General Explanation Regarding the Enforcement Rules of the Blood Derivative Act

Article 1: The Enforcement Rules are prescribed in accordance with Article 18 of the Blood Derivative Act (hereinafter referred to as the Act).

Article 2: The provision in Article 4 of the Act prescribing that the raw materials for blood derivatives shall be obtained from domestic blood donations means domestic blood derivative manufacturers shall use domestic blood donations as its primary source for domestic supply.

Article 3: Blood derivative manufacturers, when applying to the central governing authority for import approval of blood derivative raw materials in accordance with Article 4 of the Act, shall submit the following documents:

1. **A report on the application for importation of blood derivative raw materials, which shall contain the following:**
   (1) Analysis on the insufficient supply of domestic blood derivative raw materials;
   (2) Total volume of the blood derivative raw materials planned to be imported;
   (3) The name of the country from which the blood derivative raw materials planned to be imported and the export permit of that country; and
   (4) The categories and volume of blood derivatives planned to be manufactured.

2. **Application for the importation of pharmaceuticals under special permit.**

3. **Photocopy of the permit for the manufacturing of pharmaceuticals.**

4. **Specifications for the inspection of blood derivative raw materials.**

Article 4: Imported blood derivative materials shall not be mixed with materials obtained from domestic blood donations.

Domestic blood derivative products shall conspicuously mark

the source of raw materials in the labeling, package and package inserts. The packing of the products made from foreign and domestic raw materials shall be distinctively different.

Article 5: In accordance with Article 10 of the Act, blood donation institutions shall, by the 31st day of July of each year, submit a blood collection plan for the next year to the central governing authority for file and reference.

Article 6: Blood derivative manufacturers and importers shall, in accordance with Article 11 of the Act, report to the central governing authority, for file and reference, in January and July of each year regarding the following matters:

1. **The estimated volume of blood derivatives to be manufactured or imported for the next six months (including the month of the report); and**
2. **The actual volume of blood derivatives being manufactured or imported for the past six months (excluding the month of the report).**

Article 7: The central governing authority shall, in accordance with Article 12 of the Act, announce its annual plan concerning the estimated demand of blood derivatives no later than the 31st day of December of the previous year.

The plan indicated in the preceding paragraph may be made for a period of one to three years.

Article 8: Blood donation institutions supplying the collected blood raw materials to blood derivative manufacturers shall, in accordance with Article 13 of the Act, petition for approval from the central governing authority by submitting a photocopy of the blood derivative manufacturers' pharmaceutical manufacturing permit and specifying the volume blood raw materials to be supplied. Any change thereto shall follow the same procedure.

Article 9: The Enforcement Rules shall take effect on the day the Act becomes effective.