable, otherwise national tariff heading): Drugs (CCCN: Chapter 30)

5. Title: Amendment to the Minimum Requirements for Antibiotic Products of Japan

6. Description of content: Contents of the amendment to the said requirements, which have been established according to the provision of Article 42 of the Pharmaceutical Affairs Law, are as follows: (1) To amend General Notices, General Rules for Preparations, and General Rules for Monographs; (2) To eliminate 156 drug monographs from the section of Monographs; (3) To establish 3 test methods and to amend 12 test methods under the section of General Tests; (4) To eliminate 4 reference standards, 4 reference standards for common use, one buffer solution, and 19 reagents and test solutions from the section of Attached Tables; (5) To establish 12 reagents and test solutions under the section of Attached Tables.

7. Objective and rationale: Quality


9. Proposed dates of adoption and entry into force: April 1982

10. Final date for comments: 20 March 1982

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