Regulation on Labels of Quasi-Drugs

KFDA Notification No. 2012-136 (Enacted on Dec. 28, 2012)
MFDS Notification No. 2013-32 (Revised on Apr. 05, 2013)
MFDS Notification No. 2014-99 (Revised on Feb. 26, 2014)
MFDS Notification No. 2014-154 (Revised on Sept. 4, 2014)
MFDS Notification No. 2015-10 (Revised on Mar. 17, 2015)
MFDS Notification No. 2015-112 (Revised on Dec. 30, 2015)
MFDS Notification No. 2016-114 (Revised on Oct. 12, 2016)

Article 1 (Purpose) The purpose of this notification is to set forth the matters related to recording methods, exceptions, etc. in recording quasi-drug container, packaging and attached leaflets in accordance with Article 65-2 of the Pharmaceutical Affairs Act (hereinafter referred to as “the Act”) and Article 75 Subparagraph 10 of the Enforcement Regulation on the Safety of Pharmaceuticals, etc. to provide accurate information of quasi-drugs.

Article 2 (Definition) The term "point" used in this document means the size of the print specified by Korea Industrial Standards KS A 0201 (Standard dimensions of print).

Article 3 (Scope of Application) The container, packaging or attached leaflets of quasi-drugs authorized or registered in accordance with Article 31 and Article 42 of the Act shall be labeled with the information in accordance with the method prescribed in these

regulations. However, this shall not apply to the quasi-drugs to be exported.

Article 4 (Labeling Requirements) ① The font size used for the necessary information in accordance with Article 65 of the Act and Article 74 of the Enforcement Regulation on the Safety of Pharmaceuticals, etc. shall be as follows.

1. Container and Package

a. Internal liquid formulation, internal solid formulation, ointment, cataplasma preparations, topical sprays and patches

1) Name of quasi-drug, manufacturing date or expiration date, and informative-labels such as "quasi-drug" shall be in font size 7 points or bigger

2) Information not prescribed in 1) shall be in font size 6 or bigger

b. Other dosage forms not prescribed in a

1) Name of quasi-drug, manufacturing date or expiration date and informative-labels such as "quasi-drug" shall be in font size 7 points or bigger

2) Name of manufacturer and/or importer and lot number shall be in font size 6 points or bigger

3) Other information not prescribed in 1) and 2) may be in font size less than 6 points.

2. For attached leaflets, the text shall be in font size 6 points and bigger

② The weight, volume or number of pill shall be labeled in the unit the quasi-drug is sold based on the authorized or registered information.

③ According to Article 65 Subparagraph 4 of the Act, for the

quasi-drugs not prescribed in Article 2 Subparagraph 7 Item B, manufacturing date format shall be printed by combining "manufacturing date" or "manufactured" and date (year (YY), month (MM) and day (DD) to be labeled as “manufacturing date: YY/MM/DD”, “YY.MM.DD” manufactured, “manufacturing date: YYYY/MM/DD”, “YYYY.MM.DD manufactured”, to prevent any confusion between manufacturing date and expiration date.

④ According to Article 65 Subparagraph 4 of the Act, for the quasi-drugs prescribed in Article 2 Subparagraph 7 Item B, expiration date format shall be printed by combining "exipration date" or "by" and date (year (YY), month (MM) and day (DD) to be labeled as “expiration date: YY/MM/DD”, “by YY.MM.DD”, “expiration date: YYYY/MM/DD”, “by YYYY.MM.DD”, etc. to prevent any confusion between expiration date and manufacturing date.However, if expiration date is labeled with manufacturing date as well, expiration date can be described as "○○ months from the manufacturing date" or "expiration date: ○○ years from the manufacturing date."

⑤ If a different order of the year, month and day is used, it shall be made recognizable by the customers by providing an example of the order on the container or packaging.

⑥ Required information shall be printed using ink, stamp or mark, etc., that is difficult to remove in easy-to-read Korean character fonts such as Gothic. The letters shall not overlap each other and be in a color that is distinguishable from the background color.

