(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 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 Public Notice on National Release Testing

According to Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the pharmaceuticals subject to National Release Testing which are designated by Minister of Health, Labour and Welfare (the Public Notice No. 279 of MHW, 1963) has been notified in order to stipulate the pharmaceuticals subject to National Release Testing, fees, criteria and quantities for the testing.

3. The summary of this amendment

The Minimum Requirements for Biological Products will be amended as follows:

Regarding the standard for "Freeze-dried Live Attenuated Rubella Vaccine" and "Freeze-dried Live Attenuated Measles-Rubella Combined Vaccine", the requirements in case of using human diploid cells will be added.

The Public Notice on National Release Testing will be amended as follows:

The criterion for ""Freeze-dried Live Attenuated Rubella Vaccine" and "Freeze-dried Live Attenuated Measles-Rubella Combined Vaccine" will be partially amended.