

Overview of the Draft Partial Amendment of the Minimum Requirements for Biological Products

1. The Minimum Requirements for Biological Products

According to the Law 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, 2002) has been notified in order to establish the standard for manufacturing process, properties, quality, storage and others of pharmaceuticals to which special attention must be paid for the attainment of public health and sanitation (Biological products).

2. The summary of this amendment

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

- Freeze-dried Recombinant Herpes Zoster Vaccine (Prepared from Chinese Hamster Ovary Cells)