**NOTIFICATION**

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

1. **Party and Agency:** JAPAN: Evaluation and Registration Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, (1-2-2, Kasumigaseki, Chiyoda-ku, Tokyo, Japan)  
   2. **Provision of the Agreement:** 2.6.1  
   3. **Product(s) covered, CCCN Heading (National Tariff Heading where applicable):**  
      - Drugs (Products falling within CCCN heading 30)  
      - Quasi-drugs (Products falling within CCCN heading 33, 34)  
      - Cosmetics (Products falling within CCCN 33)  
      - Medical devices (CCCN 37.01, 37.02)  
   4. **Title of project:** Designation of those items which must carry indication of the periods of their use on the label  
   5. **Description:** Designation specifies those products which may degrade within three years and requires that the periods of their use be indicated and that they be guaranteed for said periods provided that they are stored under recommended conditions of storage: Designated items are as follows:  
      - Drugs (49 items) e.g. insulin and their preparations, epinephrine, its salts and their preparation, enzyme and their preparation  
      - Quasi-drugs (13 items) e.g. ascorbic acid, its ester, and preparations of their salts, enzyme and their preparation, preparations of vitamin A oil  
      - Cosmetics (2 items) e.g. cosmetics which include ascorbic acid, its ester and their salts or enzyme  
      - Medical devices (2 items) e.g. X-ray film  
   6. **Objective and rationale:** For ensuring quality  
   7. **Relevant document(s):** Pharmaceutical Affairs Law  
   8. **Where published, when adopted:** KAMPO (Official Government Gazette); 26 September 1980  
   9. **Final date for submission of comments:**  
   10. **Proposed date of adoption and entry into force:** 30 September 1980, provided however that a two-year grace period shall be established for items already in inventory or items using material ingredients correctly labelled under the superseded law within one year.