Regulations on Labeling and Description of Medical Devices

[Enforcement Date on Aug. 24, 2020] [Ministry of Food and Drug Safety Notice No. 2020-71, Partial Amendment on Aug. 24, 2020]

Ministry of Food and Drug Safety (Medical Device Management Division), 043-719-3811

Article 1 (Purpose) The purpose of the Regulations is to provide accurate and easy-to-understand information on medical devices by specifying the font size, line spacing, and other methods of labeling the information on the container, outer package, outer container or packaging, and package inserts of a medical device, pursuant to Article 23 of the Medical Devices Act, Article 44 (1) 2 of the Enforcement Rule of the Medical Devices Act, and Article 4 of the Act on In Vitro Diagnostic Medical Devices.

Article 2 (Definitions) The definitions of the terms used in this Regulation are as follows:

1. The term “point” means a unit that indicates the size of typeface as stipulated by the Korean Industrial Standard (KS) A 0201 (reference dimensions of typeface);
2. The term “line spacing” means the size of the space between the lines of a paragraph, which is the space between the bottom of the characters in the upper line and the top of the characters in the bottom line.

Article 3 (General Instructions for Labeling) (1) The label shall be printed in the ink, imprint, or stamp that cannot be easily erased, using Korean language in typefaces that are easy to read, such as the East Asian Gothic typeface. Letters in the label shall not overlap with one another and shall also be in a color that is distinct from the background color, such as black letters on a white background.

(2) Where a label is affixed on the container or outer package of a medical device, it shall be affixed where the consumer can easily find it, such as on the side of the container or outer package normally visible to the consumer during its purchase or after the installation. The label shall not be easily removed from the product.

(3) The label shall be based on the information on the license, certificate, and notification.

Article 4 (Font Size and Line Spacing) (1) The font size of characters on the label on the container, outer package, packaging, and package inserts shall be 6 points or larger. However, in the following cases, the font size shall be 7 points or larger:

1. A medical device whose item name includes the term “personal use” as specified in the Regulation on Medical Device Groups and Class by Group (hereinafter referred to as a “medical device for personal use”);
2. the name [product name, item name, and model name], the date of manufacture (including the expiry date), and the words “medical device,” “single-use,” “do not reuse,” “for a clinical trial,” and “do not use for purposes other than for a clinical trial.”

(2) The line spacing of the statements under paragraph (1) shall be at least 0.5 point.

Article 5 (Easily Comprehensible Terms) (1) For a label on a medical device for personal use, easily comprehensible

terms shall be listed together by applying the List of Easily Comprehensible Terms in the Annex of the Regulation on the Labeling of Medicinal Products, etc. (Ministry of Food and Drug Safety Notice) in the order. For other terms, modern terminology shall be listed together for easy understanding by referring to medical glossaries, etc.

(2) Notwithstanding paragraph (1), if the same term is repeatedly used, the easily comprehensible terms may be used in annotation.

Article 6 (Instructions on Labeling on Containers or Outer Packages) (1) Labeling on a container or outer package of a medical device under Article 20 of the Medical Devices Act (hereinafter referred to as the "Act") shall be based on the information on the license, certificate, and notification. Labeling instructions for each item are as follows:

1. The business name and the address of the manufacturer or importer shall be listed based on the information on the manufacturing (import) business license. However, a manufacturer located in a knowledge industry center registered pursuant to Article 28-2 (3) of the Industrial Cluster Development and Factory Establishment Act may only list the business name and the address of the main manufacturing site (a place that can be contacted or visited at any time);
2. The date of manufacture shall be listed as "YYMM," YY.MM.," YY/MM," "YY-MM," "YYYYMM," "YYYY.MM.," "YYYY/MM," or "YYYY-MM"; to add the day to it, it shall be listed as "YYMMDD," "YY.MM.DD.," "YY/MM/DD," "YY-MM-DD," "YYYYMMDD," "YYYY.MM.DD.," "YYYY/MM/DD," or "YYYY-MM-DD." However, where the order of the year, month, or year, month, and day is different from that in the former part, the label shall include an example in the container or outer package to ensure consumers can easily identify the date;
3. The expiry date shall be written in the same way as in subparagraph 2. However, the expiry date may be listed according to the classification in the following:
   (a) Where the expiry date is listed together with the date of manufacture, the expiry date shall be listed as "until ○○th day from the date of manufacture" if the expiry date is within one month from the date of manufacture; "until ○○ months from the date of manufacture" if the expiry date is in more than one month but less than twelve months from the date of manufacture; "until ○○ years from the date of manufacture" if the expiry date is in more than one year from the date of manufacture;
   (b) If multiple products with different expiry dates are packaged together, only the earliest expiry date shall be listed;
4. Weight or packaging units shall be specific units sold in accordance with the information on the license, certificate, and notification;
5. The word "medical device" shall be printed using bold letters, text boxes, etc.