⑦ In case the information on dose & administration and other precautions in use that needs to be labeled on the container or packaging material as per Article 65 Paragraph 1 Subparagraph 8 of the Act and Article 74 Paragraph 2 of the Enforcement Regulation on the Safety of Pharmaceuticals, etc. is in fact provided in the attached

leaflets, then such information may be labeled on the container or packaging material in accordance with the Guide on Labelling and Display Order in Attached Table 1.

⑧ Information to be labeled additionally in the container or packaging by item is provided in Attached Table 2.

Article 5 (Labelling Exceptions) ① For quasi-drugs subject to Article 4 Paragraph 1 Subparagraph 1 Item A, the said provision may not be applied even if the information other than name of quasi-drugs and company name of manufacturer or importer is omitted according to Article 74 Paragraph 1 of the Enforcement Regulation on the Safety of Pharmaceuticals, etc., and some of information cannot be recorded because of small areas in the primary container or packaging.

② Despite Paragraph 1, for the container or packaging in which all of the information according to this regulation cannot be recorded in the area available for the necessary information, font size for name of quasi-drugs, manufacturing date or expiration date, and informative label of “quasi-drug” must be 7 points or bigger, and the size for company names of manufacturers or importers and lot number must be 6 points or bigger. However, the information other than the above may not be applied to Article 4 Paragraph 1 Subparagraph 1 Item A.

③ For quasi-drugs subject to Article 4 Paragraph 1 Subparagraph 1 Item B, the said provision may not be applied even if the information other than name of quasi-drug and company name of manufacturer or importer is omitted according to Article 74 Paragraph 1 of the Enforcement Regulation on the Safety of Pharmaceuticals, etc., and some of information cannot be recorded because of small areas in the primary container or packaging.

Article 6 (Recommendations) It is recommended that the following information shall be appropriately included, considering the product characteristics, users, etc. in order to provide information on the quasi-drugs that is accurate and easy-to-understand to consumers.

1. Provide the product name, expiration date, precautions in use, etc. of quasi-drugs in braille to allow proper use by visually impaired
2. Include the warning: "Keep the product out of the reach of children"
3. Include the warning: "Do not use quasi-drugs past their expiration date"
4. Use food-related pictures or animation characters on labelling of insecticides to prevent children from swallowing or poisoning accident
5. Include information related to detailed product approval or notification statement in the container or packaging (refer to company's website, or ‘Pharmaceuticals, etc. Information’ on the website of Electronic Civil Affairs Services for Pharmaceuticals provided by MFDS (ezdrug.mfds.go.kr) etc.)
6. Include the instruction: "Please read the attached leaflet, Retain the attached leaflet" if a document is included
7. Include the statement: "Since this product contains fluorine or ethanol, parental/adult guidance is needed for children's use" (limited in oral care products containing fluorine or ethanol (including dental wet tissue, mouthwash, toothpaste containing ethanol, etc.))
8. Important information in Attached Table 3 such as restriction on use of young children under a certain age on the container or packaging must be distinguishable from other information and located in noticeable place

Article 7 (Timeline of Re-examination) The Minister of MFDS shall

review the feasibility of this Notification and take actions such as improvement, etc. every three years as of January 1, 2016 (refer to December 31 of every third year) in accordance with the Regulation on Issue and Management of Instruction and the Established Rule, etc.

Addendum<No. 2012-136, Dec. 28, 2012>

This Notification shall take effect on the date of notification.

Addendum<No. 2013-32, Apr. 5, 2013>

Article 1 (Enforcement Date) This Notification shall take effect on the date of notification.

Addendum<No. 2014-99, Feb. 26, 2014>

This Notification shall take effect on the date of notification.

Addendum<No. 2014-154, Sept. 4, 2014>

Article 1 (Enforcement Date) This Notification shall take effect on the date of notification.

Article 2 (Transitional measures concerning the container or packaging of masks) The container or packaging labeled with information on masks from Subparagraph 1 Item B 1) of the Designation of Scope of Quasi-drugs (MFDS Notification No. 2013-175, April 5, 2013) which was effective before the enforcement of this Notification may be used for the manufacture of the applicable mask products until Feb. 28, 2015.

