The Plasma Derivatives Act

Article 1: This Act is legislated to enhance the safety and quality of plasma derivatives and assure a stable supply thereof in order to protect the public health. Matters not provided for under this Act shall be governed by the provisions of the Medical Care Act, the Pharmaceutical Affairs Act, and other relevant acts.

Article 2: For purposes of this Act, the term "competent authority" shall mean the Ministry of Health and Welfare at the central government level, the municipal governments at the municipal level, and the county/city governments at the county/city level.

Article 3: The term “plasma derivative” refers to a pharmaceutical product of a certain form of dosage prepared and processed from human plasma.

Article 4: The materials for plasma derivatives shall be obtained from domestic blood donations. However, in the event that the domestic supply of such materials should become insufficient, plasma derivative manufacturers may, subject to the approval of the central competent authority, import the materials from foreign countries.

Article 5: To meet the domestic demand and supply of plasma derivatives, the competent authority shall actively adopt educational and promotional measures to encourage local blood donation.

Article 6: To ensure the safety, quality, and stable supply of plasma derivatives, as well as to promote research and local industrial development, the central competent authority shall promulgate development programs for plasma derivatives.

Article 7: Blood donation institutions shall make efforts to promote blood donation, enhance the safety of the materials used for plasma derivatives, assist in ensuring a stable supply, and adopt

measures to protect the health of blood donors.

Article 8: Plasma derivative manufacturers shall meet the standards of Good Manufacturing Practices (GMP) and provide safe and good quality plasma derivatives.

Article 9: Medical institutions and physicians shall give preference to plasma derivatives made from blood donated domestically and provide patients with prescription information on such usage.

To respect patients' wishes in choosing the preparations to be used, the use of preparations manufactured by other materials, methods or genetic engineering is not restricted by the preceding paragraph.

Article 10: Blood donation institutions shall establish annual blood collection plans, which shall include the blood volume from donations and for therapeutic needs, the plasma volume for plasma derivatives manufacturing, and the blood drive activities. The aforementioned plans shall be submitted to the central competent authority for further reference.

Article 11: Plasma derivative manufacturers and importers shall periodically report their estimated and actual manufactured or imported quantity of plasma derivatives to the central competent authority for further reference.

Article 12: The central competent authority shall establish and announce annual plans regarding the estimated demand for plasma derivatives.

The aforementioned plan shall include the following items:

1. **Categories of plasma derivatives**
2. **Categories and the targeted volume of plasma derivatives to be manufactured and imported annually**
3. **Volume of blood materials needed for said targeted**

volume of plasma derivatives

4. **Quantity of interchangeable pharmaceutical products in lieu of plasma derivatives**
5. **Other matters related to the effective utilization of blood materials**

Article 13: Blood donation institutions may engage in the manufacturing of plasma derivatives with the blood materials collected, or with the approval of the central competent authority, supply such blood materials to other plasma derivative manufacturers.

Blood donation institutions may charge at cost for the aforementioned supply to the plasma derivative manufacturers. The amount of said charge shall be submitted to and approved by the central competent authority.

Article 14: Blood donation institutions shall implement health screening on blood donors before collecting their blood.
The standards for health requirements of blood donors and the items of the aforementioned health screening shall be respectively prescribed by the central competent authority.

Article 15: When necessary, blood donation institutions shall provide plasma derivative manufacturers with essential informations, including collection date, examination items and results, and donors' information, so as to prevent the health hazards caused by blood materials.

Article 16: Violation of Articles 10 and 11 shall be subject to an administrative fine of no less than twenty thousand and no more than one hundred thousand New Taiwan Dollars, imposed by the central competent authority together with an order to take corrective action within a prescribed time. Failure to resolve the issue by the prescribed time may be subject to further fines successively for each violation.

Article 17: Failure to comply with the administrative fines imposed under these Acts by the prescribed time shall result in compulsory enforcement [or injunctive relief] pursuant to the relevant laws.

Article 18: The enforcement rules [of this Act] shall be promulgated by the central competent authority.

Article 19: This Act shall take effect one year after the presidential announcement.