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September 13, 2022

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 Medical Devices, *In Vitro* Diagnostics, etc.

The Act 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 Partially Amending the Act 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.

Barcode labeling on medical devices, *in vitro* diagnostics, consumable materials used repeatedly for medical care exclusively at medical institutions (hereinafter referred to as "medical devices, etc.") has been handled in accordance with "Implementation of Barcode Labeling on Medical Devices, etc." (HPB/EAD Notification No. 0328001 of March 28, 2008, Notifications issued by the Director of Economic Affairs Division, Health Policy Bureau, MHLW. Hereinafter referred to as the "previous notification")

Labeling of codes on containers to identify medical devices pursuant to the provisions of Article 68-2-5 of the Act on Securing Quality, Efficacy and Safety of Products Including

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Pharmaceuticals and Medical Devices (Act No.145 of 1960; hereinafter referred to as the "Act") amended by the Amendment Act shall be handled as described in the Attachment. Please take note of this and inform the relevant organization under your jurisdiction.

The previous notification will be discontinued as of November 30, 2022.

The titles, etc. of the previous notification cited in the “Registration, etc. in the Database of Medical Devices, Associated with the Labeling Barcodes on Medical Devices, etc.” (PSEHB/MDED Notification No. 1128-1, PSEHB/PSD Notification No. 1128-7 of November 28, 2017, Joint Notifications by the Director of Medical Device Evaluation Division, and the Director of Pharmaceutical Safety and Environmental Health Bureau, MHLW, and the Director of Pharmaceutical Safety Division) shall be replaced by this notification.

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Attachment

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

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

1. Definitions of terms

(1) Product code

The product code shall be fixed information that uniquely identifies the individual packaging unit and product itself, such as a medical device, etc. It shall be GTIN (Global Trade Item Number), the identification code for GS1. (To be more specific, it shall be GTIN-13 (those commonly referred to as JAN codes in Japan), GTIN-14 or GTIN-12.)

(2) Manufacturing identifier

Manufacturing identifier shall mean variable information that is specific to the manufacture, such as validity/expiration date, lot number, or serial number (or version number in the medical device program).

(3) Individual packaging

Individual packaging shall mean the smallest unit of packing style, and containers or wrappings that directly pack the contents.

(4) Packaging to be sold

Packaging to be sold shall normally mean the smallest packaging unit sold to medical institutions by wholesalers, etc. (minimum unit of sale). When an individual packaging is the minimum unit of sales, it shall also be treated as the packaging to be sold.

(5) Original packaging

Original packaging shall normally mean the packaging containing multiple packaging to be sold packed by marketing authorization holders. In principle the original packaging shall be applied to products that are shipped unopened, and those not containing the specified quantity of packaging to be sold or those containing two or more types of packaging to be sold together shall be excluded.

2. Target medical devices, etc.

(1) Medical devices. However, the following shall be excluded.

[1] Medical devices provided primarily for the ordinary use of general consumers

[2] Medical devices for manufacturing only

However, for reusable vision-correcting colored contact lenses, reusable vision-correcting contact lenses, single-use vision-correcting contact lenses, single-use vision-correcting colored contact lenses, reusable non-vision-correcting colored contact lenses, and single-use non-vision correcting colored contact lenses (hereinafter referred to as “contact lenses”), this notification shall be applied, although Article 68-2-5 of the Act shall not apply to contact lenses.

(2) *In vitro* diagnostics (excluding *in vitro* diagnostics that are OTC drugs.)

(3) Consumable materials used repeatedly for medical care exclusively at medical institutions, which are other than (1) - (2).

3. Exception to the 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.

(1) Medical devices

a. Medical devices packed in containers, etc. with small surface area

Identification codes shall be included in the document that accompanies the relevant medical devices. (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. Medical devices that cannot be packed in containers, etc. due to their structure and properties.

It shall be provided in a way that the users and other relevant parties can appropriately obtain information contributing to the identification of the relevant medical devices while the devices are in use. (Article 228-10-10-1-4 of the Enforcement Regulation of the Act)

c. Medical device programs provided via telecommunication lines

Those programs are to be provided by the following method [1] or [2]. (Article 228-10-10-1-5 of the Enforcement Regulation of the Act)

[1] The distributor of the relevant medical device program shall provide information that contributes to the identification of the relevant medical device to those who use the relevant medical device program before the parties who use the program receive the program through telecommunication lines.

[2] The marketing authorization holder of the medical device program shall provide electronic records containing information that contributes to the identification of the medical device together with the relevant medical device program to those who use the relevant medical device program in a manner that can be easily viewed by the parties who use the program.

d. Medical devices for export

Labeling identification codes on containers, etc. shall not be required. (Article 74-2-2 of the 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; hereinafter referred to as the "Enforcement Order of the Act"))

e. Medical devices 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 possible.

(2) *In vitro* diagnostics

a. *In vitro* diagnostics packed containers, etc. with small surface area

Identification codes shall be included in the document that accompanies the relevant *in vitro* diagnostics. (Article 228-10-10-1-1 of the Enforcement Regulation of the Act)

b. *In vitro* diagnostics for export

Labeling identification codes on containers, etc. shall not be required. (Article 74-2 of the Enforcement Order of the Act)

c. *In vitro* diagnostics 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 possible.

