

# Implementation of Bar Code Labeling of Ethical Drugs

Bar Code labeling of ethical drugs (here in after referred to as “New Bar Code Labeling”) shall be implemented as specified here in for promoting the prevention of accidents of mix-up of drugs and assurance of traceability.

## 1. Labeling items and data to be indicated

Labeling items shall be ethical drugs. A product code, expiration date, manufacturing No. or code and quantity shall be indicated as mentioned below according to the units of packaging forms and types of ethical drugs (Note 1).

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

Type of ethical drug	Product code	Expiration date	Manufacturing No. or code
Specific biological product			
Biological product (excluding specific biological products)			
Oral medicine (excluding biological products)			
Injection (excluding biological products)			
External medicine (excluding biological products)			

Biological products : Medicine that extraction refinement is done from human and animals.

**(2) Marketing package unit (Note 3)**

Type of ethical drug	Product code	Expiration date	Manufacturing No. or code
Specific biological products			
Biological products (excluding specific biological products)			
Oral medicine (excluding biological products)			
Injection (excluding biological products)			
External medicine (excluding biological products)			

Biological products : Medicine that extraction refinement is done from human and animals

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

Type of ethical drug	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)				
Injection (excluding biological products)				
External medicine (excluding biological products)				

Biological products : Medicine that extraction refinement is done from human and

## animals

(Note 1) “ ” means those which shall be indicated (essential indication), and “ ” means those which are not necessarily indicated (voluntary indication).

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

(Note 3) The marketing package unit refers to, in general, the smallest package unit of drugs sold by wholesale distributors to medical institutions; i.e. a box containing 100 formulation package units of PTP sheets for tablets and capsules, and a box containing 10 ampules for injections.

(Note 4) The logistics package unit refers to a package unit that several marketing package units are packed by marketing business license holders; i.e. a carton box containing 10 marketing package units of boxes.

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

(Note 6) biological products :

Medicine that extraction refinement is done from human and animal

## 2. Numbering of product codes and JAN codes

(1) Product codes shall be given to each type of the packaging form of an individual drug.

The product code shall be placed before a JAN code, indicating “0” for the formulation package unit, “1” for the marketing package unit and “2” for the original package unit.

The code shall consist of 14 digits.

(2) The numbering of JAN codes shall be as follows:

- JAN codes shall be given to each type of the packaging form of an individual drug (Note). However, the same JAN codes as those of marketing packages shall be used for original packages. Therefore, the JAN codes of formulation packages shall be different from those of marketing packages.
- JAN codes shall be given by each company distributing products.
- JAN codes used in the past shall not be used again for at least 10 years after discontinuing the distribution of drugs for which the concerned JAN codes were used. However, JAN codes used for specific biological products shall not be reused.

(Note) In formulation packages, a PTP sheets for 10 tablets and that for 21 tablets shall be handled as different types.

### 3. Changes of JAN codes

In the cases of requiring a change or prohibiting a change of a JAN code shall be as follows:

		JAN code of formulation package	JAN code of marketing package
1	When changing to a brand name with 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 a 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 pharmaceutical preparation were changed (limited to changes of the color, appearance and size in the DESCRIPTION section of the package insert).	×	○
5	When the contents and/or design of the labeling of a formulation package container unit or marketing package unit are changed.	×	×
6	When a product is moved from the brand name listing to the unified name listing, or is moved from the unified name listing to the brand name listing in the drug tariff	×	×
7	When the name of a company distributing a product was changed.	×	×
8	When a company distributing a product was changed (excluding the cases of merger and consolidation)	○	○

(Note) ○: The JAN code shall be changed; X: The JAN code shall not be changed.

#### 4. Bar code symbol system

The following systems shall be used according to packaging forms and data to be indicated: the RSS-14 Stacked, RSS Limited, RSS-14 Stacked Composite Symbol with CC-A, or RSS Limited Composite Symbol with CC-A specified in the “Reduced Space Symbology and EAN.UCC Composite Symbology Specification” stipulated by the GS1, which is an international distribution standardization organization, or the CODE 128 specified by the Japan Industrial Standard (JIS) X0504 (Bar code symbol - CODE128 - Basic specifications).

##### (1) Formulation package and marketing package

When a manufacturing No. or code and expiration date are indicated in addition to a product code, the RSS Limited Composite Symbol with CC-A shall be used. When the labeling space is small, the RSS-14 Stacked Composite Symbol with CC-A may be used.

When only a product code is indicated, the RSS Limited shall be used. When the labeling space is small, the RSS-14 Stacked may be used.

##### (2) Original package

The CODE 128 shall be used.

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

The order for indicating data elements and application identifiers shall be as specified below in consideration of the JIS 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
Quantity	3	30
Manufacturing No. or code	4	10

#### 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 marketing packages of oral medicines (excluding biological products) and external medicines (excluding biological products): labeling shall be made for all of those shipped out after MMM/DD/200X (2 years from the Notification) (or MMM/DD/200X (3 years from the Notification) for those with special reasons such as manufacturing is carried out only once a year) by marketing business

license holders.

- (2) The formulation package units of oral medicines (excluding biological products) and external medicines (excluding biological products): The timing of its implementation shall be notified separately since technological development and other relevant operations for each packaging form have been carried out by related industry and other parties with the target of implementing the labeling in 3 to 5 years.

## **7. Others**

- (1) Currently, the bar codes indicated for the marketing package units using the JIS X0501 (Bar code symbol for uniform commodity code) and those indicating the original package units based on the JIS X0502 (Bar code symbol for dispatch unit code) shall be mentioned together with the New Bar Code Labeling for at least 5 years after implementing the New Bar Code Labeling for the marketing package units and original package units of ethical drugs.
- (2) With regard to the product codes identifying drugs among data indicated with bar codes, they are required to be managed collectively; it is specified by the related industrial organizations that the Medical Information System Development Center (hereinafter referred to as "MEDIS-DC") shall control the product codes and provide their data. Therefore, marketing business license holders are required to register prod