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PSEHB/PSD Notification No.0913-01
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 Prescription Drugs

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 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.

Barcode labeling on prescription drugs has been handled in accordance with the Partially Amending of the "Implementation Procedures for Barcode Labeling on Prescription Drugs." (HPB/EAD Notification No. 0830-1, PSEHB/PSD Notification No. 0830-1, PSEHB/CND Notification No. 0830-1 of August 30, 2016. Notifications issued by the Director of Economic Affairs Division, Health Policy Bureau, MHLW, the Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW, the Director of Compliance and Narcotics Division, Pharmaceutical Safety and Environmental Health Bureau, MHLW. Hereinafter referred to as the “previous notification”)

Labeling of codes on containers to identify prescription drugs 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 shall be handled as described in the Attachment. Please take note of this, and inform the relevant organizations under your jurisdiction. The previous notification will be discontinued as of November 30, 2022.

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Attachment

Implementation Guidelines for Labeling of Codes on Containers to Identify Prescription Drugs

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

1. Products and data to be labeled

The labeling shall be applied to prescription drugs (excluding *in vitro* diagnostics), and the product code, expiration date (Note 9), manufacturing number or manufacturing code, and quantity (Note 5) shall be labeled as shown in the following table according to the unit of packaging and the type of prescription drug. (Note 1)

(1) Unit of dispensing packaging (Note 2)

Type of prescription drug	Product code	Expiration date (Note 9)	Manufacturing number or manufacturing code
Specified biological products	◎	◎	◎
Biological products (excluding specified biological products.)	◎	○	○
Oral drugs (excluding biological products.)	◎	○	○
Injection drugs (excluding biological products.)	◎	○	○
Topical drugs (excluding biological products.)	◎	○	○

(2) Unit of packaging to be sold (Note 3)

Type of prescription drug	Product code	Expiration date (Note 9)	Manufacturing number or manufacturing code
Specified biological products	●	●	●

Biological products (excluding specified biological products.)	●	●	●
Oral drugs (excluding biological products.)	●	●	●
Injection drugs (excluding biological products.)	●	●	●
Topical drugs (excluding biological products.)	●	●	●

(3) Unit of original packaging (Note 4)

Type of prescription drug	Product code	Expiration date (Note 9)	Manufacturing number or manufacturing code	Quantity (Note 5)
Specified biological products	◎	◎	◎	◎
Biological products (excluding specified biological products.)	◎	◎	◎	◎
Oral drugs (excluding biological products.)	◎	◎	◎	◎
Injection drugs (excluding biological products.)	◎	◎	◎	◎
Topical drugs (excluding biological products.)	◎	◎	◎	◎

(Note 1) Each symbol 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 dispensing packaging shall mean the smallest unit of packaging of pharmaceuticals marketed by a marketing authorization holder. For example, it can be a blister pack or loose packaging in a bottle for tablets and capsules, and, for injections, it can be an ampule or a vial.

(Note 3) The unit of packaging to be sold shall normally mean the smallest unit of packaging sold by wholesale distributors, etc. to medical institutions, etc. For example, it can be a box containing 100 blister packs when a blister pack is the unit of dispensing packaging for tablets and capsules, and it can be a box containing 10 ampules of them for injections.

(Note 4) 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.

(Note 5) Quantity shall be the amount of the unit of packaging to be sold included in the unit of original packaging.

(Note 6) Labeling of identification codes on the unit of dispensing packaging for radiopharmaceuticals stored in lead containers to shield against radiation shall be placed on the lead containers.

(Note 7) Labeling of identification codes on samples of drug formulations shall not be required. When labeling an identification code on the unit of dispensing packaging, the same identification code as the product shall be labeled.

(Note 8) For medical gases, labeling of identification codes for liquid oxygen and liquid nitrogen stored in stationary cryogenic storage tank, and medical gases filled in portable cryogenic container or pressure-resistant hermetic containers shall not be required, except for product codes. For those gases that are difficult to get close to, such as stationary cryogenic storage tanks, product codes may be listed on nearby signboards, etc.

(Note 9) Labeling of the expiration date shall not be required for prescription drugs whose expiration dates are not specified in the approval document or marketing notification for products.

