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SAFETY AND MANAGEMENT OF HUMAN TISSUE ACT

[Enforcement Date 23. Jan, 2024.] [Act No.20107, 23. Jan, 2024., Partial Amendment]

식품의약품안전처 (바이오의약품정책과)043-719-3304



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CHAPTER I GENERAL PROVISIONS

Article 1 (Purpose) The purpose of this Act is to provide for matters necessary for donation, management, and transplant of human tissue for the physical completion and recovery of biological functions, thereby promoting the balanced supply and safety of human tissue, and contributing to the improvement of public health.

Article 2 (Basic Ideology) (1) Donation, management, and transplant of human tissue shall be carried out in a humanitarian spirit.
(2) Expression of intention regarding donation of human tissue of a person shall be respected. In such cases, such intention shall be voluntary.
(3) A person needing a transplant of human tissue shall have an equal opportunity to receive transplant regardless of social or economic conditions.
(4) Donation, management, and transplant of human issue shall be conducted in an ethically reasonable and medically accepted manner.

Article 3 (Definitions) The terms used in this Act are defined as follows: <Amended on Jan. 27, 2005; Feb. 29, 2008; Jan. 18, 2010; Jan. 28, 2014; Feb. 4, 2016; Dec. 11, 2018>

1. The term "human tissue" means any of the following (hereinafter referred to as "tissue"), which is not an organ, etc. defined in subparagraph 1 of Article 4 of the Organs Transplant Act:
 - (a) Bones, cartilage, fasciae, skin, amnia, ligaments, and tendons;
 - (b) Heart valves and blood vessel;
 - (c) Body parts determined by Presidential Decree, which are recoverable and transplantable for a person's health, physical recovery, and prevention of disability;
2. The term "tissue donor" means a person who donates specific tissues for another person's functional recovery without compensation, and is registered as a tissue donor pursuant to Article 7-2 (1);

- 2-2. The term "candidate for tissue donation" means a person who has an intention to donate tissues at the time of death in the future, and is registered as a candidate for tissue donation pursuant to Article 7-2 (1);
- 2-3. The term "potential tissue donor" means a deceased person whose survivor requested the provision of information and consultation from tissue donation support institutions prescribed in Article 16-2 (hereinafter referred to as "tissue donation support institutions") and medical institutions defined in Article 3 of the Medical Service Act (hereinafter referred to as "medical institutions") and a person, among potential brain dead organ donor reported to organ procurement organizations prescribed in Article 20 of the Organs Transplant Act (hereinafter referred to as "organ procurement organizations"), who was connected to tissue donation support institutions after his or her family member requested the provision of information and consultation regarding tissue donation;
3. The term "tissue transplant" means transplantation of tissue donated from a tissue donor, the safety of which is guaranteed for the purpose of treatment of illness of a patient;
4. The term "tissue bank" means an institution authorized under Article 13 (1) for the management of tissue for the purpose of transplantation;
5. The term "tissue management" means recovery, storage, processing, preservation, and allocation of tissue;
6. Article 4 of the Organs Transplant Act shall apply mutatis mutandis to the definitions of the terms "living person", "brain-dead person", "family member", or "survivor".

Article 4 (Scope of Application) This Act shall apply to tissues obtained from a living, brain-dead, or deceased person with respect to donation, management, or transplantation, which are produced in the Republic of Korea or imported from abroad, for the purposes of physical completion and recovery of biological functions: Provided, That any of the following shall be excluded: <Amended on Apr. 7, 2011>

1. Tissue for self-transplantation;
2. Types of items or items governed by the Pharmaceutical Affairs Act, the Medical Devices Act, and other statutes.

Article 5 (Prohibition of Purchase or Sale of Tissue) (1) No one shall do or promise to do any of the following acts in exchange for money, financial gain, or other consideration:

1. Giving tissue of a brain-dead person or a deceased person to a third person, receiving such tissue to give it to a third person, or promising to do either act;
 2. Giving one's own tissue to another person, receiving tissue from another to transplant into one's own body, or promising to do either act;
 3. Assisting another to do any act under subparagraph 1 or 2.
- (2) No person aware of a violation of paragraph (1) shall manage or transplant any tissue relating to such violation.

Article 5-2 (Responsibilities of the State) The State and local governments shall provide every person needing tissue transplantation with an equal opportunity for transplantation, and have the donation, management, transplantation, etc. of tissues performed appropriately.
[This Article Newly Inserted on Jan. 28, 2014]

Article 6 (Human Tissue Safety and Management Advisory Committee) (1) A Human Tissue Safety and Management Advisory Committee (hereinafter referred to as the "Committee") shall be established within the Ministry of Health and Welfare to deliberate on the following matters, upon request for advice from the Minister of Health and Welfare and the Minister of Food and Drug Safety in connection with the donation, management, transplantation, etc. of tissues: <Amended on Feb. 29, 2008; Jan. 18, 2010; Jan. 28, 2014; Feb. 4, 2016>

1. Matters concerning the formulation of a basic policy on the donation, management, transplantation, etc. of tissues;
2. Matters concerning permission standards for tissue banks and operation thereof;
3. Matters concerning the operation of public tissue banks pursuant to Article 16-3 (hereinafter referred to as "public tissue bank") and the appropriation of tissue distribution;
4. Matters concerning plans for the management of imported tissues;
5. Matters concerning the review of the quality, testing or management of tissues (hereinafter referred to as "quality control");
6. Other matters submitted by the Minister of Health and Welfare for discussion in connection with the inspection, research, etc. of donation, management, and transplantation of tissues.

(2) The Committee shall be comprised of not more than 15 members, including one chairperson and one vice chairperson; the chairperson and the vice chairperson shall be

elected by mutual vote among members; and members shall consist of the following persons. In such cases, members who are not public officials shall constitute a majority of the entire membership: <Newly Inserted on Dec. 11, 2018>

1. A person designated by the head of his or her affiliated institution from among public officials in Grade III or equivalent Grade or members of the Senior Executive Service who are engaged in the work of donating, managing, and transplanting tissues in the Ministry of Health and Welfare or the Ministry of Food and Drug Safety;
 2. A person designated by the Minister of Health and Welfare from among persons who have broad knowledge and experience on donation, management and transplant of tissues.
- (3) The term of office of a member under paragraph (2) 2 shall be two years. <Newly Inserted on Dec. 11, 2018>
- (4) Other matters necessary for organization and operation of the Committee shall be prescribed by Presidential Decree. <Amended on Dec. 11, 2018>

Article 6-2 (National Tissue Donation Management Agency) (1) The Minister of Health and Welfare shall establish a tissue donation management agency (hereinafter referred to as the "National Tissue Donation Management Agency") to appropriately manage matters concerning tissue donation, however, he or she shall have the National Organ Transplant Management Agency under Article 10 of the Organs Transplant Act perform such duties.

