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To Commissioners of Prefectural Health Departments (Bureaus):

Director of Policy Planning Division for Pharmaceutical Industry Promotion and Medical Information Management,
Health Policy Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)
Director of Pharmaceutical Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Labeling of Codes on Containers to Identify Regenerative Medical Products, etc.

The Act for Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 63 of 2019; hereinafter referred to as the “Amendment Act”) was promulgated on December 4, 2019, and the Ministerial Order on the Development of Relevant Ministerial Ordinance accompanying the partial enforcement of the Act for Partially Amending the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ministry of Health, Labour and Welfare (hereinafter referred to as the “MHLW”) Ordinance No. 128 of 2022) was just promulgated on September 13, 2022.

Pursuant to the provisions of Article 68-2-5 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960; hereinafter referred to as the "Act") revised by the Amendment Act, codes to identify pharmaceuticals, etc. shall be labeled on these containers in order to prevent accidents due to mishandling of pharmaceuticals, medical devices, or regenerative medical products, etc. (hereinafter referred to as “pharmaceuticals, etc.”), to ensure traceability, and to promote efficient distribution of pharmaceuticals, etc.

Labeling of codes on containers to identify regenerative medical products, etc. shall be handled as described in the Attachment. Please take note of this, and inform the relevant organizations under your jurisdiction.

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Attachment

Implementation Guidelines for Labeling of Codes on Containers to Identify Regenerative Medical Products, etc.

The labeling of codes on containers, etc. to identify regenerative medical products, etc. (hereinafter referred to as “identification code”) shall be implemented as described below in order to prevent accidents due to mishandling of regenerative medical products, etc. in medical care, to ensure traceability, and to promote efficient distribution of regenerative medical products, etc.

1. Products and data to be labeled

The labeling shall be applied to regenerative medical products, etc. (excluding regenerative medical products, etc. dedicated to manufacturing, etc.), and the product code, expiration date, and manufacturing number or manufacturing code shall be labeled as shown in the following table according to the type of the unit of packaging. (Note 1)

(1) Unit of individual packaging (Note 2)

Type of regenerative medical product, etc.	Product code	Expiration date	Manufacturing number or manufacturing code
Designated regenerative medical products, etc. (Note 3)	◎	◎	◎
Regenerative medical products, etc. (excluding designated regenerative medical products, etc.) (Note 3)	◎	○	○

(2) Unit of packaging to be sold (Note 4)

Type of regenerative medical product, etc.	Product code	Expiration date	Manufacturing number or manufacturing code
Designated regenerative medical products, etc.	●	●	●
Regenerative medical products, etc. (excluding designated regenerative medical products, etc.)	●	●	●

(3) Unit of original packaging (Note 5)

Type of regenerative medical product, etc.	Product code	Expiration date	Manufacturing number or manufacturing code
Designated regenerative medical products, etc. (Note 3)	◎	◎	◎
Regenerative medical products, etc. (excluding designated regenerative medical products, etc.) (Note 3)	◎	◎	◎

(Note 1) Each code shall be interpreted as follows.
"●" Information that shall always be labeled in accordance with Article 68-2-5 of the Act
"◎" Information that shall always be labeled in accordance with this notification
"○" Optional labeling
(Note 2) The unit of individual packaging shall mean the smallest unit of packaging that contains a regenerative medical product marketed by marketing authorization holders.
(Note 3) Labeling of identification codes shall be optional for sub-components used to collect cells or tissues (○).
(Note 4) The unit of packaging to be sold shall normally mean the smallest unit of packaging sold by wholesale distributors, etc. to medical institutions, etc.
(Note 5) The unit of original packaging shall normally mean the unit of packaging consisting of multiple units of packaging to be sold packed by marketing authorization holders. For example, it can be a cardboard box containing 10 boxes when a box is the unit of packaging to be sold. As a rule, the unit of original packaging shall be applied to products that are shipped unopened, and those not containing the specified units of packaging to be sold or those containing two or more types of units of packaging to be sold together shall be excluded.

