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Ministry of Health, Labour and Welfare

Translated by
Pharmaceuticals and Medical Devices Agency

PSEHB/PSD Notification No.0522-1
May 22, 2023

To Commissioners of Prefectural Health Departments (Bureaus):

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

Partial Revision of the "Instructions for Package Inserts of Regenerative Medical Products (Detailed Rules)"

The instruction was notified by PSEHB Notification No. 0522-1 by the Director-General of Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare, dated May 22, 2023 "Partial Revision of the "Instructions for Electronic Package Inserts of Regenerative Medical Products." The detailed rules (attached) are revised as shown in the following old/new comparative table. Please take note of this, and inform the relevant organizations, etc. under your jurisdiction.

(Revised language is underlined.)

Revised	Current
1. (Omitted) 2. Points to consider for each description item (1) to (6) (Omitted) (7) "Shape, Structure, Ingredients, Quantity or Nature" 1) to 3) (Omitted)	1. (Omitted) 2. Points to consider for each description item (1) to (6) (Omitted) (7) "Shape, Structure, Ingredients, Quantity or Nature" 1) to 3) (Omitted)

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4) Of the raw materials or materials contained in the regenerative medical product or used in the manufacturing process, the names of human- or animal-derived ingredients, the names of humans or animals as the raw materials of the product, the sites of use, etc. shall be described. When allogeneic human cells/tissues are used as raw materials (limited to designated regenerative medical products), the country where the allogeneic raw material is collected shall be described. If human blood is used as a raw material, the country where the blood is collected and the method of blood collection (blood donation or non-donation) shall be described. However, for raw materials or materials that are not covered by the Standard for Biological Ingredients (MHLW Notification No. 210, 2003), these descriptions are not required. The specific description method shall be as follows. [1] to [3] (Omitted) [4] When the product is manufactured using allogeneic human cells/tissues as raw materials (limited to designated regenerative medical products),	4) Of the raw materials or materials contained in the regenerative medical product or used in the manufacturing process, the names of human- or animal-derived ingredients, the names of humans or animals as the raw materials of the product, the sites of use, etc. shall be described. If human blood is used as a raw material, the country where the blood is collected and the method of blood collection (blood donation or non-donation) shall be described. However, for raw materials or materials that are not covered by the Standard for Biological Ingredients (MHLW Notification No. 210, 2003), these descriptions are not required. The specific description method shall be as follows. [1] to [3] (Omitted) (N/A)

describe the country where the allogeneic raw material is collected (in principle, all countries described in the approval document as countries where it is collected). (8) to (18) (Omitted)	(8) to (18) (Omitted)

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