(2) The National Tissue Donation Management Agency shall perform the following duties: <Amended on Feb. 4, 2016>

1. Registration and management of tissue donors and candidates for tissue donation;
2. Guidance and supervision of the tissue donor registries prescribed in Article 7-3 (hereinafter referred to as "registry"), tissue donation support institutions and public tissue bank;
3. Management of distribution of tissues under Article 12;
4. Inspection and study of tissue donation and gathering information thereon and preparation of statistics thereon;
5. Other duties prescribed by Presidential Decree concerning tissue donation.

[This Article Newly Inserted on Jan. 28, 2014]

CHAPTER II MANAGEMENT OF TISSUE

Article 7 (Consent to Donate Tissues) (1) Article 12 of the Organs Transplant Act shall apply mutatis mutandis to consent to tissue donation. <Amended on Jan. 28, 2014>

(2) Consent under paragraph (1) shall include the following matters: <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 18, 2014>

1. The period for preservation of tissues and other matters concerning such preservation;
2. Matters concerning the rights of the person who consents to donation, such as withdrawal of consent, and confidentiality of information;
3. Matters concerning the inspection of blood, medical history and record of administered medicines, etc. to determine the suitability for distribution and transplantation of tissues;
4. Other matters prescribed by the Ordinance of the Ministry of Health and Welfare.

(3) When consent under paragraph (1) is obtained, a person who intends to recover tissue shall fully explain the matters under paragraph (2) in advance.

(4) Matters necessary for consent forms, preservation of tissue, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended on Feb. 29, 2008; Jan. 18, 2010>

Article 7-2 (Registration of Tissue Donors) (1) A person intending to be a tissue donor or candidate for tissue donation shall file an application for registration with a registry as prescribed by Ordinance of the Ministry of Health and Welfare: Provided, That where the tissue donor is brain dead or deceased, a person from among his or her family members or survivors may file an application for registration.

(2) Articles 14 and 15 of the Organs Transplant Act shall apply mutatis mutandis to a decision on whether to register tissue donors or candidates for tissue donation, to the notification of the decision to such persons, and to the withdrawal, cancellation, etc. of registration.

[This Article Newly Inserted on Jan. 28, 2014]

Article 7-3 (Designation of Tissue Donation Registry) (1) An entity intending to perform the duties of registration of tissue donors and candidates for tissue donation shall obtain designation of a tissue donation registry from the Minister of Health and Welfare after being equipped with facilities, human resources, etc. prescribed by Presidential Decree. The

same shall apply to the modification of significant matters prescribed by Ordinance of the Ministry of Health and Welfare among the matters designated.

(2) Entities eligible for designation as a registry are as follows: <Amended on Feb. 4, 2016>

1. The State or local governments;
2. Medical institutions;
3. Nonprofit corporations established with the purpose of carrying on tissue donation and transplantation business;
4. Public institutions defined in Article 4 of the Act on the Management of Public Institutions.

(3) The duties of a registry shall be as follows:

1. Receipt and registration of tissue donors and notification of the result thereof to the National Tissue Donation Management Agency and the Minister of Food and Drug Safety;
2. Receipt and registration of candidates for tissue donation and notification of the result thereof to the National Tissue Donation Management Agency;
3. Management of personal information on tissue donors and candidates for tissue donation and provision of information related to donation;
4. Publicity and consultation with regard to tissue donation;
5. Other duties prescribed by Ordinance of the Ministry of Health and Welfare concerning registration of tissue donors and candidates for tissue donation.

(4) Notwithstanding paragraph (1), any of the following persons may perform the duties of a registry without taking any procedures for designation:

1. An entity designated as an organ transplantation registry pursuant to Article 13 of the Organs Transplant Act;
2. An entity authorized as a tissue bank pursuant to Article 13 (2) 1 and 2;
3. An entity designated as a tissue donation support institution.

(5) Other matters necessary for procedures for designation of registries, operation thereof, etc. shall be prescribed by Ordinance of the Ministry of Health and Welfare.

[This Article Newly Inserted on Jan. 28, 2014]

Article 8 (Requirements for Recovery of Tissues) (1) Tissues may be recovered from a brain-dead or deceased person, only in the following cases: <Amended on Jan. 28, 2014>

1. Where the relevant person consents to the recovery of tissues before he or she becomes brain dead or is deceased: Provided, That cases in which his or her family members or survivors explicitly state objection to the recovery of tissues, etc. shall be excluded;
2. Where it is unclear whether the relevant person consented or objected to the recovery of tissues before he or she becomes brain dead or is deceased, but his or her family members or survivors consent to the recovery of tissues: Provided, That this shall be limited to cases in which his or her parents consent to the recovery of tissues where the person concerned is a minor under 16 years of age.
- (2) Where tissue is recovered from a living person, the persons' consent is required: Provided, That where tissue is recovered from a minor, the parent's consent is required in addition to the persons' consent.
- (3) A person who consents to recovery under paragraphs (1) or (2) may withdraw his or her consent to recovery anytime before the onset of tissue recovery surgery.

Article 9 (Prohibition of Distribution or Transplantation of Tissues) None of the following tissue shall be distributed or transplanted: <Amended on Jan. 27, 2005; Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Mar. 18, 2014>

1. Tissues infected or suspected of being infected with any contagious disease making it unsuitable for transplant, such as hepatitis B or C, syphilis, acquired immunodeficiency syndrome, etc.;
2. Tissues from a donor having a degenerative neurological disease, such as Alzheimer's disease, etc.;
3. Tissues from a donor with uncertain cause of death;
4. Tissues from a donor exposed to any hazardous substance;
5. Tissues from a donor whose cancer may have spread to and affected such tissues;
6. Tissues in violation of Article 8 (1) and (2), 13 (1) or 17 (1);
7. Tissues corresponding to those under subparagraphs 1 through 6, which are deemed unsuitable for transplantation as they are likely to cause harm to the life or body of a transplant recipient as prescribed by Ordinance of the Prime Minister.

