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New Standards of Mandatory Labeling for Natural Medicines, Quasi-Medicines, and Health Supplements. What is the Impact for Local Distributors and Foreign Principals?

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Reflecting on the urgent need for new standards for drug safety in Indonesia, the Indonesian Food and Drug Authority (*Badan Pengawas Obat dan Makanan* or "**BPOM**") passed BPOM Regulation Number 10 of 2024 concerning Labeling of Natural Medicines, Quasi-Medicines, and Health Supplements ("**BPOM Reg. 10/2024**") on 7 June 2024. This law essentially mandates that all natural medicines, quasi-medicines, and health supplements being traded in Indonesian territory must comply with the mandatory labeling in accordance with the standards set forth in the regulation. The recently enacted regulation provides a deadline for compliance of 2 (two) years after its enactment , i.e., by 7 June 2026 .

The primary implication of BPOM Regulation 10/2024 is the requirement for business actors to label natural medicines, quasi-medicines, and health supplements in accordance with BPOM standards. Additionally, in order to protect the public health from the improper, inappropriate, or irrational use of natural medicinal products, quasi-medicines, and health supplements, it is essential to regulate the inclusion of objective, comprehensive, and accurate information on labels. The inclusion of objective, complete, and non-misleading information is one of the criteria to meet the standards of product safety, efficacy, and quality.

The labeling obligation must feature at least 17 (seventeen) types of information as provided in Article 16 paragraph (1) BPOM Reg. 10/2024. The following are some of the major types of information which it is mandatory for labels to include:[1]

Information	Annotations
Product name and dosage form	The product name can be in the form of a general name and/or trading name.[2]
	The dosage form must be in accordance with the product that is manufactured and distributed based on the distribution permit from BPOM.[3] For imported products, the name of the business actors serving as importers must begin with the statement "imported by ..." or use another phrase with similar meaning.[4]
Business actor and/or industry name and address, or contract provider and/or recipient's name and address, or license provider and/or recipient's name and address	The address on the labeling must at least include the name of the city and the name of the country.[5] For imported products, the name and address of the business actor serving as the Importer, appointed by the principal from the country of origin, must be clearly listed on the label along with the name and address of the principal.[6]

[1] Article 16 paragraph (1) BPOM Reg. 10/2024.
[2] Article 11 paragraph (1) BPOM Reg.10/2024.
[3] Article 13 BPOM Reg. 10/2024.
[4] Article 15 paragraph (2) BPOM Reg. 10/2024.
[5] PM 39/2019, Article 4.
[6] Article 15 paragraph (1) BPOM Reg. 10/2024.

Information	Annotations
Composition	The composition is the qualitative and quantitative arrangement of the active ingredients in natural medicines, quasi-medicines, and health supplements.[7] The listing of active ingredients must be preceded by the statement "Composition", "Ingredients used", "Ingredients", or "use another phrase with similar meaning".
Efficacy/benefit-related claims	The Business actor must include claims of efficacy/benefits in accordance with the approval issued by the Head of BPOM.[8]
Usage instructions	The usage instructions must be in the form of instructions on preparation in clear and easily understood language, and/or usage instructions accompanied by pictures.[9] This information must be in accordance with the serving instructions approved by BPOM.[10]
Contraindications, side effects, interactions, warnings and/or cautions	Contraindications, side effects, interactions, warnings, and/or cautions must be in accordance with the results of the registration evaluation by BPOM.[11] The format for this matter is further regulated in Appendix II of BPOM Reg. 10/2024.
Distribution permit numbers	The Distribution Permit Number on the labeling must begin with the letters 'POM' followed by 2 (two) letters and 9 (nine) digits in accordance with numbers stated in the distribution permit.[12]
Production codes	The production code consists of numbers or letters or a combination of both used as an identifier of a batch, which allows traceability and review of the complete manufacturing history of that batch, including all stages of production, control, and distribution.[13] This information can be included separately from the information on the label.[14]
Expiration dates	The expiration date must include day, month, and year or month and year.[15]
Other information	May take the form of any other information necessary for mandatory labeling, such as halal certification, alcohol content, and certain material ingredients.[16]

