REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS,
AND HEALTH SUPPLEMENTS

BY THE GRACE OF ALMIGHTY GOD

THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,

Considering : a. that in order to protect the public from the use of natural medicinal products, quasi-drugs, and health supplements that are improper, inappropriate, and irrational, thereby posing a health risk, it is necessary to regulate the inclusion of objective, complete, and non-misleading information on labeling;

b. that the inclusion of objective, complete, and non-misleading information as referred to in paragraph a is one of the criteria for the natural medicinal products, quasi-drugs, and health supplements to meet the safety, efficacy/benefit, and quality standards and/or requirements;

c. that based on the consideration as referred to in paragraphs a and b, and in order to implement Article 17 of Regulation of the Indonesian Food and Drug Authority Number 32 of 2022 on Criteria and Procedures for Health Supplement Registration, Article 23 of Regulation of the Indonesian Food and Drug Authority Number 7 of 2023 on Criteria and Procedures for Quasi-Drug Registration, and Article 15 of Regulation of the Indonesian Food and Drug Authority Number 25 of 2023 on Criteria and Procedures for Natural Medicinal Product Registration, it is necessary to issue Regulation of the Indonesian Food and Drug Authority on Labeling of Natural Medicinal Products, Quasi-Drugs, and Health Supplements;

Having regard to :

1. Presidential Regulation Number 80 of 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2017 Number 180);
2. Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Working Procedures of the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia Year 2020 Number 1002) as amended by Regulation of the Indonesian Food and Drug Authority Number 13 of 2022 on Amendment to Regulation of the Indonesian Food and Drug Authority Number 21 of 2020 on Organization and Working Procedures of the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia Year 2022 Number 629);
3. Regulation of the Indonesian Food and Drug Authority Number 32 of 2022 on Criteria and Procedures for Health Supplement Registration (Official Gazette of the Republic of Indonesia Year 2022 Number 1320);
4. Regulation of the Indonesian Food and Drug Authority Number 7 of 2023 on Criteria and Procedures for Quasi-Drug Registration (Official Gazette of the Republic of Indonesia Year 2023 Number 214);
5. Regulation of the Indonesian Food and Drug Authority Number 19 of 2023 on Organization and Working Procedures of Technical Implementation Unit within the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia Year 2023 Number 611);
6. Regulation of the Indonesian Food and Drug Authority Number 25 of 2023 on Criteria and Procedures for Natural Medicinal Product Registration (Official Gazette of the Republic of Indonesia Year 2023 Number 785);

HEREBY DECIDES:

To issue : REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON LABELING OF NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS, AND HEALTH SUPPLEMENTS.

CHAPTER I
GENERAL PROVISIONS

Article 1

In this Regulation:

1. Natural Medicinal Product means materials, ingredients, or products originating from natural resources in the form of plants, animals, microorganisms, minerals, or other materials from natural resources, or a mixture of those materials which have been used from generation to generation, or have been proven efficacious, safe, and of good quality, used

for health care, health improvement, disease prevention, treatment, and/or health recovery based on empirical and/or scientific evidence.

2. Quasi-Drug means dosage with active ingredients with pharmacological effect that has non-systemic or local characteristics for minor complaints.
3. Health Supplement means a product designed to supplement nutrient intake, to maintain, to increase, and/or to improve health functions, to have nutritional value and/or a physiological effect, to contain one or more materials in the form of vitamins, minerals, amino acids and/or other non-plant materials combinable with plants.
4. Labeling means complete information concerning the safety, efficacy/benefit, and direction of use as well as other information related to the product which is affixed to the label and/or brochure included in the packaging of Natural Medicinal Products, Quasi-Drugs, or Health Supplements.
5. Brochure means a sheet made of paper or other materials containing Labeling information about Natural Medicinal Products, Quasi-Drugs, or Health Supplements, which is included in the product packaging.
6. Packaging means any materials either directly or indirectly have contact with the content of Natural Medicinal Products, Quasi-Drugs or Health Supplements.
7. Primary Packaging means any materials directly have contact with the content of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.
8. Secondary Packaging means any materials that do not have direct contact with the content of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.
9. Marketing Authorization means a form of registration approval for Natural Medicinal Products, Quasi-Drugs, and Health Supplements to be distributed in the territory of Indonesia.
10. Business Actor means a business entity whether incorporated or not, that has been established and is domiciled in the jurisdiction of the Unitary State of the Republic of Indonesia, either individually or collectively, perform business activities in the field of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.
11. Common Name means the name used for Natural Medicinal Products, Quasi-Drugs, or Health Supplements, which may be in the form of a generic name or a name based on the common/empirical composition formula, empirical efficacy, a name of the main active ingredient, and/or a name designated in the national health program.
12. Trade Name means the brand name used for Natural Medicinal Products, Quasi-Drugs, or Health

Supplements that are traded by an individual or a group of individuals, or a legal entity, to distinguish them from other Natural Medicinal Products, Quasi-Drugs, and Health Supplements.

13. Main Supporting Composition for Efficacy means the primary active ingredient that supports the claimed indication for Natural Medicinal Products.
14. Irradiated Product means any product that is deliberately subjected to ionizing radiation regardless of the source or period of irradiation or the nature of the energy used.
15. Genetically Modified Product means a modified organism, living organism, its parts and/or its derivative that has a new genetic composition that results from the application of modern biotechnology.
16. Nano Product means a product fabricated through nanotechnology processes, with particle sizes ranging from one (1) nanometer to less than a thousand (1,000) nanometers.
17. Chairperson of the Authority means the Chairperson of the Indonesian Food and Drug Authority.

Article 2

(1) Business Actors that manufacture Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements to be distributed in the territory of Indonesia shall include the Labeling.
(2) The Natural Medicinal Products as referred to in paragraph (1) includes:
    a. traditional Indonesian herbal medicine/*jamu*;
    b. standardized herbal medicine;
    c. phytopharmaca; and
    d. other Natural Medicinal Products,

    in accordance with the provisions of laws and regulations.
(3) The Labeling as referred to in paragraph (1) may be in the form of images, writing, a combination of both, or other forms according to the innovation and advancement of science and technology in Labeling.
(4) Where the Natural Medicinal Products, Quasi-Drug, and/or Health Supplements as referred to in paragraph (2) are imported products, the Business Actors as the Importer shall affix the Labeling information at the time the Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements enter the territory of Indonesia.
(5) The Labeling as referred to in paragraphs (1) and (3) must comply with the Marketing Authorization from the Indonesian Food and Drug Authority.
(6) The fulfillment of the Marketing Authorization as referred to in paragraph (4) is implemented in accordance with the Regulation of the Indonesian Food and Drug Authority concerning the criteria and procedures for registration of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.

Article 3

The Labeling inclusion as referred to in Article 2 is affixed to:

a. Primary Packaging;
b. Secondary Packaging; and
c. Brochure/leaflet.

CHAPTER II
LABELING CRITERIA

Division One
General

Article 4

The Labeling as referred to in Article 3 shall be:

a. directly printed or firmly attached to the container and/or Packaging;
b. not easily worn off; and
c. resistant to water, abrasion, and sunlight.

Article 5

(1) The Labeling as referred to in Article 4 shall contain information that meets the criteria of objectivity, completeness, and non-misleading.
(2) The criteria of objectivity, completeness, and non-misleading as referred to in paragraph (1) are as follows:
    a. objective, meaning it provides information in accordance with existing facts and does not deviate from the characteristics of efficacy/benefit, direction of use and safety of Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements;
    b. non-misleading, meaning it provides honest, accurate, and reliable information and does not exploit public concerns about health issues; and/or
    c. complete, meaning it includes information on the use of Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements, warnings, and other important precautions for consumers.

