1-1. Institutional Framework for Promoting the Future Implementation of Regenerative Medicine

Regenerative Medicine Promotion Act [Legislation by Diet members]
Approved on April 26, 2013 Promulgated and came into force on May 10, 2013

Aims at comprehensive promotion of policies on regenerative medicine from R&D to implementation

Daily practice

Swiffness

Safety

Clinical Research

Marketing

Act on the Safety of Regenerative Medicine

[Approved on Nov 20, 2013, promulgated on Nov 27, 2013] [Came into force on Nov 25, 2014]

Standards for institutions providing regenerative medicine and cell culturing and processing facilities are newly formed for the purpose of ensuring, etc., of the safety of regenerative medicine

Revised Pharmaceutical Affairs Act

[Approved on Nov 20, 2013, promulgated on Nov 27, 2013] [Came into force on Nov 25, 2014]

A revision is made to newly establish an approval and licensing system based on the characteristics of regenerative medical products, which accommodates early implementation of regenerative medicine.

Enables medical institutions to outsource cell culturing and processing to companies

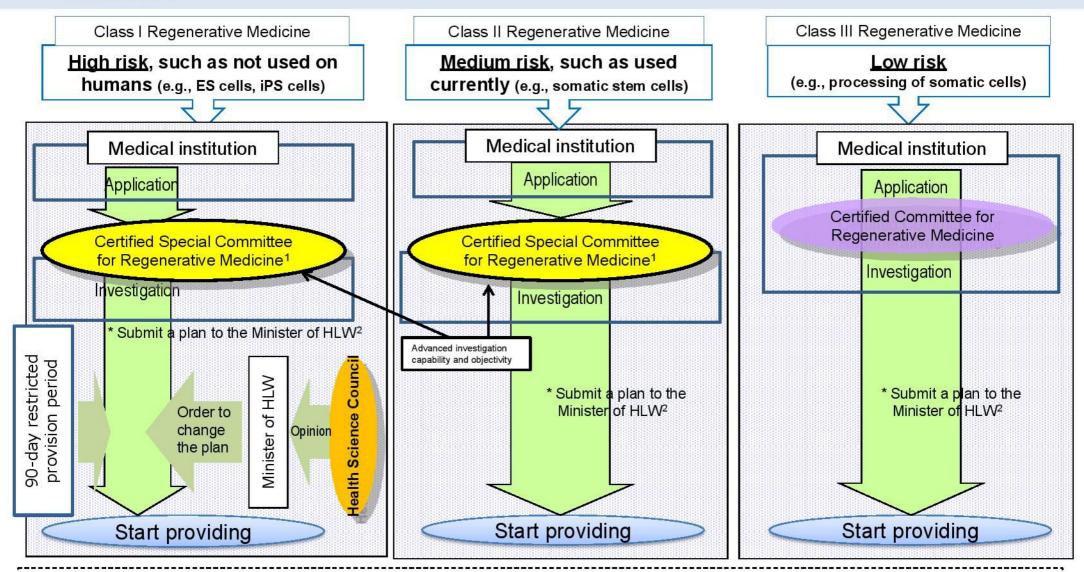
Implements an early approval system for regenerative medical products based on their characteristics

Stipulates three risk-dependent provision standards and procedures for notification of plans etc. for regenerative medicine as well as standards of cell culturing and processing facilities and licensing procedures, etc.

Adopts post-marketing safety measures such as obtaining informed consent from patients on the use of the product and recording and storing of information on treated people

Swift and smooth implementation of safe regenerative medicine

1-3. Risk-Dependent Procedure under the Act on the Safety of Regenerative Medicine



Note 1: "Certified Committee for Regenerative Medicine" is a council-type committee consisting of knowledgeable persons including experts on the technologies of regenerative medicine or legal matters, which is approved by the Minister of HLW through certain formalities. "Certified Special Committee for Regenerative Medicine" is the Certified Committee for Regenerative Medicine with specifically advanced investigation capability and objectivity.

Note 2: The procedure of submitting a provision plan will be obligated. Penalties will be imposed if regenerative medicine is provided without submitting a provision plan.