Act on the Safety of Regenerative Medicine

(Act No. 85 of November 27, 2013)

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Chapter I General Provisions

(Purpose)

Article 1 The purpose of this Act is to promote the prompt and safe provision and dissemination of regenerative medicine by clarifying measures to ensure the safety of regenerative medicine technologies used in regenerative medicine, measures related to bioethics considerations (referred to below as "ensuring safety and considering bioethics"), and other measures to be taken by those intending to provide this treatment. In addition, this Act establishes a system for granting permission and other approval for the manufacturing of specific processed cells or specific nucleic acids and the related compounds, thereby contributing to the improvement of medical care quality and public health.

(Definitions)

Article 2 (1) The term "regenerative medicine" as used in this Act means medical

care using regenerative medicine technology (excluding cases that fall under clinical trials as provided in Article 80-2, paragraph (2) of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; referred to below as the "Act on Pharmaceuticals and Medical Devices")).

(2) The term "regenerative medicine technology" as used in this Act refers to medical technology intended to be used for the reconstruction, repair, or formation of the structure or function of the human body, or for the treatment or prevention of human diseases, and which is specified by Cabinet Order from among the following as technology for which it is necessary to take measures to ensure its safety and consider bioethical and other measures specified by this Act:

(i) medical technology that uses processed cells (excluding technology that uses only regenerative medicine products (meaning regenerative medicine products approved pursuant to Article 23-25 or Article 23-37 of the Act on Pharmaceuticals and Medical Devices; the same applies below in this Article) as processed cells for approval uses and conditions (meaning usage, dosage, method of use, efficacy, effect, and performance; the same applies below in this item), or for uses and conditions specified by Order of the Ministry of Health, Labour and Welfare as posing the same or lower risk to human life and health as the approval uses and conditions); and

(ii) medical technology that uses nucleic acids and related compounds (excluding technology that uses only pharmaceuticals (meaning pharmaceuticals approved pursuant to the provisions of Article 14 or Article 19-2 of the Act on Pharmaceuticals and Medical Devices; the same applies below in this Article) or regenerative medicine products as nucleic acids and related compounds for the approved uses and conditions (meaning the usage, dosage, efficacy, and effect in the case of pharmaceuticals, and the usage, dosage, method of use, efficacy, effect, and function in the case of regenerative medicine products; the same applies below in this item), or for uses and conditions specified by Order of the Ministry of Health, Labour and Welfare as posing the same or lower risk to human life and health as the approved uses and conditions).

(3) The term "cell" as used in this Act (excluding paragraph (5)) means a human or animal cell that is used as a raw material for a processed cell.

(4) The term "processed cells" as used in this Act refers to human or animal cells that have been cultured or otherwise processed. The term "specific processed cells" as used in this Act refers to processed cells used for regenerative medicine, excluding those classified as regenerative medicine products.

(5) The term "nucleic acids and related compounds" as used in this Act refers to substances that process nucleic acids or other substances closely related to

gene expression, which are introduced into the cells of a person in the human body (including substances containing these substances). The term "specific nucleic acids and related compounds" as used in this Act refers to nucleic acids and related compounds used for regenerative medicine, excluding those classified as pharmaceuticals and regenerative medicine products.

(6) The term "specific processed cells, specific nucleic acids, and related compounds" as used in this Act refers to specific processed cells, specific nucleic acids, and related compounds. The term "manufacturing", when applied to specific processed cells, specific nucleic acids, and related compounds, means culturing or otherwise processing human or animal cells in the case of specific processed cells, or producing specific nucleic acids and related compounds by chemical synthesis or other methods in the case of specific nucleic acids and related compounds. The term "manufacturing facility of specific processed cells, specific nucleic acids, and related compounds" refers to a facility engaged in the manufacture of these products.

(7) The term "class I regenerative medicine technology" as used in this Act refers to regenerative medicine technology specified by Order of the Ministry of Health, Labour and Welfare as requiring measures to ensure safety, consider bioethics, and implement other measures prescribed in this Act, due to unclear effects on human life and health or the risk of serious effects, even with considerable care. The term "class I regenerative medicine" as used in this Act refers to regenerative medicine that uses class I regenerative medicine technology, as specified by Order of the Ministry of Health, Labour and Welfare.

(8) The term "class II regenerative medicine technology" as used in this Act refers to regenerative medicine technology specified by Order of the Ministry of Health, Labour and Welfare as requiring measures to ensure safety and to consider bioethics and other measures prescribed in this Act (excluding class I regenerative medicine technology) due to the risk of affecting human life and health even with considerable care.

(9) The term "class III regenerative medicine technology" as used in this Act refers to regenerative medicine technology that does not fall under class I or class II regenerative medicine technology. The term "class III regenerative medicine" as used in this Act refers to regenerative medicine that uses class III regenerative medicine technology.

(10) The term "manufacturer of specific processed cells, specific nucleic acids, and related compounds" as used in this Act means a person who has obtained the permission referred to in Article 35, paragraph (1) or the certification referred to in Article 39, paragraph (1), or a person who has made a notification under the provisions of Article 40, paragraph (1).

Chapter II Provision of Regenerative Medicine

Section 1 Provision Standards for Regenerative Medicine

Article 3 (1) The Minister of Health, Labour and Welfare must specify the provision standards for regenerative medicine (referred to below as the "provision standards for regenerative medicine") by Order of the Ministry of Health, Labour and Welfare.

(2) The provision standards for regenerative medicine are required to prescribe the following matters for each of class I, class II, and class III regenerative medicine (excluding the matters stated in item (i) for class III regenerative medicine):

(i) matters concerning the personnel, structure, equipment, and other facilities of a hospital (as defined in Article 1-5, paragraph (1) of the Medical Care Act (Act No. 205 of 1948); the same applies below) or a clinic (as defined in paragraph (2) of the same Article; the same applies below) that provides regenerative medicine;

(ii) matters concerning methods of obtaining cells to be used for regenerative medicine, as well as methods of manufacturing and quality control of specific processed cells, specific nucleic acids, and related compounds;

(iii) beyond what is stated in the preceding two items, matters concerning measures to ensure the safety and bioethical standards of regenerative medicine technologies;

(iv) matters concerning methods of compensation for health damage to a person who provides cells used for regenerative medicine and to a person who receives the treatment (limited to cases specified by Order of the Ministry of Health, Labour and Welfare, such as those conducted as research or other specified cases); and

(v) other necessary matters concerning the provision of regenerative medicine.

(3) Regenerative medicine must be provided in accordance with the provision standards for regenerative medicine.

Section 2 Procedures for Starting, Changing, and Discontinuing the Provision of Regenerative Medicine

Subsection 1 General Rules

(Submission of a Provision Plan for Regenerative Medicine)

Article 4 (1) Pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare, the administrator of hospitals or clinics where regenerative medicine is to be provided (including the addresses of physicians or dentists as specified in Article 5, paragraph (1) of the Medical Care Act; the same applies below, except in item (iii)) (including physicians or dentists

prescribed in the same paragraph; the same applies below in this Chapter and the following Chapter) must submit a plan to the Minister of Health, Labour and Welfare in advance for the provision of regenerative medicine (referred to below as the "provision plan for regenerative medicine"). This plan must describe the following matters (excluding the matters stated in item (iii) if the regenerative medicine in item (ii) is class III regenerative medicine) for each category of regenerative medicine specified by the Order of the Ministry of Health, Labour and Welfare, including class I, class II, and class III regenerative medicine:

(i) the name and address of the hospital or clinic and the name of the administrator;

(ii) regenerative medicine to be provided and the its details;

(iii) the personnel, structure, equipment, and other facilities of the hospital or clinic with respect to the regenerative medicine described in the preceding item;

(iv) the method of obtaining cells to be used for the regenerative medicine described in item (ii), as well as the method of manufacturing and quality control of specific processed cells, specific nucleic acids, and related compounds to be used for the regenerative medicine (in cases where the manufacturing of specific processed cells, specific nucleic acids, and related compounds is entrusted, the name of the entrusting party and the content of the entrustment);

(v) beyond what is stated in the preceding two items, measures to ensure the safety and bioethical standards of regenerative medicine technologies used in the regenerative medicine described in item (ii);

(vi) the method of compensation for health damage to a person who provides cells used for the regenerative medicine described in item (ii) and a person who receives such treatment (limited to cases where it is performed as research or other cases specified by Order of the Ministry of Health, Labour and Welfare);

(vii) the name and composition of the members of the certified committee for regenerative medicine (meaning the certified committee for regenerative medicine specified in Article 26, paragraph (6), item (ii) of the same Article; the same applies below in this Chapter) that carries out the operations specified in the items of Article 26, paragraph (1) with regard to the regenerative medicine described in item (ii); and

(viii) other matters specified by Order of the Ministry of Health, Labour and Welfare.

