ATD LAW
in association with
MORI HAMADA

Newsletter

April 3, 2026

Indonesia Healthcare Regulatory Transition on the Horizon: Halal Compliance and TKDN Trends for Pharmaceutical and Healthcare Businesses

Dyah Paramita
Partner
dyah.p@morihamada.com

Dave Wiryawan
Associate
dave.w@morihamada.com

Introduction

Indonesia's healthcare sector is entering a more operational and enforcement-focused phase of halal compliance and domestic content obligations. New rules are expected to provide more prescriptive direction on product status, packaging, disclosure and local-content substantiation, particularly for medicines, biological products and medical devices that contain animal-derived inputs or use manufacturing processes that are not yet halal-compliant.

This newsletter highlights upcoming developments that healthcare businesses should monitor, with a focus on non-halal labelling, phased halal certification deadlines and the evolving TKDN framework.

I. Non-Halal Labelling

Current regulatory regime

Under the Law No. 33 of 2014 on Halal Product Assurance (as amended) and Government Regulation No. 42 of 2024 on the Implementation of Halal Product Assurance ("**GR 42/2024**"), products made from non-halal (*or haram*) materials do not require halal certification, but must carry a clear non-halal label. The statement must be easily visible, legible and not easily removed.

For healthcare companies, compliance therefore involved both identifying products that contain non-halal inputs and ensuring such non-halal status is properly disclosed.

Healthcare-specific treatment

Presidential Regulation No. 6 of 2023 on the Halal Certification of Medicines, Biological Products and Medical Devices ("**PR 6/2023**") applies the non-halal labelling principle specifically to medicines, biological products, and certain medical devices. It acknowledges that some healthcare products will continue circulating with non-halal materials, provided that they carry a non-halal indication. For medicines and biological products, the non-halal indication must be linked to the composition details and highlighted in a different color. For medical devices containing animal-derived components, the non-halal indication must appear in the product marking.

The policy intent is not to prohibit the circulation of non-halal healthcare products, but to ensure transparent disclosure to users and regulators.

Medical device implementation

For medical devices, Minister of Health Regulation No. 3 of 2024 on the Guidelines for Halal Manufacturing Practices for Medicines, Biological Products and Medical Devices, as well as the Inclusion of Information on the Origin of Materials for Medical Devices ("**MOH Reg. 3/2024**"), provides a specific example of implementation. It requires:

- disclosure of the material source or non-halal information on the primary and secondary packaging;
- the name of any non-halal ingredient to be displayed in a different color and in a manner that remains visible and legible; and
- clear identification where ingredients may be halal but the manufacturing process is not yet halal-certified.

Upcoming BPJPH Rule on Non-Halal Labelling (expected Q4 2026)

The Halal Product Assurance Agency (*Badan Penyelenggara Jaminan Produk Halal* or **BPJPH**) is preparing a regulation to standardize the form and procedure for non-halal labelling, which is expected to be issued in Q4 2026. It is expected to introduce:

- a consistent visual standard across product categories (including the healthcare sector);
- specific criteria relating to materials and processes; and

- tighter requirements on packaging, storage segregation and distribution practices.

Healthcare companies should anticipate more prescriptive rules and potentially stricter scrutiny of labelling workflows.

II. Expected Timelines on Halal Certification

Phased Timelines

Under GR 42/2024, the key deadlines most relevant to healthcare businesses are:

- 17 October 2026: Natural medicines, quasi drugs, health supplements and Class A medical devices
- 17 October 2029: Over-the-counter (**OTC**) and limited OTC medicines, as well as Class B medical devices
- 17 October 2034: Prescription medicines (other than psychotropics) and Class C medical devices
- 17 October 2039: Biological products and Class D medical devices (under PR 6/2023, as stipulated by GR 42/2024).

Transitional relief

Regulators recognize that some products cannot immediately shift to halal-sourced materials or fully halal-compliant processes. GR 42/2024 and PR 6/2023 therefore allow the continued circulation of certain drugs, biological products, and medical devices, if information on the source of materials is properly disclosed.

For medical devices, MOH Reg. 3/2024 already sets out the implementing mechanism. For medicines and biological products, PR 6/2023 anticipates a forthcoming Food and Drug Authority (*Badan Pengawas Obat dan Makanan* or **BPOM**) regulation on how information on the source of materials should be presented, making this a key watchpoint.

III. Expected TKDN Provisions

Pharmaceutical industry focus

Director General of the Chemical, Pharmaceutical and Textile Industry Regulation No. 3 of 2025 ("**DG IKFT Reg. 3/2025**") introduces a main-component listing for TKDN purposes. This signals a shift towards a more data-driven TKDN verification process, especially where imported active ingredients or other high-value non-local components dominate.

Further developments to watch

Recent news reporting [link] suggests the regulation may be revised up to four times a year (quarterly review) based on:

- industry developments, and
- proposals from associations and companies seeking inclusion in the TKDN component list.

While amendment texts are not yet available, the direction appears to be towards a more structured and disciplined TKDN system, with closer scrutiny of how healthcare companies substantiate local content at the product level.

IV. Conclusion

The regulatory landscape is moving towards:

- more specific non-halal labelling requirements;
- clearer disclosure of non-halal or not-yet-halal inputs;
- stricter alignment between product status and packaging; and
- a more granular and data-informed TKDN component analysis and verification.

Healthcare companies should proactively:

1. map product portfolios against the halal certification deadlines;
2. reviewing non-halal and source-of-material statements;
3. assess packaging and labelling workflows; and
4. evaluate TKDN components for products marketed in Indonesia.

Key items to monitor include the upcoming BPJPH regulation on non-halal labelling, the anticipated BPOM regulation as mandated by PR 6/2023, as well as any further amendments to the healthcare TKDN framework (particularly under DG IKFT Reg. 3/2025).

If you have any questions in relation to the topic raised in this briefing, please contact the authors listed herein.