DENTONS HPRP

Grow | Protect | Operate | Finance

Unlocking Opportunities: The Growing Potential of Distribution of Imported Pharmaceuticals, Medical Devices and Household Health Supplies in Indonesia

Prepared by:
Nashatra Prita (Partner) and Yasyfa Alifya Radiany (Assosiate)

Following our first article on **"New Legal Landscape for the Tobacco and E-Cigarette Business in Indonesia"** as part of our comprehensive healthcare article series in response to the recent enactment of Government Regulation No. 28 of 2024, which implements Law Number 17 of 2023 on Health ("**GR 28/2024**"), we are pleased to introduce a new topic focused on the potential growth in distribution of pharmaceuticals, medical devices, and household supplies in Indonesia. This article will explore the implications for industry players and the opportunities that may arise from these regulatory changes.

In this second article, we will delve into the regulations concerning distribution of imported pharmaceuticals, medical devices and household health supplies in Indonesia and their implications for the industry. The distribution of pharmaceuticals, medical devices, and household health supplies was previously governed by Ministry of Health Regulation No. 62 of 2017 concerning Distribution Licenses for Health Equipment, In Vitro Diagnostic Health Equipment, and Household Health Supplies. However, with the recent issuance of Government Regulation 28/2024, stricter provisions regarding the distribution of these items have been established.

The commercial demand for pharmaceuticals, medical devices, and household health supplies in the healthcare industry is rapidly increasing, fuelled by the growing need for advanced technology in patient care and diagnostics. Many healthcare providers encounter challenges in acquiring high-quality pharmaceuticals, medical devices, and household health supplies due to the complexities of distribution networks and inconsistent regulatory oversight.

The distribution of imported pharmaceuticals, medical devices, and household health supplies in Indonesia presents significant investment opportunities, particularly on an international scale, as the industry opens 100% (one hundred percent) to foreign investment. Despite the challenges posed by regulatory complexities, the sector remains appealing to international investors, driven by the country's increasing healthcare demands and expanding medical infrastructure across Indonesia.

With Indonesia's growing demand for advanced medical technologies and its substantial aging population, the market presents a compelling opportunity for investors looking to enter or expand in the healthcare industry. The heightened emphasis on enhancing healthcare standards further enhances the sector's appeal to foreign investors.

Quality Assurance

In the field of pharmaceuticals, medical devices, and household health supplies, every business actor within these areas must prioritize maintaining product quality and safety from production through distribution.[1] Quality assurance measures require risk-based sampling and testing.[2]

[1] Article 407 paragraph (1) GR 28/2024.
[2] Article 407 paragraph (3) GR 28/2024.

The responsibilities to conduct proper sampling and testing are supervised by the Ministry of Health or the Indonesian Food and Drug Authority (*Badan Pengawas Obat dan Makanan* - "**BPOM**"), ensuring that health products have meet safety and quality standards under their authority.[3] Proper sampling and testing of pharmaceuticals will be supervised by BPOM, while the sampling and testing of medical devices and household health supplies will fall under the supervision of the Ministry of Health. Additional, specific regulations for pharmaceutical sampling and testing will be guided by government regulations, while similar measures for medical devices and household health supplies will be regulated by Ministerial regulations, ensuring comprehensive oversight across all health product categories.

Measurement of Pharmacovigilance and Vigilance

To ensure public protection from unsafe pharmaceuticals, medical devices, and household health supplies, the license holders must conduct strict measures, primarily pharmacovigilance and vigilance.[4] Pharmacovigilance involves all activities related to spotting, evaluating, understanding, communicating, managing, and preventing side effects or other problems linked to the use of medications, herbal products, health supplements, cosmetics, and quasi-drugs.[5] Vigilance, on the other hand, means all activities focused on finding, evaluating, understanding, communicating, managing, and preventing side effects or problems related to using medical devices and household health supplies.[6] Distribution license holders of pharmaceuticals are required to carry out pharmacovigilance activities and report findings to the Indonesian - BPOM, while distributor license holders for medical devices and household health supplies must conduct vigilance and report to the Minister of Health.[7] Distribution license holders for pharmaceuticals, medical devices and household health supplies may also collaborate with Health Service Facilities to enhance monitoring efforts.[8]

The Health Service Facilities mentioned previously are places and/or equipment used to provide health services, such as Community Health Centers (*Pusat Kesehatan Masyarakat* – "**Puskesmas**"), clinics and hospitals.[9] Additionally, government authorities are authorized to take samples from various locations to verify product safety, with the power to take appropriate action based on sampling results and report analyses, thereby safeguarding public health with regard to the products distributed.[10]