(2) When the administrator of a hospital or clinic intending to provide regenerative medicine to submit a provision plan for regenerative medicine pursuant to the provisions of the preceding paragraph, the administrator must

hear the opinions of the certified committee for regenerative medicine included in the plan in advance regarding whether the provision plan for regenerative medicine complies with the provision standards for regenerative medicine.

(3) The following documents must be attached to the provision plan for regenerative medicine described in paragraph (1):

(i) a document describing the details of the opinions referred to in Article 26, paragraph (1), item (i), provided by the certified committee for regenerative medicine described in the provision plan for regenerative medicine; and

(ii) other documents specified by Order of the Ministry of Health, Labour and Welfare.

(Changes to the Provision Plan for Regenerative Medicine)

Article 5 (1) The administrator of a hospital or clinic that intends to make changes to the provision plan for regenerative medicine (excluding minor changes specified by Order of the Ministry of Health, Labour and Welfare; the same applies in the following paragraph) must submit the revised plan to the Minister of Health, Labour and Welfare in advance, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(2) The provisions of paragraphs (2) and (3) of the preceding Article apply mutatis mutandis to changes to the provision plan for regenerative medicine; provided, however, that documents referred to in item (ii) of the same paragraph may be omitted if there is no change to the content of the documents that have already been submitted to the Minister of Health, Labour and Welfare.

(3) The administrator of hospitals or clinics who has made minor changes to the provision plan for regenerative medicine specified by Order of the Ministry of Health, Labour and Welfare, as prescribed in paragraph (1), must notify the certified committee for regenerative medicine specified in the plan and inform the Minister of Health, Labour and Welfare of the change within 10 days from the date of the change, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(Suspension of Provision of Regenerative Medicine)

Article 6 The administrator of an institution providing regenerative medicine (meaning hospitals or clinics covered by the provision plan for regenerative medicine submitted pursuant to the provisions of Article 4, paragraph (1) or paragraph (1) of the preceding Article; the same applies below) must, when discontinuing the provision of regenerative medicine described in the plan, notify the certified committee for regenerative medicine described in the plan and inform the Minister of Health, Labour and Welfare to that effect within 10 days from the date of discontinuation, pursuant to the provisions of the Order

of the Ministry of Health, Labour and Welfare.

Subsection 2 Special Provisions on the Provision of Class I Regenerative Medicine

(Requirements for a Certified Committee for Regenerative Medicine in a Provision Plan for Class I Regenerative Medicine)

Article 7 A certified committee for regenerative medicine that performs the operations specified in the items of Article 26, paragraph (1) concerning class I regenerative medicine described in a provision plan for class I regenerative medicine (meaning a provision plan for such regenerative medicine; the same applies below) must be a specific certified committee for regenerative medicine (meaning a certified committee for regenerative medicine that meets all of requirements specified in the items of paragraph (4) of the same Article; the same applies in Article 11).

(Order to Change the Provision Plan for Class I Regenerative Medicine)

Article 8 (1) If a provision plan for class I regenerative medicine is submitted pursuant to Article 4, paragraph (1), and the Minister of Health, Labour and Welfare determines that the class I regenerative medicine described in the plan does not comply with the provision standards for regenerative medicine, the Minister may order the administrator of the institution providing regenerative medicine under the plan to change the plan or take other necessary measures within 90 days from the date of submission.

(2) If a provision plan for class I regenerative medicine is submitted pursuant to Article 4, paragraph (1), and there are reasonable grounds for not being able to issue the order prescribed in the preceding paragraph within the prescribed period, the Minister of Health, Labour and Welfare may extend that period. In such cases, the Minister must notify the administrator of the institution providing regenerative medicine under the plan of the extension, the extended period, and the grounds for the extension within the originally prescribed period.

(3) If a provision plan for class I regenerative medicine is submitted pursuant to Article 4, paragraph (1), and the Minister of Health, Labour and Welfare determines that the class I regenerative medicine described in the plan conforms to the provision standards for regenerative medicine, the Minister may shorten the period referred to in paragraph (1). In such cases, the Minister must notify the administrator of the institution providing regenerative medicine under the plan of the shortened period without delay.

(Restriction on the Provision of Class I Regenerative Medicine)

Article 9 The administrator of an institution providing regenerative medicine under a provision plan for class I regenerative medicine submitted pursuant to the provisions of Article 4, paragraph (1) must not provide the class I regenerative medicine described in the plan until the period prescribed in paragraph (1) of the preceding Article has elapsed (or, when a notice is given under the provisions of paragraph (2) or (3) of the same Article, the period specified in the notice).

(Application Mutatis Mutandis)

Article 10 (1) The provisions of the preceding two Articles apply mutatis mutandis to changes to the provision plan for class I regenerative medicine (excluding minor changes specified by Order of the Ministry of Health, Labour and Welfare under Article 5, paragraph (1)). In this case, any necessary technical replacement of terms is specified by Cabinet Order.

(2) Notwithstanding the provisions of the preceding Article, as applied mutatis mutandis pursuant to the preceding paragraph, the administrator of an institution providing regenerative medicine that changes the provision plan for class I regenerative medicine may continue to provide class I regenerative medicine (limited to the provision of medicine in accordance with the plan before the change) until the end of the period prescribed in the same Article.

Subsection 3 Special Provisions on the Provision of Class II Regenerative Medicine

Article 11 A certified committee for regenerative medicine that carries out the operations specified in the items of Article 26, paragraph (1) concerning class II regenerative medicine described in a provision plan for class II regenerative medicine (meaning a provision plan for such medicine; the same applies in Article 26, paragraph (4), item (i)) must be a specific certified committee for regenerative medicine.

Section 3 Measures for the Proper Provision of Regenerative Medicine

(Entrustment of the Manufacturing of Specific Processed Cells, Specific Nucleic Acids, and Related Compounds)

Article 12 When the administrator of an institution providing regenerative medicine intends to entrust the manufacturing of specific processed cells, specific nucleic acids, and related compounds, they must do so to a manufacturer of specific processed cells, specific nucleic acids, and related compounds.

(Confirmation of a Provision Plan for Regenerative Medicine)

Article 13 When a physician or dentist intends to provide regenerative medicine, they must confirm the following matters:

(i) the regenerative medicine refers to the regenerative medicine described in a provision plan for regenerative medicine submitted pursuant to the provisions of Article 4, paragraph (1), or Article 5, paragraph (1); and

(ii) if the regenerative medicine is classified as class I regenerative medicine, the period prescribed in Article 9 (including as applied mutatis mutandis pursuant to Article 10, paragraph (1)) has elapsed with respect to the provision plan for class I regenerative medicine, which describes the relevant class I regenerative medicine.