Article 6

(1) The Labeling as referred to in Article 2 shall at least contain the following information:
    a. product name and dosage form;
    b. name and address of the industry and/or Business Actor;
    c. name and address of contract giver and/or contract acceptor for contracted products;
    d. name and address of licensor and/or licensee for licensed products;
    e. net content, net weight, and/or quantity;
    f. composition;
    g. inactive ingredients;
    h. efficacy/benefit claims;

i. usage instruction/direction of use;
j. contraindications, side effects, interactions, warnings, and/or precautions;
k. Marketing Authorization number;
l. production code;
m. expiry date;
n. storage condition;
o. 2D Barcode;
p. logo and text for Natural Medicinal Products or text Health Supplements ("*Suplemen Kesehatan*"); and
q. other information, in compliance with the standards and/or requirements of safety and quality.

(2) The other information as referred to in paragraph (1) subparagraph q may be in the form of:
a. halal label;
b. alcohol content; and
c. information on the origin of specific ingredients.

(3) The inclusion of other information on Labeling as referred to in paragraph (2) is regulated by a Regulation of the Indonesian Food and Drug Authority.

(4) Where the Natural Medicinal Products and/or Health Supplements containing nutrients, the Labeling may include the percentage of the Recommended Dietary Allowance (RDA/AKG) per day, in accordance with the provisions of laws and regulations.

(5) The Recommended Dietary Allowance (RDA/AKG) as referred to in paragraph (4) represents the average daily nutrient requirements for all individuals, based on age group, sex, body size, and physical activity, to achieve optimal health.

(6) The inclusion of information as referred to in paragraph (1) subparagraphs a, b, c, d, e, j, k, l, m, n, o, p, and/or q must be placed on the most visible and readable part of the label.

(7) Information other than those as referred to in paragraph (1) that may be included in the Labeling is set out in Annex I as an integral part of this Regulation.

(8) The inclusion of information other than those contained in Annex I as referred to in paragraph (7) must be supported by evidence and relevant studies on the safety and efficacy/benefit.

Article 7

(1) Where the label area on the Primary Packaging, based on the evaluation by the Indonesian Food and Drug Authority, does not allow the inclusion of the information as referred to in Article 6 paragraph (1), the Labeling must include:
a. product name;
b. name and address of Business Actor, at least the city and country;
c. Marketing Authorization number;
d. production code; and
e. expiry date.

(2) Where the label area on the Primary Packaging as referred to in paragraph (1) is 10 cm^2 (ten square centimeters) or less, the inclusion of name and address of Business Actor as referred to in paragraph (1) subparagraph b, may be included on the Secondary Packaging.

(3) Where Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements are packaged in Primary Packaging with limited dimensions and design, supplementary information in the form of data and/or information other than that referred to in paragraph (1) shall be provided on a separate Labeling media, such as a hangtag, brochure, display panel, shrink wrap, or other attached Labeling media.

Article 8

(1) The information as referred to in Article 6 paragraph (1) must be written and printed in the Indonesian language, Arabic numerals, and Latin characters, except for the product name.

(2) The product name as referred to in paragraph (1) may be written in a language other than Indonesian.

(3) The text as referred to in paragraph (2) must be printed in Arabic numerals and Latin characters.

(4) Where the information as referred to in paragraph (1) is printed in a language other than Indonesian, Arabic numerals, and Latin characters, the inclusion of information must be accompanied by an equivalent translation in Indonesian, obtained from a sworn translator in Indonesia.

(5) Where the information as referred to in paragraph (2) does not have an equivalent translation in Indonesian, the information may be included in a language other than Indonesian and/or foreign terms.

(6) The foreign terms as referred to in paragraph (5) may include:
   a. words, sentences, numbers, or characters other than Indonesian; and/or
   b. technical or scientific terms to describe a specific ingredient in the list of ingredients.

Article 9

Other images, colors, and/or designs may be used as background provided that they do not compromise the legibility of the text included in the Labeling.

Article 10

Information in the form of text shall be presented in a regular, clear, visible, readable, and proportional manner to the surface area of the Labeling.

Division Two
Information on Labeling

Subdivision 1
Product Name and Dosage Form

Article 11

(1) The product name as referred to in Article 6 paragraph (1) subparagraph a may be in the form of:
   a. Common Name; and/or
   b. Trade Name.

(2) The product name as referred to in paragraph (1) must meet the following criteria:
   a. be clear and reflective of the unified product name;
   b. not in conflict with the provisions of laws and regulations, religious moral principles, cultural values, ethics, and/or public decency;
   c. not use promotional or misleading language, codes, symbols, or images;
   d. not use a name that is similar in essence or entirely, including spelling and pronunciation, to a product name that has already been granted a Marketing Authorization;
   e. not use the same Trade Name for different compositions;
   f. not use the name of a disease that requires clinical diagnosis by a doctor;
   g. not use part of or entire names of Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements that have been revoked, with the following conditions:
      1. contain isolated or synthetic chemical substances with medicinal properties; or
      2. contain unauthorized ingredients.
   h. not use the same name for different groups of Natural Medicinal Products, except for the registration of products that were previously registered in the same group of Natural Medicinal Products with different dosage forms or packaging.

(3) The group of Natural Medicinal Products as referred to in paragraph (2) subparagraph h is in accordance with the provisions of laws and regulations.

(4) The Trade name of Natural Medicinal Products, Quasi-Drugs, or Health Supplements may use an umbrella name derived from:
   a. product name with similar efficacy/benefit; or
   b. trademark or company name.

(5) The trademark or company name as referred to in paragraph (4) subparagraph b may be used as long as it does not conflict with the aspects of safety, efficacy/benefit, and/or quality.

Article 12

(1) The addition of information to a product name must be in the form of information that indicates a difference in content, strength, or efficacy/benefit of the product.
(2) The addition of information as referred to in paragraph (1) may use terms such as “plus”, “forte”, or other similar terms.
(3) The addition of information as referred to in paragraph (2) must meet the following criteria:
    a. originating from a product with the same primary composition;
    b. originating from a product with a Common Name; or
    c. having evidence of greater benefits compared to the product without the added term.

Article 13

The inclusion of dosage forms as referred to in Article 6 paragraph (1) subparagraph a shall accurately reflect the product that is manufactured and distributed pursuant to a Marketing Authorization issued by the Indonesian Food and Drug Authority.

Subdivision 2
Names and Addresses of Industry and/or Business Actor, Contract Givers/Contract Acceptors, and/or Licensors/Licensees

Article 14

The inclusion of the address as referred to in Article 6 paragraph (1) subparagraphs b, c, and d on the Labeling at least includes the names of city and country.

Article 15

(1) The name and address of the Business Actor as an Importer who has obtained an appointment from the manufacturer in the country of origin shall be included on the Labeling along with the name and address of the manufacturer in the country of origin.
(2) The inclusion of the name of the Business Actor as an Importer as referred to in paragraph (1) must begin with the statement "imported by ..." or use a similar phrase.
(3) The information included in the address of the Business Actor as an Importer as referred to in Article 14 at least includes the city name and Indonesia.

Article 16

The inclusion of the name of the contract giver and/or contract acceptor as referred to in Article 6 paragraph (1) subparagraph c must be accompanied with the information "Manufactured by... for ...” or a similar phrase.