Article 3 (Revision of Other Notifications) In the Appendix of the

Standards and Analytical Methods of Quasi-drugs (MFDS Notification No. 2014-77, February 12, 2014) which was notified by the Minister of Food and Drug Safety with this Notification, “labeling information of quasi-drugs” shall be deleted.

Addendum<No. 2015-10, Mar. 17, 2015>

Article 1 (Enforcement Date) This Notification shall take effect on the date of notification.

Article 2 (Transitional measure concerning container or packaging) ① For the container or packaging of oral-care products containing ethanol which was manufactured before the enforcement of this Notification shall be deemed to have included the revised necessary information in accordance with Attached Table 2.

② The container or packaging labeled with the information according to the previous regulations may be used for the manufacture of respective products for one year from the enforcement date of this Notification.

Addendum<No. 2015-112, Dec. 30, 2015>

This Notification shall take effect on the date of notification.

Addendum<No. 2016-114, Oct. 12, 2016 >

Article 1 (Enforcement Date) This Notification shall take effect on the date of notification.

Article 2 (Application) This Notification shall be applied from quasi-drugs manufactured or imported for the first time after enforcement of this Notification.

Article 3 (Transitional measure concerning labelling instructions) If the

dose & administration and precautions in use were recorded in the outer container or packaging according to the previous Attached Table 1 before the enforcement of this Notification, they shall be regarded to have recorded according to the revised regulations in Attached Table 1.

[Attached Table 1] Guide on Labelling and Display Order including Precautions in Use in Container or Packaging by Product (in relation to Article 4 Paragraph 7)

1. Internal liquid formulation and internal solid formulation

<table>
<tr><th colspan="2">Information</th><th>Guide on Labelling and Display Order</th></tr>
<tr><td colspan="2">Dose & Administration</td><td>Dose & Administration
Describe briefly</td></tr>
<tr><td rowspan="8">Precautions in use</td><td></td><td>Precautions in Use</td></tr>
<tr><td>Warning</td><td>1. Warning
Describe briefly (human, ingredients, activity, etc.)</td></tr>
<tr><td rowspan="3">Contraindication</td><td>2. The following individuals should not use this product
Describe the individuals concerned briefly</td></tr>
<tr><td>3. The following products should not be used while using this product.
Describe the name of ingredients briefly</td></tr>
<tr><td>4. The following behaviors are banned while using this product
Describe the behaviors briefly</td></tr>
<tr><td rowspan="2">Discreet dosing</td><td>5. The following individuals should consult with a doctor, dentist or pharmacist before using this product
Describe the individuals concerned briefly</td></tr>
<tr><td>6. In the following situations, stop using this product immediately and consult with a doctor, dentist or pharmacist. Bring the attached leaflet, if possible, for consultation with a medical professional.</td></tr>
<tr><td>Other precautions in use</td><td>7. Other precautions in use of this this product
Describe briefly or add the statement: "please refer to the attached leaflet"</td></tr>
<tr><td>Storage instructions</td><td>8. Precautions in Storage
Describe briefly or add the statement: "please refer to the attached leaflet"</td></tr>
</table>

2. Quasi-drugs In Addition to Internal Liquid Formulations and Internal Solid Formulation

<table>
<tr><th colspan="2">Information</th><th>Guide on Labelling and Display Order</th></tr>
<tr><td rowspan="4">Precautions in use</td><td></td><td>Precautions in use</td></tr>
<tr><td>Warning</td><td>⚠ Warning
Describe briefly (Individuals, ingredients, behaviors, etc.)</td></tr>
<tr><td>Restriction</td><td>⃠ Restriction
Describe briefly (Individuals, ingredients, behaviors, etc.)</td></tr>
<tr><td>Precautions</td><td>⚠ Precaution
Describe briefly (Individuals, ingredients, behaviors, etc.)</td></tr>
<tr><td colspan="2"></td><td>Details of precautions in use and other precautions in use
Include a statement: “refer to attached leaflet or ‘Pharmaceuticals, etc. Information’ on the website of Electronic Civil Affairs Services for Pharmaceuticals provided by MFDS (ezdrug.mfds.go.kr) etc.”</td></tr>
</table>

a. Safety Sign Standards

1) Design model for warning, restriction and precaution signs

①
②

a) Instructions for sign in design

(1) Insert a symbol to distinguish ‘warning’, ‘restriction’ and ‘precaution’ on white background in ① and write letters of ‘warning’, ‘restriction’ and ‘precaution’ in black.