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. Pharmaceuticals whose areas of containers, etc. are too small to be labeled with their identification codes

A document with the identification code shall be attached to the relevant product. (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 (Order of the Ministry of Health and Welfare No. 1 of 1961. (Hereinafter referred to as the “Enforcement Regulation of the Act”))

b. Pharmaceuticals 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. Pharmaceuticals 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. Pharmaceuticals requiring guidance, OTC drugs, pharmacy-made drugs

These are purchased directly by customers and are not applicable to this measure. (Article 228-10-10-3-1 of the Enforcement Regulation of the

Act)

e. Gases for medical use (limited to those filled in containers to be managed by books under Article 60 of the High Pressure Gas Safety Act (Act No. 204 of 1951))

Under the High Pressure Gas Safety Act, there is already a system (system for recording and managing information on recipient of filling containers, date of delivery and receipt, etc. in books) in place to ensure traceability of high-pressure gas containers. Therefore, labeling of identification codes on containers, etc. shall not be required. (Article 228-10-10-3-2 of the Enforcement Regulation of the Act)

f. Pharmaceuticals dedicated to manufacturing

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 for the unit of dispensing packaging and GTIN-14 for the unit of packaging to be sold and the unit of original packaging shall be used.) When labeling a barcode, use a 14-digit code with a leading zero for the unit of dispensing packaging. The indicator (leading number) for GTIN-14 shall be “1” for the unit of packaging to be sold and “2” for the unit of original packaging.

(2) GTIN shall be assigned as follows.

・GTIN shall be assigned to each type of packaging unit (Note 1) for each drug. However, the product code for original packaging shall be the same as for packaging to be sold (Note 2). In addition, the product code for dispensing packaging shall be different from that for packaging to be sold.

・GTIN should be assigned by each distributor of the drug. However, the numbers for medical gases shall be assigned by each marketing authorization holder.

・GTIN that has been used in the past shall not be reused for other drugs, even if the products with the relevant GTIN have been discontinued.

(Note 1) For dispensing packaging, blister packs for 10 tablets and for 21 tablets shall be handled as different types.

(Note 2) Product codes, which are included in the GTIN code system, are numbers that indicate the differences between products.

4. Changing GTIN

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

		GTIN for dispensing packaging	GTIN for packaging to be sold
1	When the brand name remains unchanged, but the product name is changed to that with information on the dosage form and the content (or concentration, etc.) of active ingredients through an application for approval of a new substitute	Not required	Required
2	When the brand name is changed through an application for approval of a new substitute	Required	Required
3	When ingredients other than active ingredients or their amounts are changed	Not required	Not required
4	When the color, shape, or size of a drug product is changed (As a rule, this is only applicable when an electronic package insert is revised and an application for partial changes is approved.)	Required○	Not required
5	When the content or design of the labeling for unit of dispensing packaging or unit of packaging to be sold is changed	Not required	Not required
6	When shifting from the brand name listing to the unified name listing or from the unified name listing to the brand name listing in the National Health Insurance（NHI）drug price standard	Not required	Not required
7	When a distributor changes its name	Not required	Not required
8	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.

Example: ・When a biological product is no longer a biological product due to a change in additives

・When the color, shape, size, smell, or taste of a drug product is apparently changed

(Note 3) When changing the brand name (business name, etc.) of a product due to a change in the name of the marketing authorization holder, etc., 2 in the table shall be applied.

5. Barcode symbol system

The following barcodes or two-dimensional codes shall be used depending on the unit of packaging and data to be labeled.

(1) Dispensing packaging

When labeling the manufacturing number or manufacturing code and the expiration date in addition to the product code, GS1 DataBar Limited Composite Symbol with CC-A shall be used. GS1 DataBar Stacked Composite Symbol with CC-A may be used when the labeling area is small.

When labeling the product code only, GS1 DataBar Limited shall be used. GS1 DataBar Stacked may be used when the labeling area is small.

(2) Packaging to be sold

GS1 DataBar Limited Composite Symbol with CC-A shall be used. GS1 DataBar Stacked Composite Symbol with CC-A may be used when the labeling area is small.

(3) Original packaging

The GS1-128 symbol shall be used.

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

The order of notation of the data elements and GS1 application identifier are described in the following table, 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
Quantity	3	30
Manufacturing number or manufacturing code	4	10 or 21

7. Applicable period

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

8. Other

(1) It is desirable that, among the information shown by identification codes, the management and operation of product codes that identify drugs 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 the dispensing packaging unit, 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 stickers printed with an 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.

(3) For continuous inner packages such as blister pack, suppository container, and unit dose eye drops, the identification code shall be labeled in at least one place on each of the inner packages.
(4) For labeling of identification codes on inner packages (blister pack, single dose package, etc.) with an endless design, the labeling shall always be surrounded in a frame.