Article 17

The inclusion of the name and address of licensor and/or licensee as referred to in Article 6 paragraph (1)

subparagraph d must be accompanied with the information "Manufactured by ... under license of ..." or a similar phrase.

Subdivision 3
Net Content, Net Weight, and/or Quantity

Article 18

(1) The net content and net weight as referred to in Article 6 paragraph (1) subparagraph e are information regarding the content or weight of Natural Medicinal Products, Quasi-Drugs, and Health Supplements contained in a single Packaging unit or container, expressed in metric units.
(2) The inclusion of metric units as referred to in paragraph (1) includes:
    a. Net content for liquid formulations of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.
    b. Net weight for solid formulations of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.
    c. Net content or net weight for semi-solid or liquid formulations of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.
(3) The inclusion and inscription of the net content or net weight as referred to in paragraph (2) includes:
    a. weight measurements expressed in milligrams (mg), grams (g), or kilograms (kg); or
    b. volume measurements expressed in milliliters (mL), liters (L);
(4) Where the Natural Medicinal Products, Quasi-Drugs, and Health Supplements as referred to in paragraph (1) are in the form of solid or liquid preparations, in addition to inclusion of the net content or net weight as referred to in paragraph (3), the Labeling must also include the quantity as referred to in Article 6 paragraph (1) subparagraph e for each Packaging unit.
(5) The provision as referred to in paragraph (5) is exempted from Natural Medicinal Products, Quasi-Drugs, and Health Supplements in the form of patches, oral thin film, or other forms, which only require the inclusion of quantity.
(6) Other dosage forms as referred to in paragraph (5) is in accordance with the innovation and advancement of science and technology in the field of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.
(7) Net content, net weight, and/or quantity as referred to in paragraphs (1) to (6) must be prominently displayed in a location that is readily visible and/or legible to consumers.

Subdivision 4
Composition

Article 19

(1) The composition as referred to in Article 6 paragraph (1) subparagraph f consists of the qualitative and quantitative formulation of the active ingredients of Natural Medicinal Products, Quasi-Drugs, and Health Supplements.
(2) The inclusion of active ingredients as referred to in paragraph (1) is preceded by the inclusion of the following text:
    a. “Komposisi:” (Composition:);
    b. “Bahan yang digunakan:” (Ingredients used:);
    c. “Bahan-bahan:” (Ingredients:) or
    d. other equivalent phrases.

Article 20

(1) Where the active ingredients as referred to in Article 19 paragraph (1) are the Main Supporting Composition for Efficacy, the active ingredients shall be listed on the Labeling both qualitatively and quantitatively.
(2) Where the active ingredients as referred to in Article 19 paragraph (1) do not include the Main Supporting Composition for Efficacy as referred to in paragraph (1), the active ingredients shall be listed on the Labeling qualitatively.
(3) Where the active ingredients as referred to in paragraph (2) consist of more than one (1) type of active ingredients, the inclusion of the quantitative composition is done cumulatively based on the total weight.
(4) The active ingredients as referred to in paragraph (1) that are derived from animals, plants, animal extracts, or plant extracts shall be listed according to their Latin/scientific name, including the genus and species, along with the part used.
(5) In addition to the inclusion as referred to in paragraph (4), the active ingredients as referred to in paragraph (1) that are derived from animals, plants, animal extracts, or plant extracts may also be accompanied by their Common Name.
(6) Where the active ingredients as referred to in paragraph (1) that are derived from non-marine animals, in addition to complying with the provisions as referred to in paragraph (4), the Common Name shall also be included.

Article 21

(1) Active ingredients in the composition as referred to in Article 19 paragraph (2) subparagraph a used in the manufacture of Quasi-Drugs or Health Supplements shall be included qualitatively and quantitatively.
(2) The active ingredients as referred to in paragraph (1) are included using the active ingredient name according to

the generic name or international generic name designated by the World Health Organization.

(3) The active ingredients or inactive ingredients as referred to in Article 19 paragraph (2) that do not have an international generic name may use another name according to internationally recognized references.

(4) Where the active ingredients used in Quasi-Drugs or Health Supplements are derived from plants and/or animals, the listing of active ingredients comply with the provisions as referred to in Article 20 paragraph (4).

(5) Where the active ingredients used in Health Supplements contain probiotics, they shall be listed according to the genus name, species name, and strain.

Article 22

Where the Labeling includes the content of a group/compound of active ingredients in the composition as referred to in Article 19, the Labeling must be accompanied by supporting data from quantitative testing.

Subdivision 5
Inactive Ingredients

Article 23

(1) The inactive ingredients used in the manufacture of Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements as referred to in Article 6 paragraph (1) subparagraph g must be qualitatively included in the composition.

(2) The inactive ingredients as referred to in paragraph (1) may be in the form of:
   a. sweeteners;
   b. preservatives;
   c. coloring agents; and/or
   d. flavorings.

Subdivision 6
Efficacy/Benefit Claims

Article 24

(1) The Business Actors shall include efficacy/benefit claims as referred to in Article 6 paragraph (1) subparagraph h in accordance with the approval issued by the Chairperson of the Authority.

(2) The inclusion and approval of efficacy/benefit claims as referred to in paragraph (1) are implemented in accordance with the provisions of laws and regulations.

Subdivision 7
Usage Instruction/Direction of Use

Article 25

(1) The inclusion of information regarding usage instruction/direction of use as referred to in Article 6 paragraph (1) subparagraph i is in the form of:

a. information on preparation instruction with clear and easily comprehensible language; and/or
b. direction of use accompanied by images.

(2) Where the Labeling includes information on preparation instructions for Natural Medicinal Products, Quasi-Drugs, and Health Supplements, the Labeling shall comply with the preparation instructions that have been approved by the Indonesian Food and Drug Authority.

Subdivision 8
Contraindications, Side Effects, Interactions, Warnings, and/or Precautions

Article 26

(1) The contraindications, side effects, interactions, warnings, and/or precautions as referred to in Article 6 paragraph (1) subparagraph j shall be included in the Labeling in accordance with the results of the registration evaluation by the Indonesian Food and Drug Authority.
(2) The inclusion of information regarding contraindications, side effects, interactions, warnings, and/or precautions as referred to in paragraph (1) is set out in Annex II, as an integral part of this Regulation.

Subdivision 9
Marketing Authorization Number

Article 27

(1) The inclusion of Marketing Authorization Number as referred to in Article 6 paragraph (1) subparagraph k on the Labeling must begin with the "POM" text, followed by two (2) letters and nine (9)-digit numbers.
(2) The inclusion of two (2) letters and nine (9)-digit numbers as referred to in paragraph (1) is implemented in accordance with the letters and digits listed in the Marketing Authorization.
(3) In addition to including two (2) letters and nine (9)-digit numbers, the Labeling for export Packaging also adds letter "E" after the inclusion of nine (9)-digit numbers.
(4) The Marketing Authorization Number as referred to in paragraph (1) must be included in the most visible and readable part of the Labeling.

Subdivision 10
Production Code

Article 28

(1) The production code as referred to in Article 6 paragraph (1) subparagraph l is the Labeling that consists of numbers or letters or a combination of both.

(2) The production code as referred to in paragraph (1) serves as an identifier for a specific batch, enabling traceability and a comprehensive review of the batch's production history, including all stages of production, supervision, and distribution.
(3) The production code as referred to in paragraph (1) may be separately included from other information on Labeling.

