NOTIFICATION

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

1. Party to Agreement notifying: JAPAN

2. Agency responsible: Biologies and Antibiotics Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare

3. Notified under Article 2.5.2, 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 Biological Products

6. Description of content: (1) To extend the expiration date for dried human anti-haemophilic globulin, dried human blood coagulation factor IX complex and dried pepsin-treated human normal immunoglobulin and (2) To revise the test relating to content of sulfonated human normal immunoglobulin G concerning sulfonated human normal immunoglobulin G.

   The above requirements have been established according to the provision of Article 42 of the Pharmaceutical Affairs Law.

7. Objective and rationale: Quality


10. Final date for comments: -

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