Article 10 (Securing Safety of Tissues) (1) A tissue bank shall examine the availability of the tissue recovered and processed directly in Korea or the tissue imported from outside Korea for transplantation before distributing such tissue to another tissue bank or a medical institution performing tissue transplantation (hereinafter referred to as "tissue transplant

hospital"), as prescribed by Ordinance of the Prime Minister. In such cases, if the tissue bank finds a tissue to be unavailable for distribution or transplantation, it shall destroy the tissue, as prescribed by Ordinance of the Prime Minister, and report the fact to the Minister of Food and Drug Safety. <Amended on Dec. 11, 2018>

(2) A tissue bank that intends to recover tissue shall inquire of the tissue donor or his or her survivor about his or her medical history and record of administered medicines. <Newly Inserted on Dec. 11, 2018>

(3) A tissue bank that intends to recover tissue shall request the Health Insurance Review and Assessment Service under the National Health Insurance Act (hereinafter referred to as "Review and Assessment Service") to inspect the medical history and record of administered medicines of a tissue donor. In such cases, the Review and Assessment Service shall comply with such request, without good cause, and notify the tissue bank of the result. <Newly Inserted on Mar. 18, 2014; Dec. 11, 2018>

(4) Notwithstanding paragraph (3), upon receipt of results of inspection from a tissue donation support institution pursuant to Article 16-2 (7), the tissue bank need not request the inspection of medical history and records of administered medicines from the Review and Assessment Service. <Newly Inserted on Mar. 18, 2014; Dec. 11, 2018>

(5) Upon inquiry under paragraph (2) or upon receipt of notice under paragraph (3) or (4), the tissue bank shall inspect whether a tissue falls under any of the subparagraphs of Article 9, and if the tissue bank finds the tissue to be unavailable for distribution or transplantation, it shall destroy such tissue as prescribed by Ordinance of the Prime Minister and report the fact to the Minister of Food and Drug Safety. <Newly Inserted on Mar. 18, 2014; Dec. 11, 2018>

(6) Notwithstanding the latter part of paragraph (1) and paragraph (5), a tissue bank may directly use a tissue unavailable for distribution and transplantation or supply it to another tissue bank that seeks to use it without destroying it, if it falls under any of the following. In such cases, the tissue bank shall report to the Minister of Food and Drug Safety the use and demand-supply status of the tissue, such as its use and quantity and the name of the tissue bank that uses or is supplied with it, as prescribed by Ordinance of the Prime Minister: <Newly Inserted on Dec. 11, 2018>

1. Where it is used for medical research for a person's health, physical recovery, and prevention of disability;

2. Where it is used for evaluation, verification and management of the quality level of tissue.

(7) Matters necessary for the criteria for determining whether a tissue is available for transplantation under paragraph (1), the methods and procedures for inspection under paragraphs (2) through (5), and the methods and procedures for report under paragraph (6) shall be prescribed by Ordinance of the Prime Minister. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Mar. 18, 2014; Dec. 11, 2018>

Article 11 (Quality Control of Tissue Banks) (1) The Minister of Food and Drug Safety may order a tissue bank to be subject to quality control and may disclose the results thereof. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>

(2) The procedures for quality control under paragraph (1), disclosure of the results of quality control, and other matters necessary for quality control shall be prescribed by Ordinance of the Prime Minister. <Amended on Jan. 18, 2010; Mar. 23, 2013>

Article 12 (Priority Order for Distributing Tissues) Where a tissue bank that recovered tissues from tissue donors distributes tissues to other tissue banks or tissue transplant hospitals, such tissue bank shall apply the priority order for distribution prescribed by Presidential Decree in consideration of the urgency and expected effect of tissue transplantation in the medical respect. <Amended on Jan. 28, 2014; Dec. 11, 2018>
[Title Amended on Jan. 28, 2014]

Article 13 (Permission for Tissue Banks) (1) A person who intends to establish a tissue bank shall have the facilities, equipment, human resources, quality control system, etc. prescribed by Presidential Decree and obtain permission from the Minister of Food and Drug Safety. The same shall apply to the modification of significant matters prescribed by Ordinance of the Prime Minister, among permitted matters. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014>

(2) Any of the following persons may obtain permission for a tissue bank: Provided, That no person falling under subparagraph 3 or 4 shall engage in tissue donation or tissue recovery: <Amended on Feb. 4, 2016>

1. Medical institutions;

2. Non-profit corporations, the main purpose of which is to engage in business related to human tissue;

3. Tissue processing business operators;

4. Tissue importers.

(3) Tissue banks shall engage in the following activities: <Amended on Dec. 11, 2018>

1. Recovery, storage, processing, import, preservation and distribution of tissue;

2. Management of tissue donors, and public relations and consultation for tissue donation;

3. Selection of tissue donors and tissue quality assurance;

4. Other matters prescribed by Presidential Decree, which are necessary for ensuring safety of tissue transplants.

Article 13-2 (Medical Managers) (1) The head of a tissue bank shall appoint at least one medical manager in each tissue bank, who performs the duties of examining the medical history of tissue donors, diagnosing whether tissues are infected, recovering tissues, etc. (hereinafter referred to as "medical management duties"), and has a doctor's or dentist's license.

(2) In performing medical management duties, the medical managers under paragraph (1) shall comply with the following matters:

1. To approve the distribution of only appropriate tissues after judging whether tissues are to be prohibited from distribution or transplantation as prescribed in Article 9;

2. To recover tissues from a deceased person in circumstances in which tissues are safe in consideration of the condition of recovery, etc.;

3. Other matters prescribed by Ordinance of the Prime Minister.

(3) A medical manager under paragraph (1) may concurrently work as a doctor, etc. in a medical institution, etc.: Provided, That where a medical manager of a tissue bank falling under Article 13 (2) 1 or 2 intends to hold an additional position, the location of a tissue bank and that of a medical institution, etc. shall be in the same place.

(4) The head of a tissue bank shall not interfere with any medical management duty; and where a medical manager makes a request necessary for performing duties, the head of the tissue bank shall not refuse the request without good cause.

[This Article Newly Inserted on Mar. 18, 2014]

Article 13-3 (Succession to Status) (1) Where a person granted permission under Article 13 dies or transfers his or her business or where an incorporated tissue bank is merged, the successor, the transferee of the business, or the legal entity surviving such merger or the

legal entity established in consequence of such merger (hereinafter referred to as "transferee, etc.") shall succeed to the status of the person granted permission. In such cases, the transferee, etc. shall fall under any of the subparagraphs of Article 13 (2).

(2) Anyone who succeeds to the status of a person granted permission under paragraph (1) shall report such fact to the Minister of Food and Drug Safety within one month, as prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted on Dec. 11, 2018]

Article 13-4 (Succession to Effect of Disposition of Administrative Sanctions) Where the status is succeeded to under Article 13-3, the effect of a disposition of administrative sanctions imposed on the former person granted permission shall devolve on the transferee, etc. for one year from the date of such disposition, and where the formalities for disposition of administrative sanctions are proceeding, such formalities may continue for the transferee, etc.: Provided, That the foregoing shall not apply where the transferee, etc. does not know of such disposition or offense at the time of succeeding to his or her status.