4. Products and data to be labeled

Identification codes including the product codes (Note 1) and the manufacturing identifier (Note 2) shall be labeled per unit of packaging according to the type of medical devices, etc. as shown in the following (Note 3).

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(1) Medical devices that fall under special treatment materials

No.	Classification	Individual packaging (Note 4)		Packaging to be sold		Original packaging	
		Product code	Manufacturing identifier	Product code	Manufacturing identifier	Product code	Manufacturing identifier
1	Implantable medical devices	◎	◎	●	●	◎	◎
2	Single-use medical devices other than 1	◎	◎	●	●	◎	◎
3	Reusable medical devices other than 1	◎	◎	●	●	◎	◎

(2) Medical devices that fall under specially controlled medical devices or specially designated maintenance-and-management-required medical devices other than (1)

No.	Classification	Individual packaging (Note 4)		Packaging to be sold		Original packaging	
		Product code	Manufacturing identifier	Product code	Manufacturing identifier	Product code	Manufacturing identifier
4	Implantable medical devices	○	○	●	●	◎	◎
5	Single-use medical devices other than 4 (Note 5)	○	○	●	●	◎	◎
6	Reusable medical devices other than 4 (Note 5)	○	○	●	●	◎	◎

(3) Medical devices other than (1) and (2)

No.	Classification	Individual packaging (Note 4)		Packaging to be sold		Original packaging	
		Product code	Manufacturing identifier	Product code	Manufacturing identifier	Product code	Manufacturing identifier
7	Implantable medical devices	○	○	●	● (Note 6)	◎	◎
8	Single-use medical devices other than 7	○	○	●	● (Note 6)	◎	◎
9	Reusable medical devices other than 7	○	○	●	● (Note 6)	◎	◎

(4) *In vitro* diagnostics

No.	Individual packaging (Note 4)		Packaging to be sold		Original packaging	
	Product code	Manufacturing identifier	Product code	Manufacturing identifier	Product code	Manufacturing identifier
10	○	○	●	●	◎	◎

(5) Consumable materials used repeatedly for medical care exclusively at medical institutions, which are other than (1) - (4).

No.	Individual packaging (Note 4)		Packaging to be sold		Original packaging	
	Product code	Manufacturing identifier	Product code	Manufacturing identifier	Product code	Manufacturing identifier
11	○	○	◎	○	◎	○

(Note 1) 1. (1) shall be referred to for the specifications to be used for the product codes.

(Note 2) 1. (2) and 5. shall be referred to for the items to be used for the manufacturing identifier.

(Note 3) 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 4) [1] When individual packaging is the minimum unit of sales, the conditions for the labeling on the package to be sold shall be applied.
[2] For medical devices that cannot be stored in containers, etc. due to their structure or properties, the conditions for the labeling on the package to be sold shall be applied.
[3] When there is a packaging form between the individual packaging and the packaging to be sold, the conditions for the labeling of the individual packaging shall be applied to the labeling on the packaging form.

(Note 5) Labeling of the product code and manufacturing identifier for contact lenses shall be mandatory（◎） on the packaging to be sold and optional（○）on individual packaging and original packaging.

(Note 6) When individual packaging is the minimum unit of sales, labeling of the manufacturing identifier for the package to be sold shall be optional（○）.

5. Labeling of the expiration date of manufacturing identifier

For the validity/expiration date, the final expiration date for the use of the relevant medical devices, etc. shall be labeled. (In YYMMDD format - ISO - 8601 format. The year shall be shown as the last two digits of the Western calendar year, and the month and date shall be shown as two digits each. When no date is set, the date shall be 00 or the last date of the relevant month.) This shall apply to those products which have an expiration date because they are assured for sterilization for a limited period, they may deteriorate over time, etc. However, this shall not apply to the “service life” of durable medical devices.

6. Barcode symbol system

For barcodes or two-dimensional codes (hereinafter referred to as “codes, etc.”), GS1-128 symbols or GS1 DataMatrix shall be used. However, for products in which GS1 DataBar Limited/Stacked, or their composite symbol (CC-A), are currently used at the time of issuance of this notification, GS1 DataBar Limited/Stacked, or their composite symbol (CC-A), may be used for the time being.

If there are any questions regarding codes, etc., refer to the following GS1 Japan website, etc.

https://www.gs1jp.org/standard/barcode/ (in Japanese)
https://www.gs1jp.org/en/about/index.html (in English)

7. Applicable period

(1) Medical devices (excluding contact lenses), *in vitro* diagnostics, and consumable materials other than medical devices

This shall be applied to products for which decisions for release are made by the marketing authorization holders (or distributors of consumable materials used repeatedly for medical care exclusively at medical institutions) on or after December 1, 2022.

(2) Medical devices (limited to contact lenses)

This shall be applied to products for which decisions for release are made by the marketing authorization holders on or after December 1, 2025.

8. Database registration

Since it is necessary to collectively manage the handling of information to be shown by identification codes, marketing authorization holders of medical devices and *in vitro* diagnostics, as well as manufacturers, etc. of consumable materials used repeatedly for medical care exclusively at medical institutions, shall register the data related to the relevant product at the time of shipment of the products with the identification code in the database for medical devices that is publicly available.