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

1. Party to Agreement notifying: Japan

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

5. Title: Good laboratory practice standard for safety studies on drugs

6. Description of content: The Ministry of Health and Welfare (MHW) will establish the standard concerning good laboratory practices for nonclinical laboratory studies that are conducted to support applications for manufacture (or import) permits of new drugs among other things with a view to ensuring the reliability of safety data thereof. The MHW will advise manufacturers, importers and so on to conduct nonclinical safety studies by the standard. The main items of the draft standard are as follows:
   - The purpose and the coverage of the standard
   - Organization of personnel, their education and training, and responsibility pertinent to the conduct of studies
   - Designation of the quality assurance unit and its duties
   - The standard of facilities (animal care facilities, animal supply facilities, facilities for handling test and control articles, laboratory operation areas, archives, administrative facilities and so on)
   - Design and function, location, and control of equipment
   - Testing facilities operation (preparations of standard operating procedures and so on)
   - Determination, handling, and storage of test and control articles
   - Content of protocol and operating procedures of studies
   - Reports, records, and storage of related materials

7. Objective and rationale: For ensuring the reliability of nonclinical safety data.


9. Proposed date of adoption and entry into force: The administrative notice on the said standard will be issued in April 1982. However, the standard will be applied totally one year later from then.

10. Final date for comments: 20 March 1982

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