(Explanation and Consent regarding Regenerative Medicine)

Article 14 (1) When providing regenerative medicine, except in cases where obtaining the consent of the person is difficult due to illness or other circumstances specified by Order of the Ministry of Health, Labour and Welfare, physicians or dentists must provide appropriate explanations to the recipient of the regenerative medicine regarding the necessary matters to ensure the safety, bioethical standards, and proper provision of the regenerative medicine technology used, and must obtain their consent.

(2) When collecting cells to be used for regenerative medicine from a person other than the recipient of such treatment, a physician or dentist must appropriately explain to the person providing the cells the intended use of the collected cells and other necessary matters concerning their collection, and obtain their consent, except in cases where it is difficult to obtain the consent of the person due to illness or other circumstances specified by Order of the Ministry of Health, Labour and Welfare.

(Protection of Personal Information Related to Regenerative Medicine)

Article 15 The administrator of an institution providing regenerative medicine must take necessary measures to prevent the leakage, loss, or damage of personal information (meaning information about an individual that can identify them by name, date of birth, or other descriptions (including information that can identify the individual when compared with other information); the same applies below in this Article) for both the provider of cells used for regenerative medicine and the recipient of such treatment, and must appropriately manage such personal information.

(Records of Regenerative Medicine and Their Retention)

Article 16 (1) When a physician or dentist provides regenerative medicine, they must prepare a record that includes the date, time, and place of provision,

details of the treatment provided, and other matters specified by Order of the Ministry of Health, Labour and Welfare, pursuant to its provisions.

(2) The records prescribed in the preceding paragraph must be preserved by the administrator of an institution providing regenerative medicine, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Reporting of Diseases, etc. to the Certified Committee for Regenerative Medicine)

Article 17 (1) When the administrator of an institution providing regenerative medicine learns of the occurrence of any diseases, disabilities, deaths, or infectious diseases suspected to be caused by the provision of regenerative medicine as specified in the provision plan for regenerative medicine, the administrator must report this to the certified committee for regenerative medicine specified in that plan, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(2) In the case referred to in the preceding paragraph, when a certified committee for regenerative medicine expresses its opinion, the administrator of the institution providing regenerative medicine must respect the opinion and take the necessary measures.

(Reporting of Diseases, etc. to the Minister of Health, Labour and Welfare)

Article 18 When the administrator of an institution providing regenerative medicine becomes aware of the matters specified by Order of the Ministry of Health, Labour and Welfare concerning the occurrence of any disease, disability, death, or infectious disease suspected to be caused by the provision of regenerative medicine as specified in the provision plan for regenerative medicine, the administrator must report this to the Minister of Health, Labour and Welfare pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(Reporting to the Health Science Council)

Article 19 (1) Each fiscal year, the Minister of Health, Labour and Welfare is to report the status of the report under the preceding Article to the Health Science Council. When the Minister finds it necessary, they are to hear the opinions of the Council and take necessary measures to prevent the occurrence or spread of public health hazards caused by the provision of regenerative medicine.

(2) In addition to the measures outlined in the preceding paragraph, the Health Science Council may study and deliberate on necessary measures to prevent the occurrence or spread of public health hazards caused by the provision of regenerative medicine. If deemed necessary, it may provide its opinions to the

Minister of Health, Labour and Welfare.

(Periodic Reporting to the Certified Committee for Regenerative Medicine)

Article 20 (1) The administrator of an institution providing regenerative medicine must periodically report the status of the provision of regenerative medicine described in the provision plan for regenerative medicine to the certified committee for regenerative medicine described in that plan, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(2) In the case referred to in the preceding paragraph, when a certified committee for regenerative medicine provides its opinion, the administrator of the institution providing regenerative medicine must respect the opinion and take the necessary measures.

(Periodic Reporting to the Minister of Health, Labour and Welfare)

Article 21 (1) The administrator of an institution providing regenerative medicine must periodically report to the Minister of Health, Labour and Welfare on the status of the provision of regenerative medicine as described in the provision plan for regenerative medicine, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(2) The Minister of Health, Labour and Welfare must compile the reports required under the provisions of the preceding paragraph and publicize their outline.

(Emergency Orders)

Article 22 When the Minister of Health, Labour and Welfare deems it necessary to prevent the occurrence or spread of public health hazards caused by the provision of regenerative medicine, the Minister may order the administrator of hospitals or clinics providing such treatment to temporarily suspend the provision of such treatment or take other emergency measures to prevent such hazards.

(Improvement Order)

Article 23 (1) When the Minister of Health, Labour and Welfare deems it necessary to ensure the safety of and bioethical standards for regenerative medicine technologies and the proper provision of regenerative medicine, the Minister may order the administrator of an institution providing such treatment to revise the plan for its provision and to take other necessary measures to ensure proper provision, as required for the enforcement of the provisions of this Chapter.

(2) When the administrator of an institution providing regenerative medicine does not comply with the order under the provisions of the preceding

paragraph, the Minister of Health, Labour and Welfare may order the administrator to restrict the provision of all or part of the regenerative medicine described in the provision plan for regenerative medicine for a specified period.

(On-Site Inspections)

Article 24 (1) The Minister of Health, Labour and Welfare may, as required for the enforcement of the provisions of this Chapter, require the administrator or the founder of an institution providing regenerative medicine (including physicians or dentists prescribed in Article 5, paragraph (1) of the Medical Care Act; the same applies in the following paragraph and Article 26, paragraph (1)) to make necessary reports, may have the relevant officials enter the institution to inspect its structure, equipment, books, documents, and other items, or may question relevant persons.

(2) Beyond what is prescribed in the preceding paragraph, when the Minister of Health, Labour and Welfare finds that the administrator of a hospital or clinic has violated the provisions of this Chapter or any order or disposition issued based on its provisions, or determines it necessary to ensure the safety of and bioethical standards for regenerative medicine technologies and the proper provision of regenerative medicine, the Minister may require the administrator or founder of the hospital or clinic to make necessary reports, may have the relevant officials enter the hospital or clinic to inspect its structure, equipment, books, documents, and other items, or may question relevant persons.

(3) When an official enters a facility pursuant to the provisions of the preceding two paragraphs, the official must carry an identification card and present it to the relevant persons.

(4) The authority under the provisions of paragraphs (1) and (2) must not be construed as being granted for the purpose of criminal investigation.

(Matters to Be Determined by the Order of the Ministry of Health, Labour and Welfare)

Article 25 Beyond what is prescribed in this Chapter, procedures necessary for the provision of regenerative medicine and other matters are specified by Order of the Ministry of Health, Labour and Welfare.

Chapter III Certified Committee for Regenerative Medicine

(Accreditation of the Regenerative Medicine Committee)

Article 26 (1) A person (limited to the founder of hospitals or clinics, academic organizations related to medical science or medical technology, or other organizations specified by Order of the Ministry of Health, Labour and Welfare

(in the case of a non-corporate organization, limited to one with designated representatives or administrators)) who establishes a committee composed of individuals with expertise in regenerative medicine to perform the following services (referred to below as "review and other duties") (referred to below as the "regenerative medicine committee" in this Article) must be certified by the Minister of Health, Labour and Welfare. This accreditation confirms that the regenerative medicine committee meets the requirements specified in the items of paragraph (4) (excluding the requirements in item (i) of the same paragraph, except for the part related to the provision plan for class III regenerative medicine (meaning the provision plan for such medicine; the same applies below), when the committee performs review and other duties exclusively related to that plan):

(i) when the administrator of a hospital, clinic, or institution providing regenerative medicine intending to provide regenerative medicine pursuant to the provisions of Article 4, paragraph (2) (including as applied mutatis mutandis pursuant to Article 5, paragraph (2)) requests an opinion on the provision plan for such medicine, the regenerative medicine committee should examine the plan in light of the provision standards for regenerative medicine and provide an opinion to the administrator regarding whether the treatment should be provided and the matters to be noted in its provision;