[This Article Newly Inserted on Dec. 11, 2018]

Article 14 (Validity Period of Permission for Tissue Banks) (1) The period of validity of permission for a tissue bank under Article 13 shall be three years from the date the permission is granted. <Amended on Dec. 11, 2018>

(2) A person who intends to continue operation of a tissue bank after the period of validity under paragraph (1) expires shall obtain permission for renewal from the Minister of Food and Drug Safety. <Amended on Dec. 11, 2018>

(3) Where a tissue bank has no track record of recovering, storing, processing, importing, preserving or distributing tissues for three years before renewal of permission, the Minister of Food and Drug Safety need not grant permission for renewal. <Newly Inserted on Dec. 11, 2018>

(4) The Minister of Food and Drug Safety shall give notice to an applicant of whether or not to grant permission for renewal, within the period prescribed by Ordinance of the Prime Minister from the date of receipt of a renewal permission application under paragraph (2). <Newly Inserted on Dec. 11, 2018>

(5) Where the Minister of Food and Drug Safety fails to give notice to an applicant of whether or not to grant permission for renewal or to extend the processing period thereof

under statutes and regulations related to civil petitions handling, within a period specified under paragraph (4), the permission for renewal shall be deemed to be granted on the day following the end of the period (referring to the extended or re-extended period if the processing period is extended or re-extended under the statutes and regulations related to civil petitions handling). <Newly Inserted on Dec. 11, 2018>

(6) Matter necessary for the criteria and procedures for permission for renewal under paragraphs (2) through (5) shall be prescribed by Presidential Decree. <Amended on Mar. 18, 2014; Dec. 11, 2018>

[Title Amended on Dec. 11, 2018]

Article 15 (Matters to Be Observed by Tissue Banks) (1) The head of a tissue bank shall

observe matters prescribed by Ordinance of the Prime Minister for the safety of tissues, such as tissue management, quality assurance, etc. <Amended on Mar. 18, 2014>

(2) Where a tissue bank performs duties in cooperation with other tissue banks, their cooperative relationship and contractual relationship shall be clarified: Provided, That where it recovers tissues, it may use the facilities of other tissue banks or medical institutions, as prescribed by Ordinance of the Prime Minister. <Amended on Jan. 28, 2014>

(3) Where a tissue bank provides another tissue bank or tissue transplant hospital with tissues necessary for surgery, it shall follow non-profit principles: Provided, That the tissue bank may request that the other tissue bank or tissue transplant hospital reimburse the following expenses as prescribed by Ordinance of the Ministry of Health and Welfare: <Amended on Feb. 29, 2008; Jan. 18, 2010; Jan. 28, 2014>

1. Expenses incurred in donation, management, transplantation, etc.;
2. Expenses needed where tissues are not produced by the tissue bank which is a noncommercial corporation or medical institution.

(4) Medical personnel who handle tissue, and other workers prescribed by Ordinance of the Prime Minister, both of whom are employed by a tissue bank shall receive the required training prescribed by Ordinance of the Prime Minister. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>

(5) The head of a tissue bank shall have the personnel of the tissue bank who are to undergo education pursuant to paragraph (4), undergo education. <Newly Inserted on Mar. 18, 2014>

(6) Procedures for providing tissues, the scale of tissues to be stored, chief manager, report on the present condition of management and other necessary matters, shall be prescribed by Ordinance of the Prime Minister. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Mar. 18, 2014>

(7) The head of a tissue bank shall seal the final containers or packages of tissues, the processing of which is completed so that transplantation is possible, as prescribed by Ordinance of the Prime Minister, and he or she shall not distribute tissues after opening the sealed containers or packages, or repacking them. <Newly Inserted on Mar. 18, 2014>

Article 15-2 (Mark of Tissues and Matters to Be Indicated) The head of a tissue bank shall enter the following matters on the containers or packages of tissues: Provided, That he or she may enter part of the following matters on certain containers or packages as prescribed by Ordinance of the Prime Minister:

1. Name and location of the tissue bank (including the producer of the exporting country in cases of imported tissues);
2. Names and detailed descriptions of tissues;
3. Production numbers of tissues and use-by date;
4. Size, weight and measurement of tissues;
5. Methods of storing tissues;
6. Letters indicating "human tissues";
7. Other matters prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted on Mar. 18, 2014]

Article 15-3 (Matters to Be Entered on Accompanying Documents) The head of a tissue bank shall enter the following matters and attach them on the containers or packages of tissues: Provided, That where he or she distributes tissues to a medical institution affiliated with the tissue bank, such matters may be omitted:

1. Methods of storing and using tissues;
2. Name of country in which tissues were recovered;
3. Results of inspection of tissue donors;
4. Matters concerning restriction on the hours of use after opening packages;
5. Matters that separately packed tissues shall be used for only one patient;

6. Other matters prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted on Mar. 18, 2014]

Article 15-4 (Caution in Indication) (1) Matters prescribed in Articles 15-2 and 15-3 shall be recorded in Korean letters on the part where such are more readily visible than other letters, news items, pictures or designs, as prescribed by Ordinance of the Prime Minister and, if necessary, Chinese letters, etc. may be recorded side by side with the Korean letters. (2) The head of a tissue bank shall not record the following matters on containers, packages or attached documents:

1. False information about tissues or matters that are likely to be misunderstood;
2. Matters with a purport that government agencies or specific organizations recognize officially, recommend, guide, or use the tissues, or illegally indicating foreign trade marks, trade names, etc.

[This Article Newly Inserted on Mar. 18, 2014]

Article 16 (Matters to Be Observed in Recovering Tissues) (1) A tissue bank intending to recover tissues shall observe the following matters: <Amended on Mar. 18, 2014>

1. A tissue bank shall confirm consent under Articles 7 and 8 (1) and (2);
2. A tissue bank shall fully explain the following matters to donors or persons authorized to give consent:
 - (a) Matters concerning the blood test, inspection of medical history, and records of administered medicines of tissue donors;
 - (b) Details of surgical extraction of tissues;
 - (c) Advance explanation of funeral procedures after tissue donation;
 - (d) Other matters a person must be made aware of before tissue donation.

(2) The details of the procedures, matters to be explained and other necessary matters, which shall be complied with when explaining under paragraph (1) to donors and persons authorized to give consent, shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended on Feb. 29, 2008; Jan. 18, 2010>

Article 16-2 (Tissue Donation Support Institutions) (1) To support the stable supply of and demand for tissues, the Minister of Health and Welfare may designate tissue donation support institutions performing the following duties: <Amended on Feb. 4, 2016>

1. Management of potential tissue donors and discovery of tissue donor candidates in cooperation with other relevant institutions, such as tissue banks, medical institutions, organ procurement organizations, etc.;
2. Perusal of medical records to determine the availability for tissue donation by potential tissue donors (in such cases, the perusal shall be made by medical persons defined in Article 2 of the Medical Service Act);
3. Management of and support for tissue donors and their survivors;
4. Inspection, research and education concerning tissue donation;
5. Other duties prescribed by Ordinance of the Ministry of Health and Welfare for encouraging tissue donation.

(2) Entities qualified as a tissue donation support institution are as listed hereunder:

1. Medical institutions;
2. Non-profit corporations established with the main purpose of business related to tissue donation and transplant.

