(Attachment)

Partial amendment to the Minimum Requirements for Biological Products and the Public Notice on National Release Testing.

1. The Minimum Requirements for Biological Products

The Article 42, paragraph 1 of Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145, 1955) stipulates that the Minister of Health, Labour and Welfare will establish necessary standards for the manufacturing methods, properties, quality, storage, etc. of drugs after seeking the opinions of Pharmaceutical Affairs and Food Safety Council. Based on this, the standards for manufacturing methods, properties, quality, and storage of biological products such as vaccine and blood products are specified in the Minimum Requirements for Biological Products (Ministerial Notification No. 155 of the Ministry of Health, Labour and Welfare on 2004).

2. The summary of this amendment

The Minimum Requirements for Biological Products shall be amended as follows ;

・ GENERAL RULES

- The test for abnormal toxicity (“test for freedom from abnormal toxicity”) will be deleted from monographs for “Freeze-Dried Japanese Encephalitis Vaccine”, “Pneumoniae Vaccine Polyvalent”, “Pneumococcal 10-valent conjugate vaccine”, “Freeze-Dried Haemophilus Type b Vaccine (Tetanus Toxoid Conjugate)”