(ii) upon receiving a report from the administrator of an institution providing regenerative medicine, pursuant to the provisions of Article 17, paragraph (1), regarding matters concerning the occurrence of any disease, disability, death, or infectious disease suspected to be caused by the provision of regenerative medicine, and finding it necessary, the regenerative medicine committee should provide opinions to the administrator regarding the investigation of the cause of the occurrence and the measures to be taken;

(iii) upon receiving a report from the administrator of an institution providing regenerative medicine on the status of the provision of regenerative medicine pursuant to the provisions of Article 20, paragraph (1), and, if deemed necessary, expressing an opinion to the administrator regarding matters to be noted or improved in the provision of such treatment, or an opinion suggesting that the provision of such treatment should be discontinued; and

(iv) in addition to the cases stated in the preceding three items, when it is deemed necessary to ensure the safety of and bioethical standards for regenerative medicine technologies and the proper provision of regenerative medicine, to provide opinions to the administrator of the institution providing regenerative medicine regarding matters described in the provision plan for regenerative medicine, including the name of the regenerative medicine committee.

(2) A person seeking the accreditation referred to in the preceding paragraph

must submit a written application to the Minister of Health, Labour and Welfare, providing the following information pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare:

(i) the name and address of the applicant, and, if the applicant is a corporation, the name of the representative (or, if the applicant is a non-corporate organization with a designated representative or administrator, the name of the representative or administrator);

(ii) the name of the regenerative medicine committee;

(iii) the names and occupations of the members of the regenerative medicine committee;

(iv) a statement to that effect in cases where the regenerative medicine committee conducts review and other duties exclusively related to a provision plan for class III regenerative medicine;

(v) matters related to the system for conducting review and other duties;

(vi) if any fee is collected for review and other duties, the criteria for calculating the fee; and

(vii) other matters specified by Order of the Ministry of Health, Labour and Welfare.

(3) The following documents must be attached to the written application referred to in the preceding paragraph:

(i) a document outlining the career histories of the members of the regenerative medicine committee;

(ii) rules concerning the review and other duties of the regenerative medicine committee; and

(iii) other documents specified by Order of the Ministry of Health, Labour and Welfare.

(4) In cases where an application for the accreditation referred to in paragraph (1) is filed, if the Minister of Health, Labour and Welfare determines that the regenerative medicine committee related to the application meets the following requirements (excluding the requirements specified in item (i), except for the part related to the provision plan for class III regenerative medicine, when the regenerative medicine committee is solely engaged in review and other duties related to that plan), the Minister is to grant the accreditation:

(i) with regard to plans for the provision of class I, class II, and class III regenerative medicine, the committee consists of medical or legal experts and other persons specified by Order of the Ministry of Health, Labour and Welfare who are capable of appropriately carrying out the review and other duties in accordance with the respective provision standards for class I, class II, and class III regenerative medicine;

(ii) the composition of the committee members conforms to the criteria specified by Order of the Ministry of Health, Labour and Welfare, ensuring

that it is unlikely to impede the fair implementation of review and other duties;

(iii) the corporation has established a system for properly implementing review and other duties, including methods for conducting these duties, managing information acquired during the process, and maintaining confidentiality;

(iv) when fees are collected for review and other duties, the criteria for calculating the fees conform to those specified by Order of the Ministry of Health, Labour, as reasonable in light of the costs required for those duties; and

(v) beyond what is stated in the preceding items, the applicant meets other criteria specified by Order of the Ministry of Health, Labour and Welfare, as necessary for the proper implementation of review and other duties.

(5) Notwithstanding the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare must not grant the accreditation referred to in paragraph (1) if the applicant falls under any of the following items:

(i) when the person has been sentenced to imprisonment or a more severe punishment, and the sentence has not yet been fully served or has not yet ceased to apply;

(ii) when the person has been sentenced to a fine under the provisions of this Act or other Acts concerning citizens' health and medical care specified by Cabinet Order, and the sentence has not yet been fully served or has not yet ceased to apply;

(iii) if the person is one whose accreditation referred to in paragraph (1) has been revoked pursuant to the provisions of Article 33, paragraph (1), and three years have not yet passed since the date of revocation of the accreditation (this includes a person who was previously an officer of a corporation whose accreditation has been revoked within 60 days prior to the date of notice under Article 15 of the Administrative Procedures Act (Act No. 88 of 1993) relating to the revocation of the accreditation (referred to below as the "date of notice" in this paragraph) (an officer refers to members, directors, executive officers, or any other person equivalent to those who execute the business, including those found to have control over the corporation that is equivalent to or greater than that of members, directors, executive officers, or any other person equivalent to those who execute the business; the same applies in item (vi) and Article 35, paragraph (4), items (i) and (iv)), and for whom three years have not yet passed since the date of revocation of the accreditation; or a person who was previously the representative or administrator of an organization whose accreditation has been revoked within 60 days prior to the date of notice, and for whom three years have not yet passed since the date of revocation of the accreditation); provided, however, that this does not apply if the revocation of the

accreditation falls under circumstances specified by Order of the Ministry of Health, Labour and Welfare, whereby it is determined that the revocation should not be considered in the same manner as the revocation described in the main clause of this item, based on factors such as the facts constituting the grounds for the revocation, the status of efforts made by the establisher of the certified committee (as defined in item (i) of the following paragraph) to establish a system for preventing the occurrence of those facts, and the degree of responsibility of the establisher of the certified committee with respect to those facts;

(iv) a person that has filed a notification of discontinuation under the provisions of Article 30, paragraph (1) during the period from the date of notification of the revocation of the accreditation referred to in paragraph (1) under the provisions of Article 33, paragraph (1) to the date of the revocation or the date of the decision not to revoke the accreditation (excluding a person that has reasonable grounds for the discontinuation), provided that it has not been three years since the date of the notification;

(v) when the person has committed a wrongful or significantly unjustifiable act in relation to the review and other duties within three years prior to the application for accreditation referred to in paragraph (1);

(vi) a corporation whose officers fall under any of the preceding items; or

(vii) a non-corporate organization whose representative or administrator falls under any of items (i) through (v).

(6) After granting the accreditation referred to in paragraph (1), the Minister of Health, Labour and Welfare must issue a public notice regarding the following matters:

(i) the name and address of the person who has been authorized (referred to below as the "establisher of the certified committee");

(ii) the name of the regenerative medicine committee related to the accreditation (referred to below as the "certified committee for regenerative medicine"); and

(iii) in cases where the regenerative medicine committee has been authorized to conduct review and other duties exclusively related to the provision plan for class III regenerative medicine, a statement to that effect.

(Approval of Changes)

Article 27 (1) When an establisher of the certified committee intends to change any of the matters specified in paragraph (2), item (iii), (v), or (vi) of the preceding Article, the establisher must obtain approval from the Minister of Health, Labour and Welfare; provided, however, that this requirement does not apply to minor changes specified by Order of the Ministry of Health, Labour and Welfare.

(2) If the establisher of the certified committee makes minor changes specified by Order of the Ministry of Health, Labour and Welfare, as referred to in the proviso of the preceding paragraph, the establisher must notify the Minister of Health, Labour and Welfare of the changes without delay.
(3) The provisions of paragraphs (2) through (4) of the preceding Article apply mutatis mutandis to the approval of changes referred to in paragraph (1).
(4) If there has been a change to any matter stated in paragraph (2), item (i), (ii), or (vii) of the preceding Article, or any matter listed in the documents specified in the items of paragraph (3) of that Article (excluding cases where the change is a minor change specified by Order of the Ministry of Health, Labour and Welfare), the establisher of the certified committee must notify the Minister of Health, Labour and Welfare of the change without delay.
(5) The provisions of paragraph (6) of the preceding Article apply mutatis mutandis if a notification under the provisions of the preceding paragraph is made regarding the matters stated in item (i) or (ii) of that paragraph.

