

Legal Update – Healthcare

NEW REGULATORY REQUIREMENTS FOR MEDICAL SUPPLIES IN INDONESIA

7 September 2026

Indonesia has introduced new requirements governing medical supplies (*perbekalan kesehatan*). Here is what your business needs to know to stay compliant.

The new framework is set out under Minister of Health Regulation Number 5 of 2026 on Medical Supplies (“**MHR 5/2026**”), which applies to businesses across the healthcare sector, including pharmaceutical companies, medical device manufacturers, distributors, and retail operators.

MHR 5/2026 introduces key requirements covering the supply and distribution of medical supplies, including expanded distribution channels, greater use of electronic systems, a preference for products using domestic raw materials and components, and increased price transparency and reporting through the National Health Information System (*Sistem Informasi Kesehatan Nasional* or “**SIKN**”).

This Legal Update highlights selected key requirements under MHR 5/2026 that may have practical implications for businesses involved in the production, distribution and supply of medical supplies in Indonesia.

Production and Supply Requirements

MHR 5/2026 gives priority to imported medicines used for public health programs, newly discovered medicines, and medicines that cannot be produced domestically. These imported medicines must be registered and subsequently produced in Indonesia within five (5) years or in accordance with the applicable technology transfer roadmap. This requirement was also included in the previous rules under Minister of Health Regulation Number 1010/MENKES/PER/XI/2008 on Drug Registration, which has now been revoked by MHR 5/2026.

For supply planning, providers must take into account buffer stock requirements of at least ten percent (10%) and up to thirty percent (30%) of their planned requirements. The Central Government, Regional Governments and Healthcare Facilities must prioritize medical supplies using domestically produced raw materials and/or components. This priority is given to products with the highest domestic component level (*Tingkat Komponen Dalam Negeri* or “**TKDN**”) or a domestic product marketing authorization, as applicable.

Medicine Distribution

MHR 5/2026 introduces additional distribution channels by allowing over-the-counter (“OTC”) medicines and limited OTC medicines to be distributed directly to certain retail facilities, including hypermarkets, supermarkets, minimarkets and other retailers, expanding the channels available to pharmaceutical businesses for distributing these medicines. This allows certain medicines to reach consumers through modern retail channels in addition to the existing distribution channels.

MHR 5/2026 also allows medical supplies to be made available through vending machines, subject to applicable requirements and technical guidelines to be issued by the Minister of Health. This provides another permitted channel for making medical supplies available to consumers. The medical supplies may also be distributed through pharmaceutical service facilities, subject to applicable service standards, as well as other types of facilities. For other facilities, only certain products may be distributed, including OTC medicines, limited OTC medicines, natural medicines, health supplements, quasi-drugs, cosmetics and certain medical devices.

These changes represent an expansion of the regulatory framework as set out in Minister of Health Regulation Number 1148 of 2011 on Pharmaceutical Wholesalers (“**MHR 1148/2011**”), which generally limited the distribution of pharmaceutical products to other pharmaceutical wholesalers and pharmaceutical service facilities, including pharmacies, hospital pharmacies, community health centers, clinics and drugstores. The MHR 1148/2011 also imposed restrictions on the distribution of prescription medicines to drugstores.

Digital Reporting Requirements

Before MHR 5/2026 came into force, MHR 1148/2011 required pharmaceutical wholesalers and their branches to submit quarterly reports, either manually or electronically, to the relevant Director General of the Ministry of Health on the receipt and distribution of pharmaceutical products.

MHR 5/2026 requires medical supply manufacturers and distributors to use an electronic distribution or delivery system integrated with SIKN to report their activities. In addition, the distribution or delivery of medical supplies through the electronic system must also be reported through the SIKN-integrated system.

Medicine Pricing and Price Transparency

The highest selling price of a medicine is calculated based on its acquisition price, including Value Added Tax (“**VAT**”), plus the pharmaceutical service fee determined by the Minister of Health. The acquisition price of medicines supplied to healthcare facilities and other facilities is calculated based on the cost price, after deducting any discounts and/or other incentives. Accordingly, the calculation can be summarized as follows:

$$\begin{aligned} &\textbf{Highest Selling Price} = \\ &(\text{Cost Price} - \text{Discounts and/or Other Incentives} + \text{VAT}) \\ &+ \\ &\text{Pharmaceutical Service Fee} \end{aligned}$$

Medical supply producers, distributors, healthcare facilities and other facilities are also required to transparently disclose the prices of medical supplies, including applicable discounts and/or other incentives through an integrated health information system connected to SIKN.

Additionally, MHR 5/2026 also provides that medical supplies containing domestic components, including raw materials and/or other production components, may be priced higher than comparable products using imported components or imported medical supplies.

What Happens If the Requirements Are Not Met?

Businesses that do not meet the reporting, distribution, pricing, or other requirements under MHR 5/2026 are subject to the following administrative sanctions: a warning, temporary suspension of business activities, fines, coercive measures, and/or revocation of the business license. These administrative sanctions will take effect on 4 May 2027, one (1) year after the regulation was promulgated.

What Should Businesses Do Now?

The transition period gives businesses time to prepare for the new requirements before the administrative sanctions take effect. Businesses in the pharmaceutical and broader healthcare sectors should use this period to assess the operational and compliance implications of the new requirements and make the necessary adjustments.

Businesses can use the transition period to:

- a. identify medicines, products, and supply arrangements that may be affected by the new requirements on the use of domestic products and applicable distribution restrictions;
- b. review current medicine pricing calculations and price disclosure practices against the new pricing and price transparency requirements;
- c. ensure that the relevant electronic systems are integrated with SIKN and ready to support the required distribution and delivery reporting;
- d. identify areas that do not yet meet the new requirements and make the necessary operational adjustments before the transition period ends; and
- e. assess whether existing distribution arrangements with retail facilities remain compliant with the new permitted distribution channels and applicable product restrictions.

For pharmaceutical companies and other businesses in the healthcare sector, preparing for the new requirements early can help ensure compliance and avoid disruptions to existing operations. Taking action during the transition period can also give businesses sufficient time to address any issues before the administrative sanctions take effect.

If you have any questions about the new requirements for medical supplies, please feel free to contact our team.



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