(3) Where an entity designated as a tissue donation support institution intends to modify the designation matters prescribed by Ordinance of the Ministry of Health and Welfare, it shall report such fact to the Minister of Health and Welfare.

(4) Entities intending to be designated as a tissue donation support institution shall have the facilities, human resources, etc. prescribed by Presidential Decree.

(5) A tissue donation support institution may request the Review and Assessment Service to inspect the medical history and record of administered medicines. In such cases, the Review and Assessment Service shall comply with the request without good cause, and notify the results thereof. <Newly Inserted on Mar. 18, 2014>

(6) A tissue donation support institution in receipt of notification under paragraph (5) may verify whether tissues fall under any subparagraph of Article 9. Where a donor's tissues are unavailable for distribution and transplant, it shall notify the relevant person, or family members or survivors thereof. <Newly Inserted on Mar. 18, 2014>

(7) Where a tissue donation support institution transfers tissue donors to a tissue bank, it shall notify the tissue bank of the result of verification under paragraph (6). <Newly Inserted on Mar. 18, 2014; Dec. 11, 2018>

(8) Article 10 (7) shall apply mutatis mutandis to matters necessary for the methods of inspection, procedures, etc. under paragraphs (5) through (7). <Newly Inserted on Mar. 18,

2014; Dec. 11, 2018>

(9) Where the family member or survivor of a potential tissue donor requests the provision of information and consultation regarding tissue donation, the head of a medical institution shall promptly inform the head of a tissue donation support institution of the fact. <Newly Inserted on Feb. 4, 2016>

(10) If necessary for the provision of information and consultation regarding tissue donation, the head of a tissue donation support institutions may request the head of an organ procurement organization to provide information on the name, gender, the date of birth of a potential brain-dead organ donor and persons who are subject to determination of brain death and the name of medical institutions where they are hospitalized. In such cases, the head of the organ procurement organization shall provide such information. <Amended on Feb. 4, 2016>

(11) Matters necessary for procedures for designation, and the management, etc. of tissue donation support institutions, shall be prescribed by Ordinance of the Ministry of Health and Welfare. <Amended on Mar. 18, 2014; Feb. 4, 2016>

[This Article Newly Inserted on Jan. 28, 2014]

- Article 16-3 (Public Tissue Bank)** (1) The Minister of Health and Welfare shall designate and operate a public tissue bank to conduct the management of tissues including recovery, processing and distribution, etc. of tissues found in tissue donation support institutions under the principle of public interest and nonprofit.
- (2) A person qualified to be designated as a public tissue bank is the tissue bank falling under Article 13 (2) 1 and 2.
- (3) No public tissue bank shall conduct the business of tissue donation of the dead and the brain-dead.
- (4) The head of the public tissue bank shall operate the public tissue bank transparently according to the finance and accounting standards prescribed by Ordinance of the Ministry of Health and Welfare.
- (5) The head of a public tissue bank shall report the status of tissue management to the head of the National Tissue Donation Management Agency and the Committee shall deliberate on the suitability of tissue distribution of the public tissue bank regularly.
- (6) Matters necessary for the designation procedure, matters to be observed and operation, etc. of the public tissue bank shall be prescribed by Ordinance of the Ministry of

Health and Welfare.

[This Article Newly Inserted on Feb. 4, 2016]

Article 17 (Import of Tissues) (1) No one, other than tissue banks, may import tissue.

(2) The head of a tissue bank intending to import tissues shall obtain approval for each tissue from the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. The same shall apply to the modification of approved matters. <Amended on Jan. 28, 2014>

(3) To ensure the safety of tissues imported from foreign countries, etc., the Minister of Food and Drug Safety may inspect the status of producers of exporting countries, such as institutions, corporations, organizations, etc. that handled relevant tissues. In such cases, the Minister of Food and Drug Safety may suspend import of the tissues of an exporting country's producer as prescribed by Ordinance of the Prime Minister, if the producer refuses such inspection without good cause or if, as a result of such inspection, a tissue imported is found to be likely to cause harm. <Newly Inserted on Jan. 28, 2014; Dec. 11, 2018>

(4) The head of a tissue bank that imports tissues shall prepare and preserve a management record in which items for each imported tissue prescribed by Ordinance of the Prime Minister are included. <Newly Inserted on Jan. 28, 2014>

Article 17-2 (Registration of Producers of Exporting Countries) (1) Where the head of a tissue bank intends to import any tissue approved under the former part of Article 17 (2), he or she shall register the exporting country's producer of the tissue with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.

(2) Where the head of a tissue bank intends to modify any of the matters registered under paragraph (1), he or she shall register such modification with the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister.

(3) Except as provided in paragraphs (1) and (2), matters necessary for the procedures and methods for registration and registration of modification shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted on Dec. 11, 2018]

Article 18 (Priority of Autopsy or Postmortem Examination) No recovery of tissue shall be performed before autopsy or postmortem examination where an autopsy or postmortem

examination is required under the Criminal Act or the Quarantine Act: Provided, that tissue recovery may be performed with approval from the prosecutor of a competent District Prosecutors' Office or its branch office or the director of a competent quarantine station and with consent of the surviving family members, where a medical personnel charged with medical care determines that there is no correlation between the tissue to be recovered and the cause of death and that, if recovery is delayed until after autopsy or postmortem examination, the effective time for tissue recovery may be exceeded.

- Article 19 (Preparing and Reporting of Records)** (1) A tissue bank shall keep records of data relating to the donation, management, and transplantation of tissue and report such data to the Minister of Food and Drug Safety annually, as prescribed by Ordinance of the Prime Minister. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>
- (2) A tissue transplant hospital shall notify tissue banks of the results of transplant, as prescribed by Ordinance of the Prime Minister. The tissue bank so notified shall include such notice in its report submitted under paragraph (1). <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>
- (3) Tissue banks and tissue transplant hospitals shall conduct follow-up inspection, from distribution through to transplantation, for each tissue as prescribed by Ordinance of the Prime Minister, and make a report on the findings, side effects, etc. to the Minister of Food and Drug Safety. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Mar. 18, 2014>

Article 20 (Maintenance of Records) The head of a tissue bank or tissue transplant hospital shall maintain the records relating to donation, management and transplantation of tissue for ten years, as prescribed by the Minister of Health and Welfare. <Amended on Feb. 29, 2008; Jan. 18, 2010>

Article 21 (Perusal of Records) Where a donor or a donor's surviving family member demands perusal of, or issuance of copies of, the records relating to recovery or transplant of relevant tissue, the head of the relevant tissue bank shall allow perusal or issue copies of the records of overall process of tissue donation or the records relating to transplant: Provided, That when a medical personnel making diagnosis determines that such act might seriously interfere with the treatment or recovery of a tissue donor or a tissue recipient, such medical personnel may refuse to allow perusal or issuance of copies of the records.

