(Attachment)

Partial Amendment of Act on the Safety of Regenerative Medicine

1. Outline of the Act on the Safety of Regenerative Medicine

The current Act on the Safety of Regenerative Medicine (Act No. 85 of 2013) defines medical care with medical techniques which uses processed cells as "regenerative medicine," and when a healthcare facility entrusts the manufacturing of processed cells used in regenerative medicine, it must entrust the manufacturing of them to the following businesses. When entrusting to a business which manufactures them in a foreign country, it is limited to a business which has obtained accreditation by the Minister of Health, Labour and Welfare.

- A business which has given a notification to the Minister of Health, Labour and Welfare (when entrusting to a domestic healthcare facility).
- A business which has obtained license from the Minister of Health, Labour and Welfare (when entrusting to a business other than domestic healthcare facility).
- A business which has obtained accreditation by the Minister of Health, Labour and Welfare (when entrusting to a business which manufactures processed cells in a foreign country).

* Processed cells: Human or animal cells that underwent processing (e.g., culturing).

2. Outline of the amendment

Gene therapy, etc. which does not use processed cells (medical care which uses nucleic acid, etc.) will be added to the scope of the Act on the Safety of Regenerative Medicine, due to the partial amendment of the Act. Therefore, when entrusting the manufacturing of nucleic acid, etc. used for such medical care to a business which manufactures them in a foreign country, it will be limited to a business which has obtained accreditation by the Minister of Health, Labour and Welfare prescribed in the Act as well as processed cells used in regenerative medicine.

* Nucleic acid, etc.: Nucleic acid which is transferred into a person's cells within a same person's body, and an item which has a function to process an item that is closely related to expression of nucleic acid and other genes (including items containing these).

3. Proposed date of adoption

The day specified by Cabinet Order (within a period of one year from the day of promulgation).