(Attachment)

Partial amendment to the Minimum Requirements for Biological Products.

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

・GENERAL RULES

- To amend the provisions for “Potency test” in the “Recombinant Adsorbed Hepatitis B Vaccine (Prepared from Yeast)”.
- To amend the provisions for “Final bulk and final product” in the “Polyethylene Glycol-treated Human Anti-HBs Immunoglobulin”.

・GENERAL TESTS

- To amend the provisions for “Test procedures” in the “Test for Measuring the Potency of Human Anti-HBs Immunoglobulin”.

- This amendment will be promulgated on November 2021.