Article 22 (Confidentiality) (1) Unless otherwise expressly prescribed by this Act, registries, tissue donation support institutions, tissue banks, tissue transplant hospitals or persons prescribed by Presidential Decree who are engaged in the duties related to the donation, management, or transplantation of tissues shall not divulge any of the following matters to persons other than those who are engaged in the duties related to the recovery and transplantation of tissues of the relevant tissue donors: <Amended on Jan. 28, 2014; Mar. 18, 2014; Feb. 4, 2016>

1. Matters regarding tissue donors and recovered tissues, matters regarding the result of investigating medical history or records of administered medicines of tissue donors, matters regarding the medical records of tissue donors and potential tissue donors, and matters regarding potential brain-dead person and persons who are subjects of determination of brain death connected from tissue donation support institutions;
2. Matters concerning transplant recipients and transplanted tissues;
3. Matters concerning persons who wish to donate tissues.

(2) Paragraph (1) shall not apply where any of the following is applicable: <Amended on Jan. 28, 2014>

1. Where a criminal investigative agency requests data relating to recovery or transplantation of tissues;
2. Where a judge requests, in connection with a trial, any data relating to recovery or transplantation of tissues;
3. Where a request is made with the purpose of donation of organs, etc. pursuant to the Organs Transplant Act.

CHAPTER III SUPERVISION

Article 23 (Reporting and Inspection) (1) The Minister of Health and Welfare, the Minister of Food and Drug Safety or the head of the National Tissue Donation Management Agency may issue necessary orders to the head of a registry, tissue donation support institution, tissue bank or tissue transplant hospital or its employee in regard to his or her duties, or may order reporting or submission of relevant documents, if deemed necessary in relation to donation, management, or transplantation of tissues. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014>

(2) The Minister of Health and Welfare, the Minister of Food and Drug Safety or the head of the National Tissue Donation Management Agency may have relevant public officials inspect relevant documents of registries, tissue donation support institutions, tissue banks, tissue transplant hospitals, etc. under paragraph (1), as prescribed by Presidential Decree. In such case, the relevant public officials in charge of inspection shall carry a certificate indicating their authority and present it to interested persons. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014>

(3) The head of a registry, tissue donation support institution, tissue bank or tissue transplant hospital or its employee shall comply with an order or cooperate with inspection under paragraphs (1) and (2), without good cause. <Amended on Jan. 28, 2014>

Article 24 (Corrective Orders) Where the head of a registry, tissue donation support institution, tissue bank or tissue transplant hospital or any of its employees fall under any of the following, the Minister of Health and Welfare, the Minister of Food and Drug Safety or the head of the National Tissue Donation Management Agency may order the head of a relevant organization to make corrections within a specified period: <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014>

1. Where no notification under Article 7-2 (2) is made;
2. Where any matter to be observed under Article 15 (3) is not observed;
3. Where a report under Article 19 is not made;
4. Where records under Article 20 are not maintained.

Article 24-2 (Orders of Collection and Destruction) (1) The Minister of Food and Drug Safety may order a tissue bank or tissue transplant hospital, which has handled or distributed tissues after importing tissues that harmed or are likely to harm national health, to suspend use of the tissues or take other necessary measures.

(2) Where the Minister of Food and Drug Safety deems injury to national health has occurred or is likely to occur from tissues, he or she may order a tissue bank or tissue transplant hospital to collect or destruct tissues in storage or take other necessary measures.

(3) Where a person in receipt of an order under paragraph (1) or (2) fails to implement the order or urgent needs arise for public health, the Minister of Food and Drug Safety may have relevant public officials destroy relevant tissues or impose necessary dispositions.

(4) Matters necessary for the collection and destruction of tissues under paragraphs (2) and (3), other measures, etc. shall be prescribed by Ordinance of the Prime Minister.

[This Article Newly Inserted on Mar. 18, 2014]

Article 25 (Revocation of Permission) (1) Where a tissue bank falls under any of following cases, the Minister of Food and Drug Safety may revoke the permission for the tissue bank or may fully or partially suspend operation of its business for a specified period of up to one year, as prescribed by Ordinance of the Prime Minister: Provided, That in cases falling under subparagraphs 6 and 7, the Minister of Health and Welfare may request the Minister of Food and Drug Safety to revoke the permission or to issue an order to fully or partially suspend operation of its business for a specified period of up to one year: <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014; Mar. 18, 2014; Feb. 4, 2016; Dec. 11, 2018; Aug. 17, 2021>

1. Where it fails to examine the availability for transplantation or to destroy or report a tissue unavailable for distribution or transplantation, in violation of Article 10 (1);
- 1-2. Where it fails to request the inspection of the medical history and records of administered medicines of a tissue donor and verify the result of such inspection, or fails to destroy tissues unavailable for distribution or transplantation, in violation of the former part of Article 10 (3) or paragraph (5) of the same Article;
- 1-3. Where it fails to report the use and demand-supply status of a tissue, in violation of Article 10 (6);
2. Where it fails to have facilities, equipment, human resources, quality control system, etc. prescribed in the former part of Article 13 (1);
- 2-2. Where it fails to obtain permission for any modification of significant matters pursuant to the latter part of Article 13 (1);
- 2-3. Where it obtains permission, permission for modification, permission for renewal, approval, or approval for modification under Article 13 (1), 14 (2), or 17 (2) by fraud or other improper means;
3. Where it violates Article 13-2;
4. Where it violates Articles 15 and 15-2 through 15-4;
5. Where it fails to observe the matters in recovering tissues under Article 16 (1);
- 5-2. Where it fails to make registration or registration of modification, in violation of Article 17-2;

6. Where it fails to comply with an order under Article 23 (1) or refuses the inspection under paragraph (2) of the same Article;

7. Where it fails to comply with the corrective order under Article 24;

8. Where it fails to comply with the order under Article 24-2 (1) or (2).

(2) Where a registry or tissue donation support institution falls under any of the following cases, the Minister of Food and Drug Safety may revoke the designation or issue an order to fully or partially suspend operation of its business for a specified period of up to one year: <Newly Inserted on Jan. 28, 2014; Mar. 18, 2014>

1. Where it fails to meet the standards for facilities, human resources, etc. under Article 7-3 (1) or 16-2 (4);

2. Where it fails to take necessary measures, in violation of the latter part of Article 16-2 (6) or paragraph (7) of the same Article;

3. Where it fails to comply with the order under Article 23 (1) or refuses the inspection under paragraph (2) of the same Article;

4. Where it fails to comply with the corrective order under Article 24.

(3) Where a registry, tissue donation support institution or tissue bank operates its business in violation of an order for suspension under paragraphs (1) and (2), the Minister of Health and Welfare or the Minister of Food and Drug Safety may revoke the permission or designation. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014>