(Validity Period of Accreditation)
Article 28 (1) The validity period of the accreditation referred to in Article 26, paragraph (1) is three years from the date of the accreditation.
(2) The establisher of the certified committee who intends to continue establishing a certified committee for regenerative medicine after the expiration of the validity period referred to in the preceding paragraph must renew the validity period.
(3) The establisher of the certified committee seeking to renew the validity period referred to in the preceding paragraph must apply to the Minister of Health, Labour and Welfare for renewal of the validity period referred to in paragraph (1) during the period from 60 to 90 days prior to the expiration date of the validity period (referred to below as the "renewal application period" in this paragraph); provided, however, that this does not apply if the application cannot be made during the renewal application period due to a natural disaster or other unavoidable circumstances.
(4) If an application referred to in the preceding paragraph has been filed but no decision has been made on the application by the day the validity period referred to in paragraph (1) expires, the previous accreditation remains in effect until a decision is reached, even after the expiration of the validity period referred to in that paragraph.
(5) In the case referred to in the preceding paragraph, if the validity period referred to in paragraph (2) is renewed, the validity period of the accreditation is to be calculated from the day following the expiration date of the previous accreditation.
(6) The provisions of Article 26 (excluding paragraph (1) and paragraph (5), items

(iii) through (v)) apply mutatis mutandis to the renewal of the validity period referred to in paragraph (2); provided, however, that the documents listed in the items of paragraph (3) of that Article may be omitted if there is no change to the content of the documents previously submitted to the Minister of Health, Labour and Welfare.

(Duty of Confidentiality)

Article 29 A person who is or has been a member of a certified committee for regenerative medicine, or a person engaged in the review and other duties of such a committee, must not disclose any confidential information obtained in the course of those duties without legitimate grounds.

(Dissolution of Certified Committees for Regenerative Medicine)

Article 30 (1) When the establisher of the certified committee intends to dissolve the certified committee for regenerative medicine it has established, the establisher must notify the Minister of Health, Labour and Welfare to that effect in advance, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(2) If a notification has been filed pursuant to the provisions of the preceding paragraph, the Minister of Health, Labour and Welfare must issue a public notice regarding it.

(On-Site Inspections)

Article 31 (1) When the Minister of Health, Labour and Welfare deems it necessary to ensure the appropriate implementation of review and other duties by the certified committee for regenerative medicine, the Minister may require the establisher to make necessary reports, may have the relevant officials enter the establisher's office to inspect its books, documents, and other items, or may question relevant persons.

(2) The provisions of Article 24, paragraph (3) apply mutatis mutandis to the on-site inspection under the provisions of the preceding paragraph, and the provisions of paragraph (4) of the same Article apply mutatis mutandis to the authority granted under the provisions of the preceding paragraph.

(Compliance Order and Improvement Order)

Article 32 (1) When the Minister of Health, Labour and Welfare finds that a certified committee for regenerative medicine no longer meets any of the requirements specified in the items of Article 26, paragraph (4) (excluding the requirement in item (i) of the same paragraph, to the extent it relates to the provision plan for class III regenerative medicine, when the committee performs review and other duties exclusively related to that plan), the Minister

may order the establisher of the certified committee to take necessary measures to ensure compliance with these requirements.

(2) Beyond what is prescribed in the preceding paragraph, when the Minister of Health, Labour and Welfare finds that the establisher of the certified committee has violated the provisions of this Chapter or any order or disposition issued based on its provisions, or otherwise determines that it is necessary to ensure the appropriate implementation of review and other duties by the certified committee for regenerative medicine, the Minister may order the establisher to improve the system for these duties, change the rules concerning these duties, or take other necessary measures.

(Revocation of Certification)

Article 33 (1) If the establisher of the certified committee falls under any of the following items, the Minister of Health, Labour and Welfare may revoke the accreditation referred to in Article 26, paragraph (1):

(i) when the accreditation under Article 26, paragraph (1), the approval for changes under Article 27, paragraph (1), or the renewal of the validity period under Article 28, paragraph (2) has been obtained through deception or other wrongful means;

(ii) when the established certified committee for regenerative medicine no longer meets any of the requirements specified in the items of Article 26, paragraph (4) (excluding the requirement stated in item (i) of the same paragraph, except for the part relating to the provision plan for class III regenerative medicine, in cases where the certified committee for regenerative medicine conducts review and other duties exclusively related to that plan);

(iii) when the establisher has come to fall under any of the items listed in Article 26, paragraph (5) (excluding items (iii) and (iv));

(iv) when the establisher has failed to make the report specified in Article 31, paragraph (1), has made a false report, has refused, obstructed, or evaded an on-site inspection under the provisions of the same paragraph, or has failed to respond without legitimate grounds or has provided a false response to the questions under the provisions of the same paragraph; or

(v) beyond what is stated in the preceding items, when the establisher has violated the provisions of this Chapter or any order or disposition issued based on its provisions.

(2) If the Minister of Health, Labour and Welfare revokes the accreditation referred to in Article 26, paragraph (1) pursuant to the provisions of the preceding paragraph, the Minister must issue public notice to that effect.

(Matters to Be Determined by the Order of the Ministry of Health, Labour and

Welfare)

Article 34 Beyond what is prescribed in this Chapter, any necessary matters concerning certified committee for regenerative medicine are specified by Order of the Ministry of Health, Labour and Welfare.

Chapter IV Manufacturing of Specific Processed Cells, Specific Nucleic Acids, and Related Compounds

(Permission for Manufacturing Specific Processed Cells, Specific Nucleic Acids, and Related Compounds)

Article 35 (1) A person intending to manufacture specific processed cells, specific nucleic acids, and related compounds (excluding those who are subject to the provisions of Article 40, paragraph (1)) must obtain permission from the Minister of Health, Labour and Welfare for each manufacturing facility that produces these products, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(2) A person intending to obtain the permission referred to in the preceding paragraph must submit a written application to the Minister of Health, Labour and Welfare, stating the following matters and attaching documents concerning the structure and equipment of the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds, as well as other documents specified by Order of the Ministry of Health, Labour and Welfare, in accordance with its provision:

(i) the name and address of the applicant, and, if the applicant is a corporation, the name of its representative;

(ii) the name and career history of the administrator of the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds;

(iii) the type of specific processed cells, specific nucleic acids, and related compounds to be manufactured; and

(iv) other matters specified by Order of the Ministry of Health, Labour and Welfare.

(3) If the Minister of Health, Labour and Welfare determines that the structure and equipment of a manufacturing facility of specific processed cells, specific nucleic acids, and related compounds, as related to an application for the permission referred to in paragraph (1), do not conform to the standards specified in Article 42, the Minister must not grant the permission.

(4) If an applicant falls under any of the following items, the Minister of Health, Labour and Welfare may choose not to grant the permission prescribed in paragraph (1):

(i) a person whose permission has been revoked pursuant to the provisions of

Article 49, if three years have not passed from the date of the revocation (if the revoked party is a corporation, this includes any person who was an officer of the corporation within 60 days prior to the date of the notice under Article 15 of the Administrative Procedure Act concerning the revocation, provided that three years have not passed from the date of the revocation);

(ii) a person who has been sentenced to imprisonment or a more severe punishment, and for whom three years have not yet passed since completing the sentence or ceasing to be subject to its enforcement;

(iii) a person, other than those falling under the preceding two items, who has violated this Act; the Act on the Appropriate Provision of Hematopoietic Stem Cells for Transplantation (Act No. 90 of 2012); the Act on Pharmaceuticals and Medical Devices; other pharmaceutical laws and regulations specified by Cabinet Order; or any disposition based on these laws and regulations, and for whom two years have not elapsed since the date of the violation; or

(iv) a corporation whose officers in charge of its business fall under any of the preceding three items.