Product Recalls and Destruction

Additionally, businesses or distribution license holders must promptly withdraw pharmaceuticals, medical devices, or household health supplies from the market if they are found to be non-compliant with safety, efficacy, quality, or labeling standards.[11] The withdrawal process is governed by regulations established by the Ministry of Health and BPOM. Adherence to these regulations ensures that any unsafe products are efficiently removed from circulation, reinforcing commitment to public safety and regulatory compliance.[12]

Furthermore, destruction of pharmaceuticals, medical devices, and household health supplies is mandated for products that fail to meet safety, efficacy, or quality standards, lack the required distribution permits, have revoked or expired permits, have surpassed their expiration dates, or are linked to health-related criminal activities.[13] Facilities involved in the production, importation, distribution, or storage of such items must destroy them in line with established standards, prioritizing both human health and environmental preservation.[14] Specific regulations guiding the destruction process are issued by the Ministry of Health and BPOM, ensuring controlled and responsible disposal practices.[15]

[3] Article 407 paragraph (2) GR 28/2024.
[4] Article 408 paragraph (1) GR 28/2024.
[5] Article 1 number 20 GR 28/2024
[6] Article 1 number 21 GR 28/2024
[7] Article 408 paragraph (2) and (3) GR 28/2024.
[8] Article 408 paragraph (5) GR 28/2024.
[9] Article 1 number 7 and 8 jo Article 765 GR 28/2024.
[10] Article 408 paragraph (6) GR 28/2024.
[11] Article 411 paragraph (1) GR 28/2024.
[12] Article 411 paragraph (2) GR 28/2024.
[13] Article 412 paragraph (1) GR 28/2024.
[14] Article 412 paragraph (4) GR 28/2024.
[15] Article 412 paragraph (5) GR 28/2024.

The distribution of pharmaceuticals, medical devices, and household health supplies must also uphold safety and compliance standards.[16] Only licensed pharmaceutical facilities, producers, and distributors are authorized to distribute these products. Additionally, they must possess valid business licenses as required by law.[17] All distribution processes must adhere to regulatory standards maintained throughout the supply chain. Further guidelines for pharmaceutical facilities and their distribution methods will be detailed in ministerial regulations.[18]

Marketing and Promotion

At the marketing and promotion level, all promotions and advertisements for pharmaceuticals, medical devices, and household health supplies are required to meet strict standards. Promotional materials must be objective, complete, and non-misleading, adhering to established advertising ethics.[19] Pharmaceuticals and medical devices can be advertised in public information media, with exceptions for prescription drugs, herbal medicines, special health supplements, and medical devices that require healthcare professional assistance.[20] These restricted items may only be promoted in scientific media intended for healthcare professionals.[21] Additionally, the labeling, publication, and advertising of narcotics, psychotropics, and pharmaceutical precursors must align with applicable regulatory guidelines.[22] With regard to this matter, we have issued an article on the new labeling obligations for natural medicines, quasi medicines, and health supplements pursuant to BPOM Regulation Number 10 of 2024, which can be accessed **here**.

Failure to comply with all the obligations above may result in a variety of administrative sanctions. Sanctions may include[23]:

a. warning;
b. temporary suspension of business activities through the suspension of business permits;
c. imposition of administrative fines
d. imposition of police force; and/or
e. revocation of business license.

Conclusion

In conclusion, the pharmaceuticals, medical devices, and household health supplies distribution sector in Indonesia is poised for steady growth, driven by increasing healthcare demands and the need for advanced medical technologies. While this expanding market offers significant opportunities for investors and businesses, industry players must navigate the complexities introduced by Government Regulation (GR) 28/2024, which enforces stricter guidelines on production and distribution practices. By proactively addressing these regulatory challenges and ensuring compliance with the evolving legal landscape, distributors and investors can mitigate risks and secure long-term sustainability in this dynamic and rapidly growing industry.

---

[16] Article 420 paragraph (1) GR 28/2024.
[17] Article 420 paragraph (2) GR 28/2024.
[18] Article 422 GR 28/2024.
[19] Article 424 paragraph (1) GR 28/2024.
[20] Article 424 paragraph (2) GR 28/2024.
[21] Article 424 paragraph (3) GR 28/2024.
[22] Article 424 paragraph (4) GR 28/2024.
[23] Article 426 paragraph (2) GR 28/2024.

- o0o -