(4) Where permission or designation of a registry, tissue donation support institution or tissue bank is revoked pursuant to paragraphs (1) through (3), the registry, tissue donation support institution or tissue bank shall not obtain permission or designation within one year from the date of revocation of such permission or designation. <Amended on Jan. 28, 2014>

(5) Detailed criteria for administrative disposition under paragraph (1) shall be prescribed by Ordinance of the Prime Minister in consideration of the types, severity, etc. of violations. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014>

(6) Detailed standards for the administrative dispositions under paragraph (2) shall be prescribed by Ordinance of the Ministry of Health and Welfare in consideration of the types, severity, etc. of violations. <Newly Inserted on Jan. 28, 2014>

[Title Amended on Jan. 28, 2014]

- Article 26 (Report on Closure of Business and Transfer of Data)** (1) Where a tissue bank intends to cease operation of its business, it shall report such fact to the Minister of Food and Drug Safety, as prescribed by Ordinance of the Prime Minister. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Dec. 11, 2018>
- (2) Where a registry or tissue donation support institution intends to cease operation of its business or intends to discontinue work of registering tissue donors and candidates for tissue donation or discovering tissue donor candidates, it shall report such fact to the Minister of Health and Welfare as prescribed by Ordinance of the Ministry of Health and Welfare. <Newly Inserted on Jan. 28, 2014>
- (3) The head of a tissue bank that ceases operation of its business pursuant to paragraph (1) or whose permission is revoked pursuant to Article 25 shall transfer the records pursuant to Article 20 to the Minister of Food and Drug Safety and submit data relating to the plan for and results of handling tissues in storage, as prescribed by Presidential Decree. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014; Dec. 11, 2018>
- (4) The head of a registry or tissue donation support institution which intends to cease operation of its business or discontinue work pursuant to paragraph (2) or whose designation is revoked pursuant to Article 25 shall transfer relevant data to the Minister of Health and Welfare, as prescribed by Presidential Decree. <Newly Inserted on Jan. 28, 2014>

- Article 26-2 (Human Tissue Supervisors)** (1) Human tissue supervisors shall be assigned to the Ministry of Health and Welfare and the Ministry of Food and Drug Safety to perform the duties of the relevant public officials under Articles 23 (2) and 24-2 (3).
- (2) Human tissue supervisors shall be appointed by the Minister of Health and Welfare or the Minister of Food and Drug Safety, respectively, from among the public officials of the Ministry of Health and Welfare or the Ministry of Food and Drug Safety.
- (3) Qualifications for and the scope of work and the procedures for appointment of human tissue supervisors, and other necessary matters, shall be prescribed by Ordinance of the Prime Minister in consultation with the Minister of Health and Welfare.
- [This Article Newly Inserted on Dec. 11, 2018]

CHAPTER IV SUPPLEMENTARY PROVISIONS

Article 27 (Projects to Aid Tissue Donation) (1) The State or local governments shall implement the following projects within budgetary limits in order to revitalize tissue donation and transplantation:

1. Formulation and promotion of policies to support tissue donors;
2. Support for publicity of tissue donation and transplantation;
3. Indication of candidate for tissue donation (placing a mark on certificates, such as driver's license, etc., issued by the State and local governments, which is implemented to wishers from among persons who has registered as a candidate for tissue donation under Article 7-2 (1)).

(2) The State and local governments may render necessary support to registries, tissue donation support institutions, tissue banks or tissue donors, within budgetary limits.

(3) The State may establish and manage a computer network system that manages information on the donation, management, transplantation, etc. of tissues.

(4) Matters necessary for entities in charge of establishment and management of computer network system, operation, etc. under paragraph (3) shall be prescribed by Presidential Decree.

[This Article Wholly Amended on Jan. 28, 2014]

Article 27-2 (International Cooperation) The Minister of Food and Drug Safety shall strive for international cooperation, such as concluding agreements with international organizations and relevant countries, for the safety and quality control of tissues.

[This Article Newly Inserted on Dec. 11, 2018]

Article 28 (Delegation of Authority) The Minister of Health and Welfare or the Minister of Food and Drug Safety may partially delegate his or her authority under this Act to the head of a subordinate agency, the Special Metropolitan City Mayor, the Metropolitan City Mayor, the Special Self-Governing City Mayor, the Do Governor, the Governor of the Special Self-Governing Province, or the head of a Si/Gun/Gu (referring to the head of an autonomous Gu; hereinafter the same shall apply), as prescribed by Presidential Decree.
<Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013>

Article 29 (Obligation to Cooperate) (1) The Minister of Health and Welfare, the Minister of Food and Drug Safety, the head of the National Tissue Donation Management Agency, the head of a tissue donation support institution or the head of a tissue bank may request the heads of relevant agencies to take measures necessary for the discovery of tissue donor candidates or for the safe and swift recovery, transportation or transplantation of tissues. In such case, the heads of relevant agencies shall comply with such requests without good cause. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014; Dec. 11, 2018>

(2) If the findings of inspecting the medical history and the record of administered medicines of a tissue donor under Article 10 (3) are not consistent with other data showing the medical history of the tissue donor or otherwise require additional verification, the head of the tissue bank may request the Minister of Food and Drug Safety to provide inspection data concerning the medical history and the record of administered medicines. <Newly Inserted on Dec. 11, 2018>

(3) Upon receipt of a request under paragraph (2), the Minister of Food and Drug Safety may request an intermediate care institution under Article 42 (1) of the National Health Insurance Act to provide data concerning the medical history and the record of administered medicines of the tissue donor. In such cases, the head of the intermediate care institution requested shall comply with such request, in the absence of good cause. <Newly Inserted on Dec. 11, 2018>

Article 29-2 (Prohibition against Use of Identical Titles) (1) No entity, other than a tissue bank provided for in this Act, shall use the title "tissue bank" in its trade name.

(2) No entity, other than a tissue bank provided for in this Act, shall use any label or advertisement by which it may be misunderstood as an authorized tissue bank.

[This Article Newly Inserted on Dec. 11, 2018]

Article 29-3 (Request for Data) If it is necessary to confirm consent to tissue donation under Article 7, if it is necessary for confirming his or her family members or bereaved family members in cases a tissue donor under the proviso of Article 7-2 (1) is a brain-dead person or deceased person, or if it is necessary to confirm consent to tissue recovery under Article 8, the head of the National Tissue Donation Management Agency or the head of a tissue donation support institution may file an application for the issuance of a certificate

under Article 15 of the Act on Registration of Family Relations with the head of a Si/Eup/Myeon/Dong under Article 3 of that Act, and request the Minister of National Court Administration to provide computerized information and data under Article 11 (4) of that Act. In such cases, a person in receipt of such application or request shall comply therewith, in the absence of good cause, and shall be exempt from usage fees or charges for data provided to the head of the National Tissue Management Agency or the head of a tissue donation support institution.

