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

1. Party to Agreement notifying: JAPAN

2. Agency responsible: Pharmaceuticals and Chemicals Safety 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: 30)

5. Title: Establishment of the Eleventh Edition of the Pharmacopoeia of Japan

6. Description of content: The Eleventh Edition of the Pharmacopoeia of Japan shall be established as follows:
   (1) To amend general rules for seven preparations under the section of General Rules for Preparations;
   (2) To establish two test methods under the section of General Tests, Processes and Apparatus;
   (3) To amend twenty-three test methods under the section of General Tests, Processes and Apparatus;
   (4) To establish monographs of eighty-one drugs under the section of Monographs;
   (5) To amend monographs of 732 drugs under the section of Monographs.

7. Objective and rationale: To regulate the properties and qualities of drugs

8. Relevant documents: The basic law is the Pharmaceutical Affairs Law

9. Proposed dates of adoption and entry into force: April 1986

10. Final date for comments: 28 March 1986

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

86-0117