Subdivision 11
Expiry Date

Article 29

(1) The expiry date as referred to in Article 6 paragraph (1) subparagraph m serves as information provided on each product container stating the date until which the product is expected to remain within its specifications, provided it is stored properly.
(2) The inclusion of the expiry date as referred to in Article 6 paragraph (1) subparagraph m on the Labeling includes the following information:
    a. date, month, and year; or
    b. month and year.
(3) The expiry date information as referred to in paragraph (1) may be separately included from the Labeling attached to the packaging, accompanied by instructions on where to find the expiry date, such as:
    a. "expiry date, see bottom of bottle" ("*kedaluwarsa, lihat bagian bawah botol*"), or
    b. "expiry date, see bottle cap" ("*kedaluwarsa, lihat pada tutup botol*").
(4) The Labeling as referred to in paragraph (2) may include additional information on the maximum usage period after the Packaging is opened.
(5) The inclusion of information as referred to in paragraph (4) is implemented based on the risk assessment.

Subdivision 12
Storage Condition

Article 30

(1) The information regarding storage condition as referred to in Article 6 paragraph (1) subparagraph n must be in accordance with the quality documents submitted during registration.
(2) Where the Natural Medicinal Products, Quasi-Drugs, and Health Supplements are used more than once, the Labeling may include information on storage conditions after the Packaging is opened.

Subdivision 13
2D Barcode

Article 31

(1) The 2D Barcode as referred to in Article 6 paragraph (1) subparagraph o serves as a graphical representation of

digital data in a two-dimensional format with high decoding capacity that can be read by optical devices used for identification, tracking, and tracing.

(2) The inclusion procedures of 2D Barcode as referred to in paragraph (1) is implemented in accordance with the provision of laws and regulations.

Subdivision 14
Logo and Text for Natural Medicinal Products
or "Suplemen Kesehatan" Text

Article 32

(1) The logo and text for Natural Medicinal Products or "Suplemen Kesehatan" text as referred to in Article 6 paragraph (1) subparagraph p shall be included in Primary Packaging, Secondary Packaging, and/or Brochures in proportion to the Packaging size.

(2) The "Suplemen Kesehatan" text as referred to in paragraph (1) shall be included in vivid/contrasting colors.

(3) The provision as referred to in paragraph (1) is excluded for the Primary Packaging in the form of strips and blister packs.

Article 33

(1) The logo and text for Natural Medicinal Products as referred to in Article 32 paragraph (1) are only designated for Natural Medicinal Products that are manufactured and distributed in the territory of Indonesia.

(2) The provisions as referred to in paragraph (1) are excluded for Natural Medicinal Products under domestic manufacturing license.

(3) The procedures for writing and inclusion of logo and text for Natural Medicinal Products as referred to in paragraph (1) are set out in Annex III as an integral part of this Regulation.

Subdivision 15
Information on the Origin of Ingredients
with Specific Technology or Process

Article 34

(1) Where the Natural Medicinal Products, Quasi-Drugs, and Health Supplements that use ingredients produced with specific technology and process, the Labeling must include information in the form of:
   a. Genetically Modified Product;
   b. Irradiated Product;
   c. organic product; or
   d. Nano Product.

(2) The organic product as referred to in paragraph (1) subparagraph c is a product that is manufactured in accordance with organic production standard and certified by an official certification body.

(3) The information on the product as referred to in paragraph (1) shall be included in the Labeling based on the approval from the Indonesian Food and Drug Authority.

Article 35

(1) Where the Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements are included in Genetically Modified Products as referred to in Article 34 paragraph (1) subparagraph a, the raw materials must meet safety requirements and the Labeling shall include a statement in the form of "Produk Rekayasa Genetik" (Genetically Modified Product) text.
(2) Genetically modified materials that have been approved as safe for use as genetically modified food may be used as raw materials for Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements.
(3) In addition to fulfilling the requirements as referred to in paragraph (2), genetically modified materials that have not yet been approved as safe for use as genetically modified food may only be used as raw materials for Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements after a safety and quality assessment has been conducted by the Indonesian Food and Drug Authority.
(4) The requirement to include a statement about Genetically Modified Products as referred to in paragraph (1) applies to products that contain one or more genetically modified materials with a minimum content of 5% (five percent) deoxyribonucleic acid (DNA) of the Genetically Modified Product.
(5) Where the Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements contain more than one (1) genetically modified material, the percentage of deoxyribonucleic acid (DNA) of the Genetically Modified Product as referred to in paragraph (4) is calculated for each genetically modified material.
(6) The content of deoxyribonucleic acid (DNA) of the Genetically Modified Product is evidenced by the results of testing conducted on the genetically modified material by an accredited laboratory.
(7) The inclusion of information on the Genetically Modified Product as referred to in paragraph (1) is set out in Annex IV as an integral part of this Regulation.

Article 36

(1) Where the Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements are included in Irradiated Products as referred to in Article 34 paragraph (1) subparagraph b, the Labeling shall include a statement in the form of "iradiasi" (irradiation) text.
(2) In addition to the provisions as referred to in paragraph (1), in the case of Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements that are produced using irradiation technology, the Labeling shall include

information in the form of “iradiasi” text.

(3) The inclusion of “Iradiasi” information on the Labeling as referred to in paragraph (1) must be accompanied by an irradiation certificate issued by an irradiation facility that has obtained a permit for the utilization of nuclear energy from the government institution responsible for research, development, and utilization of nuclear science and technology, in accordance with the provisions of laws and regulations.

(4) Where the Natural Medicinal Products, Quasi-Drugs, and Health Supplements as referred to in paragraph (1) are imported, the inclusion of a statement in the form of “iradiasi” text on the Labeling must be accompanied by an irradiation certificate issued by an irradiation facility that has obtained a permit for the utilization of nuclear energy from the authorized institution in the country of origin.

(5) The inclusion of information on the Irradiated Product as referred to in paragraph (1) is set out in Annex IV as an integral part of this Regulation.

Article 37

(1) Where the Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements are manufactured using ingredients produced through organic processes and are included in organic products as referred to in Article 34 paragraph (1) subparagraph c, the Labeling may include information on organic logos and “organik” (organic) text.

(2) The products as referred to in paragraph (1) are supported by an organic certificate issued and certified by an organic certification body in accordance with the provisions of laws and regulations.

(3) The inclusion of organic information on the Labeling as referred to in paragraph (1) for Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements that contain at least 95% (ninety-five percent) organic materials by total weight of the product excludes inactive ingredients.

(4) Where the Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements as referred to in paragraph (3) are with an organic composition of less than 95% (ninety-five percent), the “organik” text may only be included in the composition after the name of the organic material.

(5) The inclusion of organic logo on the Labeling of imported products may only be carried out after re-certification by an authorized organic certification body in accordance with the provisions of laws and regulations.

(6) The inclusion of information on organic logo and “organik” text as referred to in paragraph (1) is set out in Annex IV, as an integral part of this Regulation.

Article 38

(1) Where the Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements are included in Nano Products as referred to in Article 34 paragraph (1) subparagraph d, the Labeling shall include information in the form of "nano" text.
(2) In addition to the provisions as referred to in paragraph (1), in the case of Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements that are produced using nanotechnology, the Labeling must include information in the form of "nano" text.
(3) The inclusion of information on "nano" text as referred to in paragraph (1) is set out in Annex IV, as an integral part of this Regulation.

