[MHLW Barcode Guideline for Drugs, June 29, 2012]

# Implementation Guideline for Bar Code Labeling of Prescription Drugs

Bar code labeling of prescription drugs (here in after referred to as “New Bar Code Labeling”) should be implemented as specified here in for promoting the prevention of accidents of mix-up of drugs, the assurance of traceability and the efficient supply chain of drugs.

## 1. Labeling items and data to be indicated

Prescription drugs (except in vitro diagnostic medical products) are subject to bar code labeling. A product code, expiration date, manufacturing No. or code and quantity are required to be indicated as shown below according to the unit of packaging form and the type of prescription drug (Note 1).

### (1) Dispensing package unit (Note 2)

| Type of prescription drugs | Product code | Expiration date | Manufacturing No. or code |
|---|---|---|---|
| **Specific biological products** | ◎ | ◎ | ◎ |
| **Biological product (excluding specific biological products)** | ◎ | ○ | ○ |
| **Oral medicine (excluding biological products)** | ◎ | ○ | ○ |
| **Injections (excluding biological products)** | ◎ | ○ | ○ |
| **External medicine (excluding biological products)** | ◎ | ○ | ○ |

### (2) Sales package unit (Note 3)

| Type of ethical drugs | Product code | Expiration date | Manufacturing No. or code |
|---|---|---|---|
| Specific biological products | ◎ | ◎ | ◎ |
| Biological products (excluding specific biological products) | ◎ | ◎ | ◎ |
| Oral medicine (excluding biological products) | ◎ | ○ | ○ |
| Injections (excluding biological products) | ◎ | ○ | ○ |
| External medicine (excluding biological products) | ◎ | ○ | ○ |

**(3) Original package unit (Note 4)**

| Type of ethical drugs | Product code | Expiration date | Manufacturing No. or code | Quantity (Note 5) |
|---|---|---|---|---|
| Specific biological products | ◎ | ◎ | ◎ | ◎ |
| Biological products (excluding specific biological products) | ◎ | ◎ | ◎ | ◎ |
| Oral medicine (excluding biological products) | ○ | ○ | ○ | ○ |
| Injections (excluding biological products) | ○ | ○ | ○ | ○ |
| External medicine (excluding biological products) | ○ | ○ | ○ | ○ |

(Note 1) "◎" means those which should be indicated (essential indication).
"○" means those which are not necessarily indicated (voluntary indication), however, as for sales package unit and original package unit, marketing business license holders are to implement New Barcode Labeling as it becomes available.

(Note 2) The dispensing package unit refers to the smallest unit of the package of drugs marketed by marketing business license holders; e.g. a PTP sheet and a pill bottle for tablets and capsules, and an ampule and vial for injections.

(Note 3) The sales package unit refers to, in general, the smallest package unit of drugs sold by wholesale distributors to medical institutions; e.g. a box containing 100 PTP sheets which are dispensing packages for tablets and capsules, and a box containing 10 ampules for injections.

(Note 4) The original package unit refers to a package unit that multiple sales packages are packed by marketing business license holders; e.g. a carton box containing 10 sales packages. Original packages are, in principle, shipped without opening. Boxes which do not contain the specified number of sales packages and boxes which contain assortment of 2 or more types of sales packages are not regarded as original packages.

(Note 5) The quantity refers to the number of sales package units included in an original package unit.

(Note 6) Prescription narcotic products do not need New Bar Code Labeling on the sales Package unit and original package unit.

(Note 7) New Bar Code Labeling on dispensing package unit of radio-active medicinal products in radiation shield lead containers should be done to radiation shield lead containers

(Note 8) Formulation samples do not need New Bar Code Labeling. In case of New Bar Code Labeling on dispensing package unit, the same bar code as the sales product should be labeled.

(Note 9) Clinical samples of medicinal products need New Bar Code Labeling on dispensing package unit, but do not need it on sales package unit and original package unit.

(Note 10) Of gases for medical use, liquid oxygen and liquid nitrogen stored in fixed cold tanks do not need New Bar Code Labeling.

(Note 11) Agents for intradermal tests of antibiotics, etc., need New Bar Code Labeling on dispensing package unit, but do not need it on sales package unit and original package unit.

**2. Product code**

(1) The Product code should be 14 digit codes consisting of a JAN (here in after referred to as “Common Product Code”) which is allocated to each type of package unit for the respective medicinal product and leading “0” for dispensing package unit, leading “1” for sales package unit and leading “2” for original package unit.

(2) Common Product Codes should be allocated as follows:

- Common Product Codes should be allocated to each type of package unit (Note) of the respective drug. However, the Common Product Code of an original package unit should be the same as that of the sales package unit. Therefore, the Common Product Code of a dispensing package unit should be different from that of the sales package unit.
- Common Product Codes should be allocated by each company that sells products. However, as for narcotic products for medical use and gases for medical use, Common Product Codes should be allocated by each company that manufactures and sells these products.
- A Common Product Code used in the past shall not be re-used again for at least 10 years after discontinuing the distribution of the drug for which the concerned Common Product Code was used. However, Common Product Codes used for specific biological products shall not be re-used.

