Establishment of the National Consortium for Regenerative Medicine and National Regenerative Medicine Database in Japan

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ABSTRACT

With its aim to regain the function of organs that are damaged by illness or injury, regenerative medicine has become the global focus of research. To accelerate the development and establishment of sufficient safety measures in regenerative medicine in Japan, the Pharmaceuticals and Medical Devices Act and the Act on Safety of Regenerative Medicine were enacted in 2014. Advancements in regenerative medicine are anticipated to draw attention toward the development of a system that consolidates and uses valuable data from studies performed from premarketing to postmarketing stages. Data gathered from premarketing to postmarketing stages of clinical research would promote new development avenues that would lead to the establishment of appropriate evaluation methods for new regenerative medical products by data validation. Against this background, the Japanese Society for Regenerative Medicine has been working to establish a national consortium for promoting regenerative medicine and constructing a large-scale clinical data registry, called the National Regenerative Medicine Database. This article aims to introduce the current framework of regenerative medicine in Japan, with a particular focus on the activity for establishment of a national consortium for regenerative medicine and the National Regenerative Medicine Database. (*Clin Ther*. 2018;■:1–8)

Key words: database, education, regenerative medicine, regulation.

INTRODUCTION

In 2014, the field of regenerative medicine in Japan witnessed a new era with the enactment of the Pharmaceuticals and Medical Devices Act and the Act on Safety of Regenerative Medicine.[1–3] The implementation of these laws has heightened public expectation for the development of regenerative medicine and has ushered in a new hope for the development of regenerative medicine–related products in the future. Moreover, the advancements in regenerative medicine are anticipated to draw attention toward the development of a system that consolidates and uses valuable data from clinical studies. Data gathered from premarketing to postmarketing stages of clinical research would promote a new development avenue that would lead to the establishment of an appropriate evaluation method for new regenerative medical products by validating the data. Against this background, the Japanese Society for Regenerative Medicine (JSRM) has been working to construct a large-scale clinical data registry and has established the National Regenerative Medicine Database (NRMD) in 2017.[4] Because the collaboration among the JSRM and some international societies is being promoted, this article aims to introduce the current framework of regenerative medicine in Japan, with a particular focus on the establishment of a national consortium for regenerative medicine and NRMD.

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NEW LEGISLATION FOR REGENERATIVE MEDICINE IN JAPAN

With its aim to regain the function of organs damaged by illness or injury, regenerative medicine has been the global focus of research. However, the use of living cells in regenerative medicine enhances the risk for bacterial or viral infection and tumorigenicity. Thus, the establishment of sufficient safety measures in regenerative medicine is imperative. To counter these problems, emergency economic policy measures (January 11, 2013; Japanese Cabinet decision) recommended by the government requested reexamination of the special reviewing system for regenerative medicine in 2013.[5] Following the policy recommendation, the Regenerative Medicine Promoting Act was implemented on April 26, 2013, which outlines the duty of the government and citizens of Japan to realize the concept of regenerative medicine.[6] Furthermore, the Act on Safety of Regenerative Medicine was enacted in 2014 to establish the legal basis for the guideline to ensure safety measures and promote collaboration between medical institutions and industry from the early stage of development.[2,7] The Act on Safety of Regenerative Medicine obligates health care professionals to notify the Ministry of Health, Labour and Welfare (MHLW) of their treatment plans, which in turn must be reviewed by a special committee certified by the MHLW (Figure 1). In addition, the medical institution can commission cell processing outside its institution, after obtaining approval for the process from the MHLW. In contrast, the Pharmaceutical Affairs Law was revised as the Pharmaceuticals and Medical Devices Act, which defines the category of regenerative medical products and the conditional and time-limited approval system, because the framework in the Pharmaceutical Affairs Law did not adequately describe the

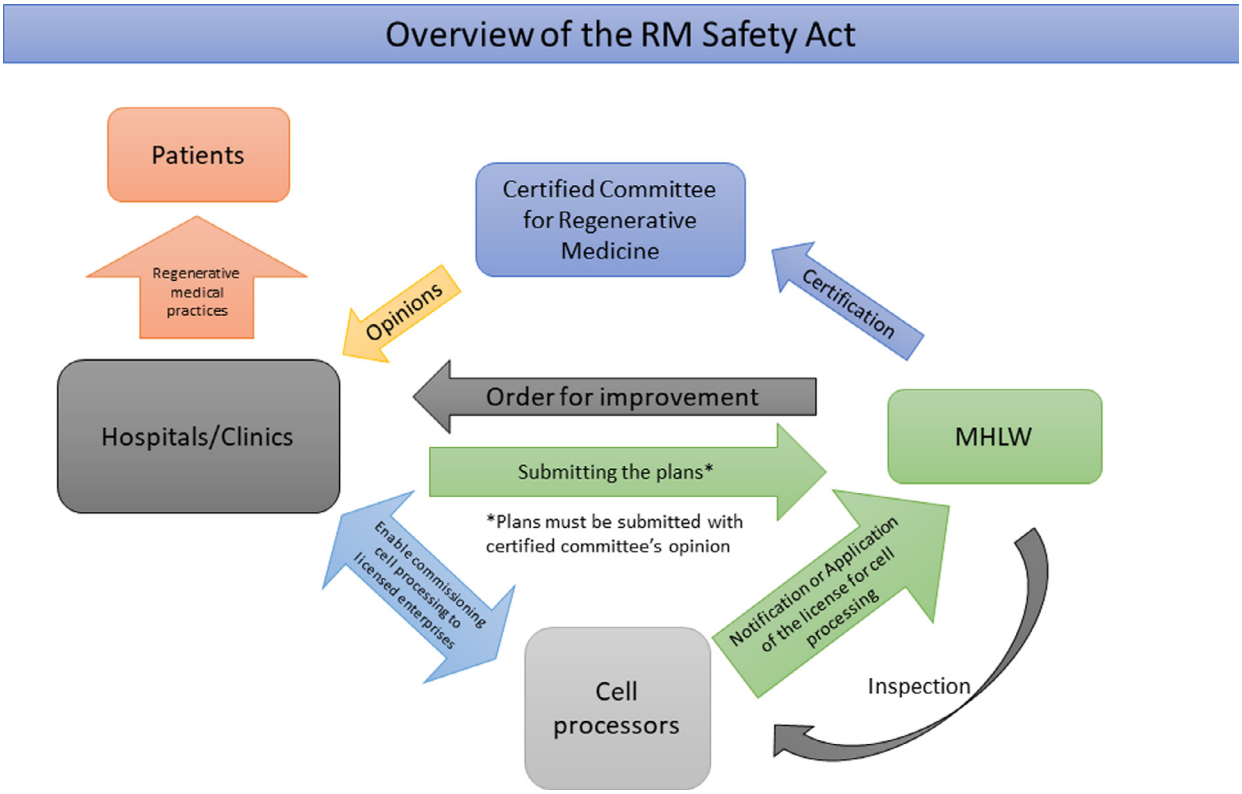

Figure 1. Overview of the Act on Safety of Regenerative Medicine. The act obligates health professionals to notify the Ministry of Health, Labour, and Welfare (MHLW) of their treatment plans, which in turn must be reviewed by a special committee certified by the MHLW. Conversely, the medical institution can commission cell processing outside its institution by obtaining process approval from the MHLW.