CHAPTER III
ASSISTANCE

Article 39

(1) Where, based on the supervision results, it is found that the Labeling is not in accordance with the Marketing Authorization, the Indonesian Food and Drug Authority may provide technical assistance to the Business Actor.
(2) The technical assistance as referred to in paragraph (1) is in corrective actions to the inclusion of Labeling.
(3) The Business Actors must submit a report to the Indonesian Food and Drug Authority as part of the implementation of the technical assistance as referred to in paragraph (1), which include:
    a. the quantity of old Packaging stock;
    b. production code;
    c. expiry date; and
    d. Packaging samples that have been affixed with sticker.
(4) Based on the report as referred to in paragraph (3), the Indonesian Food and Drug Authority conducts an evaluation to determine the type of correction action that shall be taken by the Business Actors.
(5) The corrective actions as referred to in paragraph (4) include:
    a. using the stickers; or
    b. re-printing the packaging of Natural Medicinal Products, Quasi-Drugs, and Health Supplements,

    in accordance with the Marketing Authorization issued by the Indonesian Food and Drug Authority.

CHAPTER IV
PROHIBITION

Article 40

The Business Actors shall not include information on the Labeling that contain the following information:
a. claims of being free from certain ingredients when the product actually contains those ingredients, whether intentionally or unintentionally, or as a carry-over substance;

b. images or descriptions related to healthcare professionals, religious figures, or public officials, or portrays them as healthcare professionals, religious figures, or public officials;
c. information, text, or images that offend the certain ethnic groups, religions, races, and/or social classes;
d. information about sweepstakes, contests or prizes;
e. information, text, or images that are prohibited or contradictory to the provisions of laws and regulations;
f. information that creates a perception or image that contradicts moral norms, ethics, or public order;
g. excessive or unrelated visualizations or information about Natural Medicinal Products, Quasi-Drugs, or Health Supplements; and/or
h. additional information that creates a misleading perception regarding the safety/efficacy/benefits, and quality of the product.

CHAPTER V
ADMINISTRATIVE SANCTIONS

Article 41

(1) Any Business Actors that violate the provisions in Article 2 paragraph (1), Article 2 paragraph (4), Article 4, Article 5 paragraph (1), Article 6 paragraph (1), Article 7 paragraph (3), Article 10, Article 13, Article 15 paragraph (1), Article 20 paragraph (1), Article 20 paragraph (2), Article 20 paragraph (3), Article 20 paragraph (4), Article 20 paragraph (6), Article 21 paragraph (1), Article 21 paragraph (5), Article 24 paragraph (1), Article 25 paragraph (2), Article 26 paragraph (1), Article 32 paragraph (1), Article 32 paragraph (2), Article 34 paragraph (3), Article 35 paragraph (1), Article 36 paragraph (1), Article 36 paragraph (2), Article 38 paragraph (1), Article 38 paragraph (2), Article 39 paragraph (4), and/or Article 40 are subject to administrative sanctions.

(2) The administrative sanctions as referred to in paragraph (1) are in the form of:
   a. warning;
   b. product recall;
   c. product destruction;
   d. temporary suspension of activities;
   e. revocation of certificate of Good Manufacturing Practice for Natural Medicinal Products or certificate of compliance with Good Manufacturing Practice for Natural Medicinal Products or certificate of Good Manufacturing Practice for Cosmetics or certificate of compliance with Good Manufacturing Practice for Cosmetics, and the approval letter of joint facility;
   f. cancellation/revocation of Marketing Authorization numbers; and/or
   g. public announcement.

(3) The administrative sanctions as referred to in paragraph (1) is imposed by the Chairperson of the Authority.

Article 42

The procedures for imposing administrative sanctions as referred to in Article 41 are carried out in accordance with the provisions in Regulation of the Indonesian Food and Drug Authority governing the follow-up actions on the supervision results of Natural Medicinal Products, Quasi-Drugs, Health Supplements, and cosmetics.

CHAPTER VI
TRANSITIONAL PROVISIONS

Article 43

The Natural Medicinal Products, Quasi-Drugs, and Health Supplements that have obtained Marketing Authorization prior to the entry into force of this Regulation, shall be adjusted to the provisions in this Regulation no later than twenty-four (24) months as of the date of promulgation of this Regulation.

CHAPTER VII
CLOSING PROVISIONS

Article 44

This Regulation shall enter into force as of the date of its promulgation.

In order to make this Regulation known to the public, it is hereby ordered that it be promulgated by its publication in the Official Gazette of the Republic of Indonesia.

Issued in Jakarta
on 3 June 2024

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY AD INTERIM,

signed

LUCIA RIZKA ANDALUSIA

Promulgated in Jakarta
on 7 June 2024

DIRECTOR GENERAL OF LEGISLATION
OF THE MINISTRY OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

signed

ASEP N. MULYANA

OFFICIAL GAZETTE OF THE REPUBLIC OF INDONESIA YEAR 2024 NUMBER 309

Prepared and issued as an official translation

Jakarta, 21 October 2026
DIRECTOR GENERAL OF LEGISLATION
FOR THE MINISTER OF LAW OF THE REPUBLIC OF INDONESIA,



DHAHANA PUTRA

Official Translation Notice:
This English translation is provided for information and reference purposes only. In the event of any discrepancy, inconsistency, or ambiguity between the English version and the Indonesian version, the Indonesian version shall prevail.

ANNEX I TO
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS, AND HEALTH SUPPLEMENTS

THE INCLUSION OF ADDITIONAL INFORMATION ON THE LABELING OF NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS, AND HEALTH SUPPLEMENTS

The inclusion of additional information on the Labeling of Natural Medicinal Products, Quasi-Drugs, and Health Supplements, is presented as follows:

No.	Additional Information	Requirements
1.	Nutritional Content	a. Information on the nutritional content may be included on the Labeling of Natural Medicinal Products or Health Supplements in the form of nutrition facts. b. Information in the form of nutrition facts is based on the testing results from an Indonesian industrial laboratory that holds CPOB/CPOTB certificates or an accredited laboratory. c. The requirements and procedures for including nutrition facts are implemented in accordance with the provisions of laws and regulations.
2.	Quality Assurance Documents	a. Information on the implementation of Quality Assurance may be in the form of Good Manufacturing Practice or a Quality Management System. b. This information is supported by the attachment of valid supporting data.
3.	Customer Care Information	a. The Labeling of Natural Medicinal Products, Quasi-Drugs, and Health Supplements includes information on customer care. b. The customer care may include telephone number, website, email, or social media, name of the unit, or department that can be contacted by consumers.
4.	Information on Images, Logos, and/or Text	a. Images of plants or animals may be included on the labeling of Natural Medicinal Products, Quasi-Drugs, and Health Supplements only if the product contains the active/main ingredient. b. Natural Medicinal Products, Quasi-Drugs, and/or Health Supplements that contain fruit artificial flavourings may only display animated fruit images. c. The inclusion of vegan logo and/or the 'vegan' text on the Labeling is permitted as long as the Natural Medicinal Products, Quasi-Drugs, and Health Supplements do not contain animal-derived ingredients and their by-products, including honey. The requirements for the inclusion of vegan logo must be accompanied by: 1) a vegan certificate from a domestic or overseas vegan organization; and/or

		2) the results of animal deoxyribonucleic acid (DNA) testing from an accredited laboratory.
5.	Information on Gluten-Free, Alcohol-Free, and No Additive Ingredients	a. Claims on 'gluten-free', 'alcohol-free', and 'no added ingredients' must be supported by evidence. b. The inclusion of claims on 'gluten-free', 'alcohol-free', and 'no additive ingredients' is in accordance with the provisions of laws and regulations.
6	Low Lactose and Lactose-Free Claims	a. Only applicable to products that typically contain lactose. b. In addition to the word "free", equivalent words such as "without", "does not contain" can be used. c. Lactose-Free Requirements: Not more than 10 mg/100 kcal and Low Lactose: Not more than 2 g/100 g.
7	Information on 'Clinically Tested' or 'Clinically Proven'	Information on 'Clinically Tested' or 'Clinically Proven' must be accompanied by valid and qualified clinical trial data on the finished product, conducted in accordance with good clinical practice.
8	Information on marketing achievements or awards	Claims of marketing achievements or awards must be accompanied by the year of achievement and supported by a certificate issued within the last two years.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY AD INTERIM,

signed

LUCIA RIZKA ANDALUSIA

ANNEX II
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS, AND HEALTH SUPPLEMENTS

THE INCLUSION OF INFORMATION ON CONTRAINDICATIONS, SIDE EFFECTS, INTERACTIONS, WARNINGS, AND/OR PRECAUTIONS ON NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS, AND HEALTH SUPPLEMENTS

Information on contraindications, side effects, interactions, warnings, and/or precautions is included in the Labeling using a clear and readable font type and size, as well as color.