Most importantly, the mandatory label must contain information that meets objective, complete, and non-misleading criteria.[17] The information must be written and printed in Indonesian, using Arabic numerals and Latin letters, except for the product name.[18] In addition to that, the label must be printed directly on or firmly affixed to the container and/or packaging, must not come off easily, and not be damaged by water, friction, or exposure to sunlight.[19]

The starting date for the mandatory labeling is the enactment of BPOM Reg. 10/2024, which was on 7 June 2024. However, business actors distributing natural medicines, quasi-medicines, and health supplements are given a grace period of 24 months from the date of enactment to comply with the obligation ("**Compliance Grace Period**").[20]

Business actors should ensure compliance with the mandatory labels for their products to avoid any possible sanctions for violations of mandatory labeling. Any failure to comply with mandatory labeling may be subject to the following administrative sanctions:

(i) Warning;
(ii) Withdrawal;
(iii) Destruction;
(iv) Temporary cessation of activities;
(v) Revocation of certificate;
(vi) Cancellation/revocation of distribution permit number; and/or
(vii) Public announcement.

Further to the foregoing, it is highly important for business actors to comply with these mandatory labels before the end of the Compliance Grace Period to avoid any disruption to its operations and product distribution.

[7] Article 19 paragraph (1) BPOM Reg.10/2024.
[8] Article 24 paragraph (1) BPOM Reg. 10/2024.
[9] Article 25 paragraph (1) BPOM Reg. 10/2024.
[10] Article 25 paragraph (2) BPOM Reg. 10/2024.
[11] Article 26 paragraph (2) BPOM Reg. 10/2024.
[12] Article 27 paragraph (1) and (2) BPOM Reg.10/2024.
[13] Article 28 paragraph (1) and (2) BPOM Reg.10/2024.
[14] Article 28 paragraph (3) BPOM Reg. 10/2024.
[15] Article 29 paragraph (2) BPOM Reg. 10/2024.
[16] Article 6 paragraph (2) BPOM Reg. 10/2024.
[17] Article 5 paragraph (1) BPOM Reg. 10/2024.
[18] Article 8 paragraph (1) BPOM Reg. 10/2024.
[19] Article 4 BPOM Reg. 10/2024.
[20] Article 43 BPOM Reg. 10/2024.

The enactment of BPOM Reg. 10/2024 will significantly affect local distributors who wish to distribute natural medicines, quasi-medicines, and health supplements. Every local distributor is required to obtain a distribution permit prior to commencing distribution. The distribution permit is the registration approval for natural medicines, quasi-medicines, and health supplements to be distributed within Indonesian territory.[21]

If the natural medicines, quasi-medicines, and/or health supplements are imported products, business actors as importers are required to incorporate the mandatory labels (i) once the products enter the territory of Indonesia and (ii) upon obtaining the relevant distribution permit but prior to the distribution of the products in Indonesian territory.[22] This means that local distributors will need to be vigilant about the labeling standards as required under BPOM Reg. 10/2024 to avoid any legal issues or disruptions to their business operations.

For foreign business actors, the BPOM Reg. 10/2024 indirectly introduces a new layer of responsibility. Foreign principals intending to appoint or supply medicines and health supplements to Indonesian local distributors must ensure the local distributors' compliance with the mandatory labeling specified in BPOM Reg. 10/2024. This is essential because the enforceability of the distribution agreement hinges on adherence to Indonesian regulations. It is important that the distribution agreement include provisions which accommodate the labeling obligations and compliance with BPOM Reg. 10/2024. The foregoing is to guarantee that all parties involved in the distribution agreement are aware of their respective responsibilities to ensure smooth operation of the distribution of medicines and health supplements in Indonesia.

As it may be challenging for business actors to fulfil the new labeling standards, many business actors who distribute natural medicines, quasi-medicines may not realize that they need to incorporate major adjustments to their labeling criteria. Particularly, the requirement to adjust labeling criteria in accordance with BPOM Reg. 10/2024 applies not only to the products that are to be distributed in the near future, but also to products that are already on the market.

To summarise, it is of the utmost importance for business actors to ensure compliance with the new required labels for their products to avoid any sanctions, which could put their product distribution in Indonesia and their business sustainability at risk.

[21] Article 1 number 9 BPOM Reg. 10/2024.

[22] Article 2 paragraph (4) and paragraph (5) BPOM Reg. 10/2024.

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