(Note) In terms of dispensing package, a PTP sheets for 10 tablets and that for 21 tablets should be treated as different package types.

**3. Changes of Common Product Code**

The following table shows the cases of requiring a change or prohibiting a change of the Common Product Code.

| | | Common Product Code of dispensing package | Common Product Code of sales package |
|---|---|---|---|
| 1 | When the trade name was changed by adding the information on dosage form and the content (or concentration, etc.) of an active ingredient without changing the brand name by filing a substitute new approval application | × | ○ |

| | | | |
|---|---|---|---|
| 2 | When the brand name was changed by filing a substitute new approval application | ○ | ○ |
| 3 | When compositions other than an active ingredient or their contents were changed. | ✕ | ✕ |
| 4 | When the color, form and/or size of a dosage form was changed (in principle, in case that the package insert is revised and medical product marketing approval partial change approval is given). | ○ | ✕ |
| 5 | When the information and/or design of dispensing package unit or sales package unit were changed. | ✕ | ✕ |
| 6 | When the product was moved from the brand name listing to the generic name listing, or was moved from the generic name listing to the brand name listing in the drug tariff. | ✕ | ✕ |
| 7 | When the company selling the product changed its name. | ✕ | ✕ |
| 8 | When the company selling the product was changed (excluding the cases of merger and consolidation) | ○ | ○ |

(Note 1) ○: The Common Product Code needs to be changed.
X: The Common Product Code must not be changed.

(Note 2) Under certain circumstances, the above cases of Common Product Code changes are not applicable.

Ex. -When a biological product became no longer a biological product as the additive was changed.

-When the color, profile, dimension, smell, taste, etc., of the dosage form was changed obviously.

(Note 3) When product brand name (trade name, etc.) was changed because of the change of company name of the drug manufacturer, it is corresponding to No.2 of the table.

**4. Symbology of Bar Codes**

The following symbols should be used according to the packaging unit and the data to be indicated : GS1DataBar Stacked, GS1DataBar Limited, GS1DataBar Stacked Composite Symbol with CC-A or GS1DataBar Limited Composite Symbol with CC-A that are specified by the Japanese Industrial Standards X0509(Information technology－Automatic identification and data capture techniques－bar code symbology specification －GS1DataBar) or CODE 128 specified by the Japanese Industrial Standards X0504 (Bar code symbol－CODE128―Basic specifications).

(1) Dispensing package and sales package

In case that a manufacturing No. or code and an expiration date are indicated in addition to a product code, GS1DataBar Limited Composite Symbol with CC-A should be used. When the labeling space is small, GS1DataBar Stacked Composite Symbol with CC-A may be used.

In case that only a product code is indicated, GS1DataBar Limited should be used. When the labeling space is small, GS1DataBar Stacked may be used.

(2) Original package

CODE 128 should be used.

**5. Order for indicating data elements and application identifiers**

The order for indicating data elements and application identifiers shoud be as specified below in consideration of the Japanese Industrial Standards X0531 (Information technology - EAN/UCC Application Identifiers and FACT Data Identifiers and Maintenance).

| Data element | Order | Application identifier |
|---|---|---|
| Product code | 1 | 01 |
| Expiration date | 2 | 17 or 7003 |
| Quantity | 3 | 30 |
| Manufacturing No. or code | 4 | 10 or 21 |

**6. Timing for implementation of the New Bar Code Labeling**

(1) All packaging forms of specified biological products, biological products and injections (excluding biological products) or sales packages of oral medicines (excluding biological products) and external medicines (excluding biological products): labeling

should be made for all of those shipped out after September 2008 (or September 2009 for those with special reasons such as manufacturing is carried out only once a year) by marketing business license holders.

(2) The dispensing package units of oral medicines (excluding biological products) and external medicines (excluding biological products): labeling should be made for all of those shipped out after July 2015 (or July 2016 for those with special reasons such as manufacturing is carried out only once a year) by marketing business license holders.

**7. Others**

(1) The bar codes currently marked on the sales package units using the Japanese Industrial Standards X0501 (Bar code symbology-EAN/UPC-Basic specification) and those on the original package units using the Japanese Industrial Standards X0502 (Bar code symbol for dispatch unit code) should be ongoingly marked together with New Barcode Labeling on sales package units and original package units of prescription drugs at least until September 2013, and should not be marked on those shipped out after July 2015 (or July 2016 for those with special reasons such as manufacturing is carried out only once a year) by marketing business license holders.

(2) With regard to the product codes identifying drugs among data indicated with bar codes, it is desirable that they are collectively managed for the smooth utilization. Therefore each marketing business license holder of the products is required to register the product codes to the Medical Information System Development Center and the Center is to manage the product codes and provides them to medical institutions, etc.

(3)~(5) <<skip (Detailed or exceptional way of barcoding for dispensing unit packages)

(6)With regard to the data which are not essential indication for sales package unit and original package unit, marketing business license holders are to implement New Barcode Labeling as it becomes available by taking into consideration the status of barcode labeling and its use.