The inclusion of information on contraindications, side effects, interactions, warnings, and precautions on Natural Medicinal Products, Quasi-Drugs, and Health Supplements with specific ingredients and/or claims displayed on the Labeling, refers to the table of sample inclusion of contraindications, side effects, interactions, and warnings, and/or precautions as follows:

A. Active Ingredients

No.	Active Ingredients	Contraindications, Side Effects, Interactions, Warnings, and/or Precautions
1.	*Allium sativum Bulbus*	Contraindications Not recommended for patients with stomach ulcers. Warnings and Precautions ● Consume with caution when using this product in conjunction with anticoagulants, consult your doctor before undergoing surgery. ● Discontinue use immediately if allergic reactions occur (topical products). Warnings and Precautions must be included on the following products: 1) Products containing Allium sativum in a single dose. 2) Products containing Allium sativum in combination with other ingredients, with the following compositions requirements: - Powder : more than 300 mg per single use and/or more than 900 mg/day.

		- Liquid extract: more than 110 mg per single use and/or more than 440 mg/day. - Dry extract: more than 100 mg per single use and/or more than 100 mg/day.
2.	*Aloe vera*	<u>Warnings and Precautions</u> ● Consume with caution when taking this product concomitant with diabetes medications. ● Not recommended for pregnant women, breastfeeding mothers, and children under 10 years of age.
3.	*Alpha lipoic acid*	<u>Side Effects</u> May cause headache, dizziness, and fatigue. <u>Warnings and Precautions</u> ● Avoid use in pregnant women or breastfeeding mothers. ● Consume with caution when taking this product concomitant with diabetes medications. ● Consult a doctor periodically during use.
4.	*Andrographis paniculata* herb	Indicated for single-composition products with claims to help maintain immune system function. <u>Warnings and Precautions</u> ● Consume with caution when taking this product concomitant with diabetes medications. ● Not recommended for pregnant women or breastfeeding mothers.
5.	*Angelica sinensis*	<u>Warnings and Precautions</u> ● Not recommended for patients before and after surgery, or those undergoing anticoagulant and anti-thrombotic therapy, such as warfarin and aspirin ● Not recommended for pregnant women.
6.	*Azadirachta indica*	<u>Warnings and Precautions</u> ● Do not use this product for more than 3 weeks. ● This product may cause liver and kidney damage.

		● Not recommended for children, pregnant women, or breastfeeding mothers ● Use with caution in patients with diabetes, or those undergoing insulin or oral hypoglycemic therapy. (To be included only for products with diabetes-related claims).
7.	Raw materials derived from marine sources Warnings and Precautions	<u>Warnings and Precautions</u> May cause allergic reactions in patients with seafood allergies.
8.	Iron (>15 mg/serving)	<u>Side Effects</u> ● May cause black stools. Do not use in patients with frequent blood transfusions or anemia not caused by iron deficiency.
9.	Oral Liquid contains free sugars, minimum 6 grams per 100 mL	<u>Warnings and Precautions:</u> Use with caution in patients with diabetes or hypertension.
10.	*Camphora*	*Camphora* (for external use only) <u>Warnings and Precautions</u> ● Not recommended for children under 2 years of age. ● Do not apply directly under the nostrils.
11.	*Cassia senna*/ *Cassia angustifolia*	<u>Contraindications</u> Contraindicated in patients with kidney disease, heart disease, intestinal obstruction, intestinal inflammation, appendicitis, abdominal pain of unknown cause, dehydration, and electrolyte disturbances.

		Side Effects May cause stomach cramps, abdominal pain, and diarrhea. Warnings and Precautions ● Consult a doctor before using this product with other medications. ● Not recommended for patients with gastrointestinal disorders, such as stomach pain, nausea, and vomiting. ● Avoid use in children under 12 years of age, pregnant women or breastfeeding mothers. ● May cause urine discoloration (yellow or red). ● Consult a doctor if constipation persists (for laxative and hemorrhoid claims).
12.	*Centella asiatica*	Products containing single or combination extracts of *Centella asiatica* with a daily dose exceeding 200 mg (equivalent to 2 grams of *Centella asiatica* herb) shall include warnings, precautions, and contraindications. Contraindications Not recommended for concomitant use with aspirin/anticoagulants. Warnings and Precautions ● Not recommended for children under 2 years of age and pregnant women. ● Do not use continuously for more than 6 weeks, but may be reused after a 2-week discontinuation period. ● For topical use, do not apply directly to open wounds.
13.	*Chitosan*	Side Effects: Gastrointestinal disorders such as nausea, diarrhea, or constipation may occasionally occur. Warnings and Precautions ● May cause allergic reactions in patients with seafood allergies.

		● May affect the absorption of other substances, including vitamins A, D, E, and K. It is recommended to have a 2-3-hour interval between administrations. ● Avoid use in children under 12 years of age, pregnant women or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin, heparin, and aspirin.
14.	Single *Citicholine*	<u>Warnings and Precautions</u> Use under medical supervision.
15.	*Co Enzyme* Q10 combination	<u>Warnings and Precautions</u> ● Avoid use in pregnant women or breastfeeding mothers. ● Use with caution in patients using warfarin. ● Consult a doctor before using this product with other medications.
16.	Single *Coenzyme* Q10	<u>Warnings and Precautions</u> ● Use under medical supervision. ● Avoid use in pregnant women or breastfeeding mothers. ● Use with caution in patients taking warfarin and statin. ● Consult a doctor before using this product with other medications.
17.	*Conjugated linoleic acid*	<u>Side Effects</u> May cause gastrointestinal disturbances. <u>Warnings and Precautions</u> ● Avoid use in children, pregnant women, or breastfeeding mothers. ● Discontinue use immediately if allergic reactions occur.
18.	*Creatine*	<u>Contraindications</u> Patients with impaired renal function.