(5) When an application for the permission referred to in paragraph (1) is filed, the Minister of Health, Labour and Welfare is to conduct a document-based or on-site investigation to determine whether the structure and equipment of the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds related to the application conform to the standards specified in Article 42.

(Renewal of Permission)

Article 36 (1) The permission referred to in paragraph (1) of the preceding Article, ceases to be effective upon the expiration of the relevant period unless it is renewed at intervals of no less than three years, as specified by Cabinet Order.

(2) The provisions of the preceding Article (excluding paragraph (1)) apply mutatis mutandis to the renewal of the permission referred to in the preceding paragraph.

(Notification of Changes)

Article 37 When a person who has obtained the permission referred to in Article 35, paragraph (1) (referred to below as the "permitted manufacturer") makes changes to the structure and equipment or other matters specified by Order of the Ministry of Health, Labour and Welfare concerning the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds related to the permission, the person must notify the Minister of Health, Labour and Welfare of such changes within 30 days.

(Investigations Conducted by the PMDA)

Article 38 (1) The Minister of Health, Labour and Welfare may have the Pharmaceuticals and Medical Device Agency (referred to below as "the PMDA") conduct the investigation referred to in Article 35, paragraph (5) (including as applied mutatis mutandis pursuant to Article 36, paragraph (2)) (simply referred to below as the "investigation" in this Article).

(2) When the Minister of Health, Labour and Welfare has the PMDA conduct an investigation pursuant to the provisions of the preceding paragraph, the Minister does not conduct the investigation separately. In this case, if the Minister grants the permission referred to in Article 35, paragraph (1) or renews the permission referred to in Article 36, paragraph (1), the Minister must take into account the results of the investigation notified by the PMDA pursuant to the provisions of paragraph (4).

(3) When the Minister of Health, Labour and Welfare decides to have the PMDA conduct an investigation pursuant to the provisions of paragraph (1), applicants for the permission referred to in Article 35, paragraph (1), or for the renewal of the permission referred to in Article 36, paragraph (1), must undergo the investigation conducted by the PMDA.

(4) When the PMDA conducts an investigation, it must notify the Minister of Health, Labour and Welfare of the results of the investigation without delay, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(5) With respect to a disposition related to an investigation conducted by the PMDA (excluding the results of the investigation) or to inaction concerning the investigation, a request for review may be made to the Minister of Health, Labour and Welfare. In such case, for the purposes of applying the provisions of Article 25, paragraphs (2) and (3); Article 46, paragraphs (1) and (2); Article 47; and Article 49, paragraph (3) of the Administrative Complaint Review Act (Act No. 68 of 2014), the Minister is deemed the higher administrative authority of the PMDA.

(Certification of the Manufacturing of Specific Processed Cells, Specific Nucleic Acids, and Related Compounds in Foreign Countries)

Article 39 (1) A person who intends to manufacture specific processed cells, specific nucleic acids, and related compounds in a foreign country for use in regenerative medicine in Japan may obtain certification from the Minister of Health, Labour and Welfare for each manufacturing facility of specific processed cells, specific nucleic acids, and related compounds, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(2) The provisions of Article 35 (excluding paragraph (1)) and the preceding three

Articles apply mutatis mutandis to the certification referred to in the preceding paragraph. In this case, the term "permission" in these provisions is deemed to be replaced with "certification", and any other necessary technical replacement of terms is specified by Cabinet Order.

(Notification of the Manufacturing of Specific Processed Cells, Specific Nucleic Acids, and Related Compounds)

Article 40 (1) A person who intends to manufacture specific processed cells, specific nucleic acids, and related compounds at a manufacturing facility that produces these products (limited to those established in hospitals or clinics; those classified as manufacturing facilities permitted under Article 13, paragraph (1) or Article 23-22, paragraph (1) of the Act on Pharmaceuticals and Medical Devices, or those used for umbilical cord blood supply services by a person permitted for such services under Article 30, paragraph (1) of the Act on the Appropriate Provision of Hematopoietic Stem Cells for Transplantation, as specified by Order of the Ministry of Health, Labour and Welfare; the same applies below in this Article) must notify the Minister of Health, Labour and Welfare of the following matters for each manufacturing facility of specific processed cells, specific nucleic acids, and related compounds, pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare:

(i) the name and address of the applicant, and, if the applicant is a corporation, the name of its representative;

(ii) the name and career history of the administrator of the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds;

(iii) the type of specific processed cells, specific nucleic acids, and related compounds to be manufactured; and

(iv) other matters specified by Order of the Ministry of Health, Labour and Welfare.

(2) The notification under the provisions of the preceding paragraph must be accompanied by documents regarding the structure and equipment of the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds relating to the notification, as well as other documents specified by Order of the Ministry of Health, Labour and Welfare.

(3) If a person who has made a notification under the provisions of paragraph (1) makes changes to the structure and equipment or other matters specified by Order of the Ministry of Health, Labour and Welfare regarding the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds relating to the notification, the person must notify the Minister of Health, Labour and Welfare of such changes within 30 days.

(Notification of Discontinuation)

Article 41 If a manufacturer of specific processed cells, specific nucleic acids, and related compounds discontinues the manufacture of these products, the manufacturer must notify the Minister of Health, Labour and Welfare of this within 30 days, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(Structural and Equipment Standards)

Article 42 The structure and equipment of manufacturing facilities that produce specific processed cells, specific nucleic acids, and related compounds must comply with the standards specified by Order of the Ministry of Health, Labour and Welfare.

(Appointment of Administrators)

Article 43 A manufacturer of specific processed cells, specific nucleic acids, and related compounds must, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare, appoint a person with biological expertise related to specific processed cells, specific nucleic acids, and related compounds, as well as other persons who meet the standards specified by the Order of the Ministry of Health, Labour and Welfare, for each manufacturing facility of specific processed cells, specific nucleic acids, and related compounds, and assign them to manage on-site manufacturing.

(Compliance Requirements for Manufacturers of Specific Processed Cells, Specific Nucleic Acids, and Related Compounds)

Article 44 The Minister of Health, Labour and Welfare may, by Order of the Ministry of Health, Labour and Welfare, specify the methods for manufacturing and quality control, testing and inspection, storage, and transportation of specific processed cells, specific nucleic acids, and related compounds at manufacturing facilities that produce these products, as well as other matters that manufacturers of specific processed cells, specific nucleic acids, and related compounds must comply with.

(Records on the Manufacturing of Specific Processed Cells, Specific Nucleic Acids, and Related Compounds and Their Retention)

Article 45 A manufacturer of specific processed cells, specific nucleic acids, and related compounds must, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare, prepare and maintain records regarding the type of specific processed cells, specific nucleic acids, and related compounds manufactured, the manufacturing process, and other matters specified by the Order of the Ministry of Health, Labour and Welfare.

(Periodic Reporting to the Minister of Health, Labour and Welfare)

Article 46 A manufacturer of specific processed cells, specific nucleic acids, and related compounds must periodically report the status of their manufacture to the Minister of Health, Labour and Welfare, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(Emergency Orders)

Article 47 When the Minister of Health, Labour and Welfare deems it necessary to prevent the occurrence or spread of public health hazards caused by the manufacturing of specific processed cells, specific nucleic acids, and related compounds, the Minister may order the manufacturer to temporarily suspend production and take other emergency measures to prevent such hazards.

