(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 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 shall be amended as follows；

- The standard name of "nucleoside modified coronavirus RNA Vaccine (SARS-CoV-2)" will be amended to "coronavirus (SARS-CoV-2) RNA Vaccine". Accordingly, the test for pH, storage and expiry date will be deleted and partially amended for the above-mentioned vaccine.

The Public Notice on National Release Testing shall be amended as follows；

- The Public Notice on National Release Testing will be amended as follows； The standard name of "nucleoside modified coronavirus RNA Vaccine (SARS-CoV-2)" will be amended to "coronavirus (SARS-CoV-2) RNA Vaccine". In addition, the criterion of "Adsorbed Diphtheria-purified Pertussis-tetanus-inactivated polio Haemophilus TYPE b Combined Vaccine" will be partially amended. Accordingly, the fee, criterion, and quantity for National Release Testing of the above-mentioned vaccine will be partially amended.