2. Exception to labeling of identification codes on containers, etc.

In addition to the identification codes to be labeled in accordance with Article 68-2-5 of the Act, other identification codes shall be handled as follows.

a. Regenerative medical products, etc. packed in containers, etc. with small surface area

Identification codes shall be included in the document that accompanies the relevant regenerative medical products, etc. (Article 228-10-10-1-1 of Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (MHLW Ordinance No. 1 of 1961. (Hereinafter referred to as the “Enforcement Regulation of the Act”))

b. Regenerative medical products, etc. for export

Labeling of identification codes on containers, etc. shall not be required. (Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Cabinet Order No. 11 of 1961 Article 74-2)

c. Regenerative medical products, etc. with emergency approval or special approval

When it is unavoidable, such as when there is a risk that labeling identification codes may hinder the securing of distribution, labeling on containers, etc. shall not be required. (Article 228-10-10-2 of the Enforcement Regulation of the Act)

Labeling shall be placed as soon as it becomes available.

d. Regenerative medical products, etc. for manufacturing only

Labeling of identification codes on containers, etc. shall not be required as the product is sold to manufacturers.

(Article 228-10-10-3-4 of the Enforcement Regulation of the Act)

3. Product code

(1) GS1 product code (GTIN: Global Trade Item Number) shall be used for the product code. (To be more specific, GTIN-13 (those commonly referred to as JAN codes in Japan), and GTIN-14 or GTIN-12)

(2) GTIN that has been used in the past shall not be reused for other regenerative medical products, etc., even if the products with the relevant GTIN have been discontinued.

4. Changing GTIN

Cases regarding whether GTIN needs to be changed or not be changed are shown in the following table.

		GTIN for individual packaging	GTIN for packaging to be sold
1	When the brand name is changed through an application for change of the brand name	Required	Required
2	When accessory ingredients or their amounts are changed (excluding the cases falling under newly structured regenerative medical products, etc.)	Not required	Not required
3	When the shape or size is changed (As a rule, this is only applicable when an electronic package insert is revised and an application for approval of partial changes is approved.)	Required	Not required
4	When the content or design of the labeling for the unit of individual packaging or the unit of packaging to be sold is changed	Not required	Not required
5	When a distributor changes its name	Not required	Not required

6	When a distributor is changed (excluding cases of merger or absorption.)	Required	Required

(Note 1) Each code shall be interpreted as follows.
"○": GTIN needs to be changed.
"×": GTIN shall not be changed.
(Note 2) There may be cases that do not fall under the above requirement as to whether a change of GTIN is necessary, depending on individual circumstances.

5. Barcode symbol system

For barcodes or two-dimensional codes, an appropriate barcode among GS1 DataBar Limited/Stacked, their composite symbol (CC-A), GS1-128 symbol, and GS1 DataMatrix shall be used.

6. Order of notation of the data elements and GS1 application identifier

For the order of notation of the data elements and GS1 application identifier, the following shall be recommended, based on JIS X0531 (information technology - automatic identification and data acquisition technology - GS1 application identifiers and ASC MH10 data identifiers and their management).

Elements of data	Order of notation	GS1 application identifier
Product code	1	01
Expiration date	2	17 or 7003
Manufacturing number or manufacturing code	3	10 or 21

7. Applicable period

This shall be applied to products for which decisions for release are made by the marketing authorization holder on or after December 1, 2022.

8. Other

(1) It is desirable that, among the information shown by the identification codes, the management and operation of product codes that identify regenerative medical products, etc. be centralized so that they can be used smoothly at medical institutions, etc. For this reason, the distributors of each product shall register these product codes with the Medical Information System Development Center, and the center shall manage the product codes and provide the data to medical institutions, etc.

(2) Depending on the packaging form of individual packaging, it may be difficult to read the label when it is directly on the packages. For such cases, it is acceptable to affix, per unit of dispensing packaging, at least one multi-layered sticker printed with the identification code and the brand name, etc., which can be removed one by one, on a secondary container or a container of the unit of packaging to be sold.