(Improvement Order)

Article 48 (1) When the structure and equipment of a manufacturing facility of specific processed cells, specific nucleic acids, and related compounds—established by a permitted manufacturer or a person who has made a notification under the provisions of Article 40, paragraph (1) (referred to below as the "notified manufacturer")—fail to conform to the standards specified in Article 42, the Minister of Health, Labour and Welfare may order the permitted or notified manufacturer to make necessary improvements to the structure and equipment, or prohibit the use of all or part of the facility until such improvements are made.

(2) If a permitted manufacturer or a notified manufacturer violates any provision of this Chapter or any order or disposition issued based on its provisions, and the Minister of Health, Labour and Welfare deems it necessary to ensure the safety of and bioethical standards for regenerative medicine technologies and the proper provision of regenerative medicine, the Minister may order the permitted manufacturer or notified manufacturer to take necessary measures to improve the operation of its services.

(Revocation of Permission)

Article 49 If a permitted manufacturer falls under any of the following items, the Minister of Health, Labour and Welfare may revoke its permission or order the suspension of all or part of its business of manufacturing specific processed cells, specific nucleic acids, and related compounds for a specified period:

(i) when the structure and equipment of the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds under the permission no longer conform to the standards referred to in Article 42;

(ii) when the permitted manufacturer has come to fall under any of the items

in Article 35, paragraph (4); or

(iii) beyond the cases stated in the preceding two items, when the recipient of the delivery of goods violates this Act, the Act on the Appropriate Provision of Hematopoietic Stem Cells for Transplantation, the Act on Pharmaceuticals and Medical Devices, other pharmaceutical laws and regulations specified by Cabinet Order, or any disposition based on these Acts.

(Revocation of Certification)

Article 50 (1) If a person who has received the certification referred to in Article 39, paragraph (1) (referred to below as a "certified manufacturer" in this Article) falls under any of the following items, the Minister of Health, Labour and Welfare may revoke all or part of the certification that the person has received under the same paragraph:

(i) if the Minister of Health, Labour and Welfare finds it necessary and requests the certified manufacturer to make a necessary report pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare, and the certified manufacturer fails to make the report or makes a false report;

(ii) when the Minister of Health, Labour and Welfare finds it necessary and has attempted to have the relevant officials inspect the structure and equipment, or books, documents, and other items, and question the relevant persons at the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds or at the office related to the relevant certification of the certified manufacturer, and the persons have refused, obstructed, or evaded the inspection, or have failed to respond without legitimate grounds or provided false responses to the questions;

(iii) when the certified manufacturer has failed to respond to a request made under the provisions of Article 48 as applied mutatis mutandis pursuant to the following paragraph; or

(iv) when the certified manufacturer has violated any of the provisions of this Act, the Act on the Appropriate Provision of Hematopoietic Stem Cells for Transplantation, the Act on Pharmaceuticals and Medical Devices, other pharmaceutical laws and regulations specified by Cabinet Order, or any of the dispositions based on these.

(2) The provisions of Article 48 apply mutatis mutandis to certified manufacturers. In this case, the term "permission or notification" in paragraph (1) of the same Article is deemed to be replaced with "approval", the term "order, or prohibit the use of all or part of the manufacturing facilities that produce specific processed cells, specific nucleic acids, and related compounds until improvement is implemented" in the same paragraph is deemed to be replaced with "request", and the term "order" in paragraph (2) of the same Article is deemed to be replaced with "request".

(3) The Minister of Health, Labour and Welfare may have the PMDA conduct the inspection or questioning under paragraph (1), item (ii). In this case, the PMDA must, when having conducted the inspection or questioning, notify the Minister of Health, Labour and Welfare of the results of the inspection or questioning pursuant to the provisions of Order of the Ministry of Health, Labour and Welfare.

(Order for Suspension)

Article 51 The Minister of Health, Labour and Welfare may, if a notified manufacturer falls under any of the following items, order the notified manufacturer to suspend all or part of the business of manufacturing specific processed cells, specific nucleic acids, and related compounds for a specified period:

(i) when the structure and equipment of the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds relating to the notification no longer conform to the standards referred to in Article 42;

(ii) when the notified manufacturer has come to fall under any of the items in Article 35, paragraph (4); or

(iii) in addition to the cases stated in the preceding two items, when the notified manufacturer violates this Act, the Act on the Appropriate Provision of Hematopoietic Stem Cells for Transplantation, the Act on Pharmaceuticals and Medical Devices, other pharmaceutical laws and regulations specified by Cabinet Order, or any disposition issued based on these provisions.

(On-Site Inspections)

Article 52 (1) When the Minister of Health, Labour and Welfare finds it necessary to confirm whether the structure and equipment of the manufacturing facility of specific processed cells, specific nucleic acids, and related compounds established by the permitted or notified manufacturer, conform to the standards referred to in Article 42, the Minister may require the permitted or notified manufacturer to provide necessary reports, may have relevant officials enter the manufacturing facility or office to inspect the structure, equipment, books, documents, and other items, or may question relevant persons.

(2) Beyond what is prescribed in the preceding paragraph, when the Minister of Health, Labour and Welfare finds that specific processed cells, specific nucleic acids, and related compounds are manufactured in violation of the provisions of this Chapter or any order or disposition issued based on its provisions at a manufacturing facility, or finds it necessary to ensure the safety of and bioethical standards for regenerative medicine technologies and the proper provision of regenerative medicine, the Minister may require the manufacturer

to make necessary reports, may have relevant officials enter the manufacturing facility or office to inspect its structure, equipment, books, documents, and other items, or may question relevant persons.

(3) The provisions of Article 24, paragraph (3) apply mutatis mutandis to on-site inspections conducted under the provisions of the preceding two paragraphs, and the provisions of paragraph (4) of the same Article apply mutatis mutandis to the authority granted under the provisions of the preceding two paragraphs.

(On-Site Inspections by the PMDA)

Article 53 (1) The Minister of Health, Labour and Welfare may have the PMDA conduct an on-site inspection or make inquiries pursuant to the provisions of paragraph (1) or paragraph (2) of the preceding Article.

(2) When the PMDA has conducted an on-site inspection or made inquiries pursuant to the provisions of the preceding paragraph, it must notify the Minister of Health, Labour and Welfare of the results of the inspection or inquiries, pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(3) When an official of the PMDA conducts an on-site inspection or makes inquiries pursuant to the provisions of paragraph (1), the official must carry an identification card and present it to the relevant persons.

(Matters to Be Determined by the Order of the Ministry of Health, Labour and Welfare)

Article 54 Beyond what is prescribed in this Chapter, procedures and other matters necessary for the manufacturing of specific processed cells, specific nucleic acids, and related compounds are specified by Order of the Ministry of Health, Labour and Welfare.

Chapter V Miscellaneous Provisions

(Hearing the Opinions of the Health Science Council)

Article 55 The Minister of Health, Labour and Welfare must hear the opinions of the Health Science Council in advance in any of the following circumstances:

(i) when intending to propose the enactment, amendment, or repeal of the Cabinet Order referred to in Article 2, paragraph (2);

(ii) when establishing, amending, or repealing an Order of the Ministry of Health, Labour and Welfare referred to in Article 2, paragraph (2), item (i) or (ii), paragraph (7) or (8), or an Order of the Ministry of Health, Labour and Welfare that specifies a manufacturing facility of specific processed cells, specific nucleic acids, and related compounds referred to in Article 40, paragraph (1);

(iii) when intending to establish or change the provision standards for regenerative medicine; or

(iv) when intending to issue an order under the provisions of Article 8, paragraph (1) (including as applied mutatis mutandis pursuant to Article 10, paragraph (1)).

(Delegation of Authority)

Article 56 (1) The authority granted to the Minister of Health, Labour and Welfare under this Act may be delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(2) The authority delegated to the Director-General of a Regional Bureau of Health and Welfare pursuant to the provisions of the preceding paragraph may be further delegated to the Director-General of a Regional Branch Bureau of Health and Welfare pursuant to the provisions of the Order of the Ministry of Health, Labour and Welfare.