[This Article Newly Inserted on Jan. 23, 2024]

Article 30 (Hearings) Where the Minister of Food and Drug Safety or the Minister of Food and Drug Safety intends to revoke permission for a tissue bank under Article 25, he or she shall hold a hearing. <Amended on Feb. 29, 2008; Jan. 18, 2010; Mar. 23, 2013; Jan. 28, 2014>

Article 31 (Cost-Bearing) (1) A person who receives a tissue transplant shall bear the costs of recovery and transplant of tissue: Provided, that the payment of such costs shall be made as prescribed by other statutes if such other statutes provide otherwise.

(2) The costs under paragraph (1) shall be calculated in accordance with the National Health Insurance Act: Provided, That calculation of costs not provided for in the National Health Insurance Act shall be made as prescribed by Ordinance of the Ministry of Health and Welfare. <Amended on Jan. 18, 2010>

CHAPTER V PENALTY PROVISIONS

Article 32 (Penalty Provisions) Any person who distributes tissues falling under the subparagraphs of Article 9 (excluding subparagraph 6) for transplantation to another person or who transplants such tissues, in violation of the same Article, shall be punished by imprisonment with labor for an indefinite term or imprisonment with labor for a limited term of at least two years. <Amended on Mar. 18, 2014>

Article 33 (Penalty Provisions) (1) Any person who offers, receives, or promises to offer or receive money, etc. and violates Article 5 (1) 1 or 3 shall be punished by imprisonment with labor for not more than seven years.

(2) Any person who offers, receives, or promises to offer or receive money, etc. and violates Article 5 (1) 2 shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won, or may be cumulatively sentenced to such fine and imprisonment with labor. <Amended on Dec. 11, 2018>

(3) Any of the following persons shall be punished by imprisonment with labor for not more than five years or by a fine not exceeding 50 million won: <Amended on Mar. 18, 2014; Dec. 11, 2018; Aug. 17, 2021>

1. A person who recovers tissues without obtaining consent under Article 8 (1) and (2);
 2. A person who establishes a tissue bank without obtaining permission under Article 13 (1);
 - 2-2. A person who obtains permission, permission for modification, or permission for renewal under Article 13 (1) or 14 (2) by fraud or other improper means;
 3. A person who imports tissues in violation of Article 17 (1).
- (4) Money, economic gains or other benefits in return that have been given or received in violation of paragraph (1) or (2) shall be confiscated: Provided, That where such confiscation is impossible, an amount equivalent to the value thereof shall be collected as a penalty. <Amended on Jan. 28, 2014>

Article 34 (Penalty Provisions) Any of the following persons shall be punished by imprisonment with labor for not more than two years or by a fine not exceeding 20 million won: <Amended on Jan. 28, 2014; Mar. 18, 2014; Feb. 4, 2016; Dec. 11, 2018; Aug. 17, 2021>

1. A person who manages or transplants tissues in violation of Article 5 (2);
2. A person who obtains designation deceitfully or otherwise fraudulently or makes modification without reporting, in violation of Article 7-3 (1) or 16-2 (1) and (3);
- 2-2. A person who distributes tissues falling under subparagraph 6 of Article 9 for transplantation to another person or who transplants such tissues;
- 2-3. A person who fails to examine the availability for transplantation or to destroy or report tissues unavailable for distribution or transplantation, in violation of Article 10 (1);
3. A person who fails to request the inspection of medical history or records of administered medicines or to verify the findings of such inspection or who fraudulently verifies the findings of such inspection, in violation of the former part of Article 10 (3) or paragraph (5) of the same Article;

4. A person who fails to report or destroy unavailable tissues, in violation of Article 10 (5);
5. Where a person other than a medical person peruses medical records, in violation of the proviso to Article 16-2 (1) 2;
6. A person who fails to take necessary measures, in violation of the latter part of Article 16-2 (6) or paragraph (7) of the same Article;
7. The head of a tissue bank who imports tissues without obtaining approval or approval for modification, in violation of Article 17 (2);
- 7-2. A person who obtains approval or approval for modification under Article 17 (2) by fraud or other improper means;
8. A person who divulges matters concerning tissue donors or recovered tissues, in violation of Article 22;
9. A person who fails to comply with the order pursuant to Article 24-2 (1) or (2);
10. An entity that uses the title "tissue bank" in its trade name or uses any label or advertisement by which it may be misunderstood as a permitted tissue bank, in violation of Article 29-2.

Article 35 (Concurrent Imposition of Suspension) Where a person who violates this Act is punished by imprisonment with labor for a limited term, he or she may also be punished by suspension of qualification for not more than 10 years.

Article 36 (Joint Penalty Provisions) Where the representative of a juristic person, or the agent, servant or employee a juristic person or individual commits a violation under Article 33 (2) and (3) or 34 with regard to the business of the juristic person or individual, not only shall such violator be punished, but the juristic person or individual also shall be punished by a fine under relevant provisions: Provided, That where such corporation or individual has not been negligent in exercising caution and supervision concerning the relevant business to prevent such violation, this shall not apply. <Amended on Apr. 28, 2011; Jan. 28, 2014>

Article 37 (Administrative Fines) (1) Any of the following persons shall be subject to an administrative fine not exceeding five million won: <Amended on Dec. 11, 2018>

1. A person who fails to confirm consent or give full explanation, in violation of Article 16 (1);

2. A person who recovers tissue, in violation of the main clause of Article 18.

(2) Any of the following persons shall be subject to an administrative fine not exceeding three million won: <Amended on Mar. 18, 2014; Feb. 4, 2016; Dec. 11, 2018>

1. A person who fails to report succession to status under Article 13-3 (2);

1-2. The head of a tissue bank who fails to obtain permission for renewal under Article 14 (2);

2. The head of a tissue bank who fails to have his or her employees in need of education undergo such education, in violation of Article 15 (5);

2-2. A person who fails to prepare and furnish data in violation of Article 17 (4);

3. A person who fails to keep records, file a report or make notification, in violation of Article 19;

4. A person who fails to preserve records, in violation of Article 20;

5. A person who fails to comply with a request for perusal of records or issuance of copies, in violation of the main clause of Article 21;

6. A person who fails to comply with an order under Article 23 (1);

7. A person who fails to comply with an order under Article 24;

8. A person who fails to make a report, transfer records or submit data, in violation of Article 26.

(3) Administrative fines under paragraph (1) and (2) shall be imposed and collected by the Minister of Health and Welfare, the Minister of Food and Drug Safety, the head of an affiliated institution, a Special Metropolitan City Mayor, a Metropolitan City Mayor, a Self-Governing City Mayor, a Do Governor, a Special Self-Governing Province Governor, or the head of a Si/Gun/Gu as prescribed by Presidential Decree. <Newly Inserted on Mar. 23, 2013>

Article 38 Deleted. <Mar. 23, 2013>