(2) Where Article 42 subparagraph 1 of the Enforcement Rule of the Medical Devices Act (hereinafter referred to as the "Enforcement Rule") applies, subparagraphs of Article 20 of the Act shall be on the label on the outer container or packaging.

Article 7 (Instructions on Labeling on Package Inserts) Labeling on package inserts under Article 22 of the Act and Article 43 of the Enforcement Rule shall be based on the information on the license, certificate, and notification.

Labeling instructions for each item are as follows:

1. Instructions for use:
   (a) Instructions for use approved, certified, and notified shall be listed;
   (b) Where the instructions for use under item (a) need to be further explained, additional details may be included in the label. In such case, the inserts shall include the phrase, “See the User Manual for details”;
   (c) For medical devices for personal use, the preparation before use, how to operate, how to store and care after use shall be described in steps to take to use the product to ensure that consumers easily follow the instructions;
2. Precautions for use:
   (a) The precautions for use that have been approved, certified, and notified shall be included in the label;
   (b) In the precautions for use, items for “Warning” may printed using bold letters, text boxes, etc. to make them stand out from other items, and the titles of other items may also be printed using bold letters, text boxes, etc. to make them stand out;
3. Matters concerning maintenance and inspections where maintenance and inspections are required:
   (a) Methods and procedures of maintenance and inspections shall be described in steps according to the information on the license, certificate, and notification;
   (b) Where a repeatedly used medical device requires an action to be taken for reuse of the device, the action shall be described in the matters concerning maintenance and inspections. Provided that, it may be omitted if the information overlaps with the precautions for use;
   (c) Where there is a route for obtaining information on maintenance and inspections or receiving associated services, it shall be included in the label;
4. For storage methods, appropriate methods for the medical device shall be described in accordance with the license, certificate, and notification;
5. The words “medical device,” “single-use,” “do not reuse,” “for a clinical trial,” and “do not use for purposes other than for a clinical trial” shall be printed using bold letters, text boxes, etc.

Article 8 (Recommendations) (1) In order to provide users with accurate and understandable information on the medical device in addition to the information on the label under Articles 20 through 23 of the Act, it is recommended that the following items be included in the label on the container, outer package, or package inserts, as appropriate, considering the characteristics of the item:

1. For medical devices for personal use, the statement “Be sure to read the precautions for use”;
2. Method to access the information on the license, certificate, and notification concerning the medical device, such as via the manufacturer’s or importer’s website or the Medical Device e-Civil Service of the Ministry of Food and Drug Safety (http://emed.mfds.go.kr);
3. Manufacturer’s or importer’s telephone or fax number.

(2) It is recommended that the content of package inserts stipulated in Article 22 of the Act and Article 43 of the Enforcement Rule be labeled on the container or outer package; if the container or outer package is too small to include all the information, it should be printed on the outer container or packaging. Provided that, if making the outer container or outer package large enough violates “Rules on the Standards of Product Packaging Materials and

Methods (Ordinance of Ministry of Environment), it is recommended to include the information in package inserts and print the words “See package inserts” on the container or outer package.

(3) It is recommended that medical devices subject to tracking be labeled with the words “medical device subject to tracking” on the container or outer package, using bold letters, text boxes, etc.

(4) If the medical device manufacturer or importer believes that package inserts are not sufficient to provide information on the safe use of the medical device, it is recommended that the manufacturer or importer provide a user manual in addition to package inserts and include the words “See the User Manual for details” in the package inserts.

Article 9 (Recommendations for Persons with Disabilities, Senior Citizens, Etc.) (1) To ensure the correct use of medical devices by persons with disabilities, senior citizens, etc., it is recommended that labels be also be written in Braille or voice codes.

(2) When providing details of the content of the license, certificate, and notification via a website, it is recommended that sign language, subtitles, audio, enlarged text, etc. be used to ensure that persons with disabilities, senior citizens, etc. can use the device at the same level as persons without disabilities without an assistive device.

Article 10 (Re-review of Regulations) The validity of this Regulations shall be reviewed every three years from January 1, 2016 (by December 31 of every third year) pursuant to the Article 8 of the Framework Act on Administrative Regulations and Rules on the Issuance and Management of Directives and Established Rules (Presidential Directive No. 334), and appropriate measures, such as improvement measures, shall be taken.

ADDENDA <Notice No. 2020-71, Aug. 24, 2020>

This Notice shall enter into force on the date of its promulgation.

Annexes / Forms

[Annex] List of Easily Comprehensible Terms (related to Article 5)