Outline of the draft Partial Amendment of the Minimum Requirements for Biological Products and the Public Notice on National Release Testing

1-1. The Minimum Requirements for Biological Products

According to Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, the Minimum Requirements for Biological Products (the notification No.155 of MHLW, 2004) has been notified in order to establish the standard for manufacturing process, properties, quality, storage of pharmaceuticals to which special attention must be paid for the attainment of public health and sanitation (Biological products).

1-2. 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.

2. The summary of this amendment

(1) The following article shall be added to the Minimum Requirements for Biological Products.

・Freeze-dried Concentrated Human alfa1-Proteinase Inhibitor

(2) The above-mentioned blood product shall be provided for in the Public Notice on National Release Testing.