

## Summary of Act for Appropriate Provision of Hematopoietic Stem Cells to be Used in Transplantations

Basic principles are established and the responsibilities of the national government are clarified in relation to promotion of the appropriate provision of hematopoietic stem cells (bone marrow, peripheral blood stem cells, cord blood) for use in transplantation. An attempt is made to promote the appropriate provision of hematopoietic stem cells for use in transplantations and contribute to the smooth and appropriate implementation of hematopoietic stem cell transplantation by defining the matters that form the basis of measures to promote the appropriate provision of hematopoietic stem cells for use in transplantation and carrying out the necessary regulations and subsidies for entities that serve as intermediaries for the provision of bone marrow and peripheral blood stem cells and services that provide cord blood.

### **1. Basic principles**

- (1) Efforts shall be made to promote the provision of hematopoietic stem cells for use in transplantation, with the aim of ensuring sufficient opportunities of people who need hematopoietic stem cell transplantation to receive it.
- (2) Hematopoietic stem cells used in transplantations shall be provided voluntarily.
- (3) Consideration shall be given so that opportunities to receive hematopoietic stem cell transplantation are granted fairly.
- (4) The safety of hematopoietic stem cells used in transplantation shall be ensured.
- (5) Efforts shall be made to protect the health of people who provide bone marrow or peripheral blood stem cells for use in transplantation.
- (6) Efforts shall be made to ensure the quality of cord blood used in transplantations.

### **2. Responsibilities**

- (1) The national government shall formulate and implement measures and policies to promote the proper provision of hematopoietic stem cells used in transplantation.
- (2) Local public authorities shall formulate and implement measures and policies based on an appropriate division of roles with the national government.
- (3) Service provider related to the provision of hematopoietic stem cells (service

providers in Articles 5 and 6) and a support organization shall endeavor to actively contribute to promoting the appropriate provision of hematopoietic stem cells for use in transplantations.

- (4) Healthcare professionals shall endeavor to cooperate in the measures and policies adopted by national and local government authorities. In particular, healthcare professionals shall provide information necessary for the efforts in 4.3.
- (5) Persons in (1)–(4) shall endeavor to cooperate and maintain coordination with each other.

### **3. Basic policy**

The Minister of Health, Labour and Welfare shall establish and officially announce the basic policy to promote the appropriate provision of hematopoietic stem cells for transplantation.

### **4. Measures to promote the proper provision of hematopoietic stem cells used in transplantation**

- (1) National and local government authorities shall adopt necessary measures to deepen public understanding.
- (2) The national government shall adopt necessary measures so that information on the provision of hematopoietic stem cells for use in transplantation is provided in an integrated manner.
- (3) The national government shall take necessary measures to support efforts to monitor and analyze the health status of people who provide bone marrow and peripheral blood stem cells to be used in transplantations and people who will receive hematopoietic stem cells provided for use in transplantations.
- (4) The national government shall take necessary financial and other measures to ensure the stable operation of hematopoietic stem cell related businesses.
- (5) The national government shall take necessary measures to advance research and development that will contribute to promoting the appropriate provision of hematopoietic stem cells for use in transplantations.
- (6) The national government shall take necessary measures to promote international cooperation for the provision of hematopoietic stem cells used in transplantations.
- (7) The national government shall adopt necessary measures for the development of

healthcare delivery systems related to the collection of bone marrow and peripheral stem cells for use in transplantations.

#### **5. Intermediaries in the provision of bone marrow and peripheral blood stem cells**

##### **(bone marrow banks)**

- (1) A licensing system shall be made for intermediaries in the provision of bone marrow and peripheral blood stem cells (service providers that act as intermediaries in the provision of bone marrow or peripheral blood stem cells used in transplantation)
- (2) Licenses shall not be granted unless requirements are met, including that the service provider is not planning to conduct that business for the purpose of profit, and that necessary measures are adopted to ensure the safety of bone marrow and peripheral blood stem cells for use in transplantations and protect the health of donors.
- (3) Necessary measures must be adopted to ensure the safety of bone marrow and peripheral blood stem cells for use in transplantation.
- (4) Measures must be adopted to protect the health of donors.
- (5) Appropriate explanations shall be given to people who are considering donations, and their consent obtained.
- (6) The national government may provide partial subsidies for the expenses necessary for intermediary agencies in the provision of bone marrow and peripheral blood stem cells
- (7) Stipulations for confidentiality, supervision, support, etc., shall be established.

#### **6. Umbilical cord blood supply business (cord blood bank)**

- (1) A licensing system shall be made for the umbilical cord blood supply business (activities including collection, preparation, storage, testing, and delivery of umbilical cord blood used in transplantations. Private cord blood banks are excluded).
- (2) Licenses shall not be granted unless requirements are met, including that the service provider is not planning to conduct that business for the purpose of profit, and that the cord blood supply activities will be performed in a manner that conforms to the standards in (3).
- (3) In conducting a cord blood supply business, there must be strict compliance with the standards specified in Ministry of Health, Labour and Welfare ordinances for

matters necessary to ensure safety of cord blood used in transplantations, in relation to how the cord blood supply activities are performed.

- (4) Appropriate explanations shall be given to pregnant women who are considering donations, and their consent obtained.
- (5) Information on cord blood used in transplantations must be provided to the support organization in No. 7.
- (6) To the extent that it does not hinder execution of cord blood supply activities, cord blood collected for use in transplantation may be used by the collector or provided to others for research, in accordance with the standards specified in Ministry of Health, Labour and Welfare ordinances.
- (7) The national government may provide partial subsidies for the expenses necessary for cord blood supply businesses.
- (8) Stipulations for confidentiality, supervision, support, etc., shall be established.

#### **7. Hematopoietic stem cell provision support organization (assuming the Japanese Red Cross Society)**

- (1) The Minister of Health, Labour and Welfare may designate a legal person, etc., whose purpose is not profit and who is recognized to have the ability to perform the support activities in (2) in a proper and reliable manner, upon application therefrom, as a hematopoietic stem cell provision support organization (hereinafter, “Support Organization”), limited to one throughout the country.
- (2) The Support Organization shall: 1) register donors for bone marrow and peripheral blood stem cells, and cooperate with other service providers involved in the provision of hematopoietic stem cells, (2) liaise and coordinate among entities involved in hematopoietic stem cell provision, 3) provide unified management and supply of information related to hematopoietic stem cells used in transplantation, and 4) disseminate information and raise awareness of providing hematopoietic stem cells for use in transplantation.
- (3) The national government may provide partial subsidies for the expenses necessary for the support organization in (2).
- (4) Confidentiality and supervision shall be stipulated.

#### **8. Other**

Penalties, dates of enforcement (within one year and six months from date of promulgation), interim measures, conditions under consideration, and other necessary matters shall be stipulated.