(2) For safety signs shown in ②, Summarize the details of precautions in black out of white background, and font size shall be 10 points or bigger.

b) Guide on Labelling and Criteria of Symbols and Letters in Design

Description	**Symbol**	**Specifications**
Warning		- Angle of triangle: 60° - Height: 10 mm or bigger - Line thickness: 1 mm or thicker - Font of the exclamation mark: Gothic - Position of the exclamation mark: Center of the triangle - Color of line, exclamation mark and symbol: Red
Restriction		- Diameter: 10 mm or longer - Line thickness: 1 mm or thicker - Angle of the intercepting diagonal line: ± 45° - Color of line: Red
Precaution		- Angle of triangle: 60° - Height: 10 mm or bigger - Line thickness: 1 mm or thicker - Font style of the exclamation mark: Gothic - Position of the exclamation mark: Center of the triangle - Color of line, exclamation mark and symbol: Orange

[Attached Table 2] Additional labelling information by product (pursuant to Article 4 Paragraph 8)

Description	Information
Masks	1. Name of raw materials of inner material, outer material and filter 2. Length and width of masks (in case of surgical masks) 3. Types of masks (e.g., surgical masks <Cloth type> or health mask <KF80>)
Sanitary pads for menstrual hygiene management (in case of the product not for water closet type)	'Do not flush the product in the toilet after use'
Tampons for menstrual hygiene management	1. Product Name 2. Absorption capacity 3. Name of lubricant if the product contains it 4. User instructions and precautions for use 5. Describe warnings for toxic shock syndrome as follows: Tampons may rarely cause toxic shock syndrome (TSS). If you develop symptoms including a sudden fever, vomiting, diarrhea, sunburn-like rash, mucous membrane hemorrhage or dizziness, remove the tampon immediately and consult with a doctor. 6. The material of absorber and the mixing ratio 7. 'Do not flush the product in the toilet after use'
Oral care products containing ethanol (Dental wet tissue, mouthwash, toothpaste, etc.)	Please be cautious that this product may affect the results of a breath alcohol testing taken just after using the product because it contains alcohol (ethanol).

[Attached Table 3] Symbols Available for Important Information (Pursuant to Article 6 Subparagraph 8)

Symbol	Description	Specification	Examples of Precautions
	**Warning**	- Symbol: Use a typical warning symbol - Font style: Gothic - Font size: 10 points or bigger - Font color: Black	Do not use for purposes other than its intended use.
	**Restriction**	- Symbol: Use a typical restriction symbol - Font style: Gothic - Font size: 10 points or bigger - Font color: Black	Age Restriction - Restriction to ages less than 6 months old - Restriction to ages less than 6 years old - Restriction to ages less than 12 years old
	**Restriction**	- Symbol: Use a typical restriction symbol - Font style: Gothic - Font size: 10 points or bigger - Font color: Black	Ingestion Prohibition - Do not eat - Do not drink
	**Precaution**	- Symbol: Use a typical precaution symbol - Font style: Gothic - Font size: 10 points or bigger - Font color: Black	Be careful for allergic reactions
	**Precaution**	- Symbol: Use a typical precaution symbol - Font style: Gothic - Font size: 10 points or bigger - Font color: Black	Precautions for children's use - Children should use under adult guidance - A pea-sized amount is recommended per dose when children use the product
	**Precaution**	- Symbol: Use a typical precaution symbol - Font style: Gothic - Font size: 10 points or bigger - Font color: Black	Be precautious with ventilation in use