		Warnings and Precautions ● Avoid use in children, pregnant women, or breastfeeding mothers. ● Recommended to be taken with at least 8 glasses of water per day.
19.	*Echinacea* sp	Contraindications Patients with multiple sclerosis, collagen disease, leukemia, tuberculosis, AIDS, and autoimmune disorders. Interactions Should not be used concomitant with immunosuppressive products. Warnings and Precautions ● Discontinue use immediately if allergic reactions occur. ● Not recommended for use exceeding 8 weeks. ● Avoid use in pregnant women or breastfeeding mothers. ● Consult a doctor before using this product with other medications.
20.	*Evening Primrose Oil* (*EPO*)	Warnings and Precautions ● Not recommended for pregnant women or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin, heparin, and aspirin. ● Discontinue use 2 weeks prior to surgery due to increased risk of bleeding. ● Exceeding the recommended dosage may cause gastrointestinal disturbances, skin allergies, headaches, and bleeding such as nosebleeds and subcutaneous hemorrhages. For topical use or in the form of a mixture for oral use with a small dose (less than 100 mg/day),

		warnings/precautions are not required unless combined with substances that intensify the risk of bleeding.
21.	*Ganoderma lucidum*	<u>Warnings and Precautions</u> ● If adverse reactions occur, discontinue use of this product immediately and consult a doctor. ● Consult a doctor before using this product with other medications. ● Not recommended for children, pregnant women, or breastfeeding mothers.
22.	*Gingko biloba*	<u>Warnings and Precautions</u> ● Not recommended for use exceeding 4 weeks. ● Avoid use in children under 12 years of age, pregnant women, or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin, heparin, and aspirin. ● Discontinue use 2 weeks prior to surgery due to increased risk of bleeding. ● Consult a doctor before using this product concomitant with other medications. ● Exceeding the recommended dosage may cause gastrointestinal disturbances, skin allergies, headaches, and bleeding such as nosebleeds and subcutaneous hemorrhages.
23.	*Glychirhiza glabra, Glychirhiza uralensis*	<u>Contraindications</u> Patients with hypertension, hypokalemia, kidney disease, and edema. <u>Interactions</u> ● Interacts with corticosteroid medications such as prednisolone. ● Interacts with thiazides, potent diuretics, cardiac glycosides, spironolactone, or amiloride. Warnings and precautions should be included if the product contains more than 2g/day of glycyrrhizae radix.

		Warnings and Precautions ● Not recommended for pregnant women or breastfeeding mothers. ● Use for more than 4 weeks should be under medical supervision.
24.	Herbal products containing Caffeine such as *Coffea* sp, *Cola acuminata, Cola nitida*, *Ilix paraguariensis, Paulinia cupana* combined with *Panax ginseng; Panax notoginseng; Panax pseudoginseng; Panax quinquefolius* Caffeine and Herbal products containing Caffeine such as *Coffea sp, Cola acuminata,*	Warnings and Precautions ● Not recommended for children, pregnant women, or breastfeeding mothers. ● Use with caution in patients with hypertension or diabetes ● Do not exceed the recommended dosage.

	Cola Nitida, Ilix paraguariensis, Paulinia cupana combined with *Panax ginseng; Panax notoginseng; Panax pseudoginseng; Panax quinquefolius*	
25.	Caffeine and Herbal products containing Caffeine such as *Coffea sp, Cola acuminata, Cola Nitida, Ilix paraguariensis, Paulinia cupana*	<u>Warnings and Precautions:</u> ● Not recommended for children, pregnant women, or breastfeeding mothers. ● Do not exceed the recommended dosage.
26.	Colostrum	<u>Contraindications</u> Hypersensitivity or allergy to lactose or cow's milk. <u>Warnings and Precautions</u> ● Use with caution in individuals with lactose intolerance. ● Avoid use in children under 1 year of age.
27.	Chromium	<u>Warnings and Precautions</u>

		● Consult a doctor before using this product for more than 6 months or if you have kidney or liver disease. ● Use in patients with diabetes and obesity shall be under medical supervision. ● Do not use this product during pregnancy or breastfeeding, unless recommended by a doctor.
28.	Honey	<u>Warnings and Precautions</u> ● Not recommended for children under 1 year of age ● Use with caution in individuals with history of allergy to bee products and their derivatives.
29.	Honey derivatives e.g. royal jelly, propolis, bee pollen	<u>Warnings and Precautions</u> Use with caution in individuals with history of allergy to bee products and their derivatives.
30.	*Methyl sulfonyl methane* (*MSM*)	<u>Side Effects</u> Prolonged or excessive use, particularly in elderly individuals, may lead to adverse effects such as nausea, vomiting, diarrhea, and headache <u>Warnings and Precautions</u> Avoid use in pregnant women or breastfeeding mothers.
31.	*Monascus purpureus*	<u>Warnings and Precautions</u> ● Not recommended for patients with liver and kidney disorders, children under 18 years of age, adults over 70 years of age, pregnant women or breastfeeding mothers. ● Consult a doctor periodically during use. ● Use with caution when concomitant with other medications, particularly cholesterol-lowering agents (such as atorvastatin, simvastatin, lovastatin). ● The maximum recommended duration of use is 3 months/do not exceed 3 months of continuous use.

32.	*Octacosanol*	Side Effects May cause headache, insomnia, and skin redness. Warnings and Precautions ● Avoid use in children, pregnant women, or breastfeeding mothers. ● Avoid using this product with anticoagulants such as warfarin. ● Discontinue use 2 weeks prior to surgery. ● Discontinue use immediately if allergic reactions occur.
33.	*Panax ginseng; Panax notoginseng; Panax pseudoginseng; Panax quinquefolius*	The following warnings and precautions apply only to: - Single-ingredient compositions. - Combinations with other herbal ingredients intended for male stamina, female health, and blood circulation. Warnings and Precautions ● Use with caution in patients with hypertension or diabetes. ● Avoid use in pregnant women or breastfeeding mothers.
34.	*Phsyllium husk*	Side Effects May cause bloating. Warnings and Precautions ● Adequate hydration of minimum 8 glasses of water per day and a low-fat diet are essential during use. ● Do not use without water. ● Do not consume in powder form. ● If used concomitant with other medications, administer with a 2-3-hour interval between oral administration of other medications and this product to minimize potential effects on drug absorption. ● Not recommended in patients with pancreatic enzyme disorders, as it may inhibit lipase enzyme activity. ● Discontinue use immediately if allergic reactions occur.

		• Use with caution when concomitant with antidiabetic medications.
35.	*Psyllium husk* and *Cassia senna* combination	Warnings and Precautions May cause nausea.
36.	*Policosanol*	Side Effects May cause headache, insomnia, and skin redness. Warnings and Precautions • Avoid use in children, pregnant women, or breastfeeding mothers. • Avoid using this product with anticoagulants such as warfarin. • Discontinue use 2 weeks prior to surgery. • Discontinue use immediately if allergic reactions occur.
37.	Product with higher EPA content than DHA	Warnings and Precautions • Use with caution when consuming products with higher EPA content than DHA in combination with anticoagulants, as it may intensify the risk of bleeding. • If undergoing surgery, inform your doctor about the use of this supplement.
38.	*Rutin*	Contraindications Patients with hypersensitivity to products containing *rutin*. Interactions May inhibit the effectiveness of quinolone antibiotics. Warnings and Precautions • Avoid use in pregnant women or breastfeeding mothers.

