(Appendix)

Outline of the draft Partial Amendment of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices, and the Public Notice on Designated Biological Products

1-1. The Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices

With regard to National Release Testing of biological pharmaceuticals such as vaccines and blood products by national regulatory authority, an international standard for assessment process of Summary Lot Protocol (SLP) has been provided by World Health Organization (WHO).

In Japan, the SLP dossiers to be submitted for application of National Release Testing are specified under Article 197, Paragraph 2 of the Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products including Pharmaceuticals and Medical Devices (hereinafter referred to as the "Regulation for Enforcement"), for biological pharmaceuticals designated by the Minister of Health, Labour and Welfare.

1-2. The Public Notice on Designated Biological Pharmaceuticals

According to Article 197, Paragraph 2 of the Regulation for Enforcement, designated biological pharmaceuticals are specified by the public notice of Ministry of Health, Labour and Welfare (hereinafter as to the "Public Notice on Designated Biological Pharmaceuticals").

Currently, the Public Notice on Designated Biological Pharmaceuticals specifies vaccines (excluding immunologicals for therapeutic use) only.

2. The summary of this amendment

The Regulation for Enforcement and the Public Notice on Designated Biological Pharmaceuticals will be partially amended to reflect the WHO standard on SLP. This partial amendment will extend the designated biological pharmaceuticals to any biological pharmaceuticals.