(Fees)

Article 57 (1) The persons specified in the following items must pay a fee in the amount set by Cabinet Order, taking into account the actual costs required for the review of the application provided for in those items:

(i) a person who applies for the renewal of the permission referred to in Article 36, paragraph (1); and

(ii) a person who applies for the renewal of the certification provided for in Article 36, paragraph (1), as applied mutatis mutandis pursuant to Article 39, paragraph (2).

(2) A person that intends to undergo an investigation conducted by the PMDA under Article 38, paragraph (1) (including as applied mutatis mutandis pursuant to Article 39, paragraph (2)) must pay a fee to the PMDA in the amount specified by Cabinet Order, taking into account the actual costs of the investigation.

(3) Fees paid to the PMDA pursuant to the provisions of the preceding paragraph are considered the revenue of the PMDA.

(Transitional Measures)

Article 58 When enacting, amending, or repealing a Cabinet Order or an Order of the Ministry of Health, Labour and Welfare pursuant to the provisions of this Act, necessary transitional measures (including those concerning penal provisions) may be specified by a Cabinet Order or an Order of the Ministry of Health, Labour and Welfare, to the extent deemed reasonably necessary for the enactment, amendment, or repeal.

Chapter VI Penal Provisions

Article 59 If an order under the provisions of Article 22 is violated, the person who has committed the violation is subject to imprisonment for a term of not more than three years, a fine of not more than three million yen, or both.

Article 60 (1) If a person falls under any of the following items, the person committing the violation is subject to imprisonment for a term of not more than one year or a fine of not more than one million yen:

(i) when a person, in violation of the provisions of Article 4, paragraph (1), provides class I regenerative medicine without submitting a provision plan for class I regenerative medicine, or submits such a plan that omits required information or contains false statements;

(ii) when a person, in violation of the provisions of Article 5, paragraph (1), provides class I regenerative medicine without submitting a revised provision plan for class I regenerative medicine, or submits such a plan that omits required information, or contains false statements;

(iii) when a person has violated an order issued under the provisions of Article 8, paragraph (1) (including as applied mutatis mutandis pursuant to Article 10, paragraph (1));

(iv) when a person has violated the provisions of Article 9 (including as applied mutatis mutandis pursuant to Article 10, paragraph (1));

(v) when a person has provided class I regenerative medicine in violation of the provisions of Article 13; or

(vi) when a person has violated an order issued under the provisions of Article 23, paragraph (2) (limited to the part relating to class I regenerative medicine).

(2) A person who discloses any confidential information in violation of the provisions of Article 29 is subject to imprisonment for a term of not more than one year or a fine of not more than one million yen.

Article 61 If a person falls under any of the cases referred to in the following items, the person committing the violation is subject to imprisonment for a term of not more than six months or a fine of not more than 300,000 yen:

(i) when the person manufactures specific processed cells, specific nucleic acids, and related compounds without obtaining permission, in violation of the provisions of Article 35, paragraph (1);

(ii) when the person violates an order issued pursuant to the provisions of Article 47;

(iii) when the person violates a disposition prohibiting the use of

manufacturing facilities that produce specific processed cells, specific nucleic acids, and related compounds under the provisions of Article 48, paragraph (1) (limited to dispositions against permitted manufacturers);

(iv) when the person violates an order issued pursuant to the provisions of Article 48, paragraph (2) (limited to orders issued to permitted manufacturers); or

(v) when the person violates an order issued pursuant to the provisions of Article 49.

Article 62 If a person falls under any of the cases referred to in the following items, the person committing the violation is subject to a fine of not more than 500,000 yen:

(i) when the person provides regenerative medicine, in violation of the provisions of Article 4, paragraph (1), without submitting a provision plan for regenerative medicine, or submits such a plan that omits required information or contains false statements (excluding cases falling under the provisions of Article 60, paragraph (1), item (i));

(ii) when the person provides regenerative medicine in violation of the provisions of Article 5, paragraph (1), without submitting a revised provision plan for regenerative medicine, or submits such a plan that omits required information or contains false statements (excluding cases falling under the provisions of Article 60, paragraph (1), item (ii));

(iii) when regenerative medicine is performed in violation of the provisions of Article 13 (excluding cases falling under the provisions of Article 60, paragraph (1), item (v));

(iv) when the person fails to prepare a record or prepares a false record in violation of the provisions of Article 16, paragraph (1);

(v) when the person fails to preserve records in violation of the provisions of Article 16, paragraph (2);

(vi) when the person violates an order issued pursuant to Article 23, paragraph (2) (excluding the part relating to class I regenerative medicine); or

(vii) when the person fails to report as required under Article 24, paragraph (1) or (2), makes a false report, refuses, obstructs, or evades an on-site inspection under the provisions of paragraph (1) or (2) of the same Article, fails to respond without legitimate grounds, or provides a false response to questions under the provisions of paragraph (1) or (2) of the same Article.

Article 63 If a person falls under any of the cases referred to in the following items, the person committing the violation is subject to a fine of not more than 200,000 yen:

(i) when the person manufactures specific processed cells, specific nucleic acids,

and related compounds without making a notification, or makes a false notification, in violation of the provisions of Article 40, paragraph (1);

(ii) when the person violates a disposition prohibiting the use of manufacturing facilities that produce specific processed cells, specific nucleic acids, and related compounds under the provisions of Article 48, paragraph (1) (excluding dispositions against permitted manufacturers);

(iii) when the person violates an order issued pursuant to the provisions of Article 48, paragraph (2) (excluding orders issued to permitted manufacturers);

(iv) when the person violates an order issued pursuant to the provisions of Article 51; or

(v) when the person fails to report as required under Article 52, paragraph (1) or (2), makes a false report, refuses, obstructs, or evades an on-site inspection under the provisions of paragraph (1) or (2) of the same Article (including inspections conducted by the PMDA pursuant to the provisions of Article 53, paragraph (1)), fails to respond without legitimate grounds, or provides a false response to questions under the provisions of Article 52, paragraph (1) or (2) (including questions asked by the PMDA pursuant to the provisions of Article 53, paragraph (1)).

Article 64 When the representative of a corporation, or an agent, employee, or other worker of a corporation or individual, commits a violation referred to in Article 59, Article 60, paragraph (1), or any of the preceding three Articles in connection with the business of the corporation or individual, the corporation or individual is also subject to the fine prescribed in the relevant Article, in addition to the offender being punished.

Supplementary Provisions [Extract]

(Review)

Article 2 Within five years after this Act comes into effect, the government is to review the provisions of this Act, taking into account the status of its enforcement and any changes in the circumstances surrounding regenerative medicine, and is to take necessary measures based on the results of the review, if deemed appropriate.

Supplementary Provisions [Act No. 51 of June 14, 2024] [Extract]

(Review)

Article 2 (1) Targeting a period of two years after the enforcement of this Act, the government is to review how the Act on Ensuring the Safety of

Regenerative Medicine, as amended by the provisions of Article 1 (referred to below as the "New Act on Ensuring the Safety of Regenerative Medicine"), and other relevant laws should be applied to medical technologies. The government is also to take legislative and other necessary measures based on the results of the review, taking into consideration research and development related to advanced medical technologies using cell secretions, processed embryos produced through the fertilization of human sperm and unfertilized egg cells, and other such materials, as well as the provision of medical care using such technologies, and the status of regulations on such technologies in foreign countries.

(2) Targeting a period of five years after the enforcement of this Act, the government is to review the provisions of the respective Acts amended by this Act, taking into account the status of their enforcement, and is to take necessary measures based on the results of the review if it deems such measures necessary.