		● Discontinue use immediately if allergic reactions occur.
39.	*Valeriana Officinalis*	<u>Contraindications</u> Not recommended for patients with liver function disorders. <u>Warnings and Precautions</u> ● Do not drive or operate heavy machinery that requires high concentration. ● Avoid use concomitant with alcohol or other sedative substances. ● Avoid use in children under 12 years of age, pregnant women, or breastfeeding mothers. ● If sleep disturbances persist or worsen after 2 weeks of use, consult a doctor. (These warnings are specifically applicable to Valerian products with sleep disorder claims) ● Do not use for more than 2 weeks continuously and do not exceed the recommended dose. (This warning applies when the Valerian extract dose is 300-600 mg, equivalent to 2-3 g of dried Valerian root, taken 1-5 times per day.)
40.	Vitamin D single dose, more than 800 IU up to 1000 IU	<u>Warnings and Precautions</u> ● Check blood Vitamin D levels periodically, after 6 months or more of continuous use; ● Consult a doctor before using this product, for pregnant women or breastfeeding mothers; ● Discontinue use immediately if allergic reactions occur; and ● Consume calcium within the recommended dietary allowance to avoid hypercalcemia.
41.	High-dose Vitamin E 400 IU = 240 mg	<u>Warnings and Precautions</u> Do not exceed the recommended dose, as it may induce adverse effects, including depletion of vitamin A reserves, inhibition of vitamin K absorption or activity,

		gastrointestinal disturbances such as diarrhea and stomach pain and fatigue.
42.	Vitamin K1 / Vitamin K2	Warnings and Precautions This product should not be administered to individuals undergoing treatment with warfarin (anticoagulant) or similar medications.
43.	*Whey*	Warnings and Precautions ● Not recommended for individuals with liver or kidney dysfunction. ● Long-term use exceeding recommended dosage may impair liver and kidney function. ● Patients with hypersensitivity to milk proteins. ● Not suitable for pregnant women and children under 15 years of age.

B. Inactive Ingredients (Excipients)

No.	**Inactive Ingredients**	**Warnings and Precautions**
1.	Aspartame	● Contains artificial sweetener aspartame. ● This product contains phenylalanine, not recommended for individuals with phenylketonuria.
2.	Artificial sweeteners (example: acesulfame, sucralose, neotame, sodium cyclamate, saccharin)	● Contains artificial sweetener .... (name of artificial sweetener). ● This product is not recommended for infants under 1 year of age.

C. Natural Medicinal Products Claims

No.	Claims	Warnings and Precautions
1.	UR/Urinating	● If symptoms do not improve, consult a doctor immediately. ● Drink plenty of water, at least 2 liters per day.
2.	Fever	● If fever persists for more than 3 days after using this medication, seek medical attention immediately from a doctor or healthcare facility. ● Fever-reducing medication only alleviates symptoms, but does not eliminate the underlying cause of the illness.
3.	Diarrhea	● If used concomitant with other medications, it is recommended to administer this product with a 2-3 hour interval between oral administration of other medications and this product, as it may affect the absorption of other medications. (Particularly for anti-diarrheal medications containing activated charcoal and other adsorbent materials). ● Not recommended for children under 5 years old and patients should also consume oral rehydration therapy. ● If symptoms do not improve within 3 days of use, consult a doctor immediately.
4.	Kidney/Oxalate Stone Claims	● If symptoms do not improve, consult a doctor immediately. ● Drink at least 2 liters of water per day. ● Avoid prolonged or continuous use of this product.
5.	Diabetes claims	● For use only in patients with diabetes as prescribed by a doctor. ● Consult a doctor periodically during use.
6.	Helps maintain	● Consult a doctor before taking this medication.

	health condition in cancer patients claims	• This product is intended for use as a complementary therapy in cancer treatment.
7.	Supports vaginal health and reduces excess discharge claims	Consult a doctor if discharge does not decrease, or if it has a strong odor, yellow color, or contains blood.
8.	Helps reduce body fat (weight loss) claims	The use of this product should be accompanied by regular exercise and a low-calorie and low-fat diet.
9.	Relieves cold, sinus, and flu symptoms claims	Consult a doctor if symptoms recur or persist.
10.	Supports prostate health claims	Consult a doctor before taking this medication.
11.	Helps lower high blood pressure claims	• For use only in patients with high blood pressure as prescribed by a doctor. • Consult a doctor periodically during use.
12.	Soothes digestive issues and relieves stomach discomfort claims	Consult a doctor if symptoms recur or persist.

D. Health Supplement Claims

No.	Claims	Warnings and Precautions
1.	Supplement to help support health in people with diabetes	• For use only in patients with diabetes (diabetics) as prescribed by a doctor. • Consult a doctor periodically during use.
2.	Helps reduce body fat claims	The use of this product should be accompanied by regular exercise and a low-calorie and low-fat diet.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY AD INTERIM,

signed

LUCIA RIZKA ANDALUSIA

ANNEX III
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS, AND HEALTH SUPPLEMENTS

PROCEDURES FOR INSCRIPTION AND INCLUSION OF LOGOS AND TEXTS ON NATURAL MEDICINAL PRODUCTS

No.	Natural Medicinal Products	Procedures for Inscription and Inclusion of Logos
1.	Jamu	a. The jamu logo features a "leafy branch within a circle" design, placed at the top left corner of the Primary Packaging, Secondary Packaging, and/or Brochure. The logo is printed in green on a white or contrasting background. b. The text “JAMU” must be clear and easily readable, printed in black on a white or contrasting background with the text “JAMU”. c. Jamu Logo  JAMU
2.	Standardized Herbal Medicine	a. The logo features "three pairs of leaf fingers within a circle" and is placed at the top left corner of the Primary Packaging, Secondary Packaging, and/or Brochure. The logo is printed in green on a white or contrasting background with the logo color. b. The text "OBAT HERBAL TERSTANDAR" (STANDARDIZED HERBAL MEDICINE) must be clear and easily readable, printed in black on a white or contrasting background with the text “OBAT HERBAL TERSTANDAR”.

		c. Standardized Herbal Medicine Logo 
3.	Phytopharmaca	a. The logo features "leaf fingers forming a star within a circle" and is placed at the top left corner of the Primary Packaging, Secondary Packaging, and/or Brochure. The logo is printed in green on a white or contrasting background with logo color. b. The text "FITOFARMAKA" (PHYTOPHARMACA) must be clear and easily readable, printed in black on a white or contrasting background with the text “FITOFARMAKA”. c. Phytopharmaceuticals Logo 

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY AD INTERIM,

signed

LUCIA RIZKA ANDALUSIA

ANNEX IV
REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY
NUMBER 10 OF 2024
ON
LABELING OF NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS, AND HEALTH SUPPLEMENTS

THE INCLUSION OF INFORMATION ON GENETICALLY MODIFIED PRODUCTS, IRRADIATED PRODUCTS, ORGANIC PRODUCTS, AND NANO PRODUCTS ON NATURAL MEDICINAL PRODUCTS, QUASI-DRUGS, AND HEALTH SUPPLEMENTS

No.	Inclusion of Information	Requirements
1.	Genetically Modified Products	• Natural Medicinal Products, Quasi-Drugs and/or Health Supplements that utilize genetic engineering technology display Genetically Modified Product Information in the form of the text "PRODUK REKAYASA GENETIK" (GENETICALLY MODIFIED PRODUCT). • The text "PRODUK REKAYASA GENETIK" is displayed in the composition section, immediately following the name of the genetically modified ingredient.
2.	Irradiated Products	Information on Natural Medicinal Products, Quasi-Drugs, and Health Supplements that have undergone Irradiation of the final product includes: a. the text "IRADIASI" (IRRADIATED) is included after the Irradiation Logo; b. the text "TIDAK BOLEH DIRADIASI ULANG" (DO NOT RE-IRRADIATE) c. the date, month, and year of irradiation. d. the name of country where the irradiation was completed; and e. irradiation logo:

		
3.	Organic Products	The Organic Indonesia Logo is a circular symbol consisting of two parts, inscribed with "Organik Indonesia" (Organic Indonesia) accompanied by a single leaf image attached to the letter "G" in the shape of a root bud 
4.	Nano Products	The term "nano" may be added after the name of the ingredient in the composition, in accordance with the provisions of laws and regulations.

CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY AD INTERIM,

signed

LUCIA RIZKA ANDALUSIA