Published by
Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

PSEHB Notification No.0522-1
May 22, 2023

To: Prefectural Governors

Director-General of Pharmaceutical Safety and
Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Partial Revision of the "Instructions for Electronic Package Inserts of Regenerative Medical Products"

For precautions, etc. necessary for use and handling of regenerative medical products (hereinafter referred to as "information on PRECAUTIONS, etc."), the marketing authorization holder places a code, etc. necessary to obtain information on PRECAUTIONS, etc. on the container or wrapping, and then publishes the information on PRECAUTIONS, etc. by posting it on the website of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as the "PMDA"). The instructions of documents containing matters such as information on PRECAUTIONS, etc., which are published on the website of the PMDA, are shown in the "Instructions for Electronic Package Inserts of Regenerative Medical Products" (PSEHB Notification No. 0611-13 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated June 11, 2021, hereinafter referred to as "Director-General Notification").

Since the risk of transmission of infections cannot be completely eliminated for regenerative medical products made from human-derived cells and tissues, we have decided to provide information on the country of origin, and the appendix of the Director-General Notification will be revised as shown in the following old/new comparative table. Please take note of this, and inform the relevant organizations, etc. under your jurisdiction.

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(Revised language is underlined)

Revised	Current
1. and 2. (Omitted) 3. Instructions (1) to (6) (Omitted) (7) Shape, Structure, Ingredients, Quantity or Nature (Omitted) 1) to 3) (Omitted) 4) In cases where the products are manufactured using allogeneic human cell/tissue raw materials as raw materials (limited to the designated regenerative medical products), the name of the country where the cells or tissues as the allogeneic raw material, etc. were collected (8) to (18) (Omitted)	1. and 2. (Omitted) 3. Instructions (1) to (6) (Omitted) (7) Shape, Structure, Ingredients, Quantity or Nature (Omitted) 1) to 3) (Omitted) (N/A) (8) to (18) (Omitted)

N/A: Not Applicable. No corresponding language is included in the current Notification.