

## TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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## REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

**1. What are the principal statutes, regulations, and competent authorities that govern the import, wholesale distribution, retail sale, and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?**

In Indonesia, the main legislation governing therapeutic products is Law No. 17 of 2023 on Health (Health Law) and its implementing regulation, Government Regulation No. 28 of 2024 on the Implementing Regulation of Law No. 17 of 2023 on Health (GR 28/2024). There are also further implementing regulations to GR 28/2024, issued by the relevant government agencies with authority over the respective health products.

Therapeutic products and medical devices are regulated separately. The distribution of therapeutic products such as pharmaceutical products falls under the authority of the Food and Drugs Control Agency (*Badan Pengawas Obat dan Makanan* – BPOM). Whereas, medical devices are supervised by the Ministry of Health (MoH).

**2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use, risk classes for devices, etc.) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?**

Under GR 28/2024, therapeutic products in Indonesia are classified as prescription medicine and non-prescription medicine. Prescription medicine is further classified into: (1) prescription-only medicine; (2) narcotics; and (3) psychotropics. Prescription medicine may only be supplied by a pharmacist based on a prescription issued by medical professionals.

Non-prescription medicine is further classified into: (1) over-the-counter medicines; and (2) limited over-the-counter medicines. Non-prescription medicine may be obtained from either medical service facilities or another retailer.

Prior to the distribution of any therapeutic products, all products must obtain distribution licences (*izin edar*) from the BPOM, unless the product is distributed through a special access scheme (SAS).

As for medical devices, under MoH Regulation No. 62 of 2017 on Distribution Licences for Medical Devices, In Vitro Diagnostic Medical Devices and Household Medical Supplies, as amended (MoH Reg 62/2017), they are classified into the following risk categories:

1. Class A – low risk;
2. Class B – low to moderate risk;
3. Class C – moderate to high risk;
4. Class D – high risk.

In vitro diagnostic (IVD) medical devices are classified separately based on risk:

1. Class A – low individual risk and low public health risk;
2. Class B – moderate individual risk and low public health risk;
3. Class C – high individual risk and moderate public health risk;
4. Class D – high individual risk and high public health risk.

As with therapeutic products, the distribution of any medical devices may only be conducted after obtaining a distribution licence (*izin edar*) from the MoH for each medical device, unless they are distributed through a special access scheme (SAS).

## LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

### **3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?**

Companies that carry out the wholesale distribution of therapeutic products and medical devices must have a business licence in accordance with the relevant Indonesian Standard Business Classification (*Klasifikasi Baku Lapangan Usaha Indonesia* – KBLI) for their business activities. For the wholesale of therapeutic products and medical devices, these activities fall under KBLI 46441 (the Wholesale of Pharmaceuticals Medicine for Human) and KBLI 46691 (the Wholesale of Laboratory, Pharmaceuticals and Medical Devices for Human), respectively.

Under Indonesian law, business licences for business sectors are issued according to the risk classification of the relevant line of business. Both KBLIs 46441 and 46691 are classified as high risk. Companies that engage in these KBLIs must obtain a Business Identification Number (NIB) and business licence. The business licence for these activities must be obtained from the MoH.

Under MoH Regulation No. 17 of 2024 on Business Licensing in the Health Subsector (MoH Reg 17/2024), a business licence for KBLI 46441 will be issued on fulfilment of requirements set out in the regulation, including, among others:

1. Building and facility – licence holders must have at least a warehouse for storing drugs that could ensure their safety, efficacy and quality, by also having separate storage area for the drugs as well as storage area for narcotics, psychotropics and/or pharmaceutical precursor.
2. Organisation structure and human resources – licence holders must appoint a full-time pharmacist to be the person in charge of the distribution of the products.

3. Operation – licence holders must prepare a standard operating procedure (SOP) that is based on Good Distribution Practice standards for drugs.

Meanwhile the requirements to obtain a business licence for KBLI 46691 under MoH Reg. 17/2024 include, among others:

1. Building and facility – licence holders must have at least, administration, reception, shipping, quarantine and storage area.
2. Equipment – licence holders must own the appropriate equipment to ensure the safety, efficacy and quality of medical devices.
3. Organisation structure and human resources – licence holders must appoint a full-time technical person in charge with qualification of at least holding associate degree (D-3) in health sciences, engineering or natural sciences.
4. Operation – licence holders must prepare a standard operating procedure (SOP) that is based on Good Distribution Practice standard for medical devices.

After fulfilling the above requirements and the business licence has been issued, the applicant must fulfil some obligations required by the business licence, which typically include, among others, obtaining Good Distribution Practice for Drugs (*Cara Distribusi Obat Yang Baik – CDOB*) or Good Distribution Practice for Medical Devices (*Cara Distribusi Alat Kesehatan Yang Baik – CDAKB*) certificate (as applicable) prior to conducting any distribution activities.

**4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?**

For providing therapeutic products directly to consumers, companies must have a business licence for conducting pharmacy retail activities. This activity falls under KBLI 47721 (Retail of Pharmacy Equipment and Medicines for Human in Pharmacist) or KBLI 47722 (Retail of Pharmacy Equipment and Medicines for Human other than Pharmacist). Note that the general rule in Indonesia is that a company that engages in wholesale activities is prohibited from carrying out any retail activities. Therefore, wholesaler of therapeutic products may not sell their products directly to consumers.

KBLI 47721 is classified as moderate-high risk activities. Companies engaging in this KBLI must obtain NIB and verified standard certificate.

As KBLI 47722 is classified as moderate-low risk activities, companies engaging in this KBLI must obtain NIB and standard certificate. This KBLI applies to retailers who sell therapeutic products through outlets other than pharmacist. However, this KBLI is not allowed to be engaged in by companies with foreign investments.

**5. What rules govern the sale of therapeutic products to consumers over the internet (including social-media and marketplace platforms)?**

The sale of therapeutic products over the internet is governed by GR 28/2024. Under this regulation, therapeutic products (both non-prescription and prescription drugs, with the exception of medicine containing narcotics or and psychotropics) may be sold over the internet through

telemedicine applications. Such applications may be provided by a health facility (eg, hospital, pharmacy, clinic, etc.) or the Pharmacy Electronic System Provider (*Penyedia Sistem Elektronik Farmasi* – PSEF).

If the telemedicine application is provided by PSEF, the PSEF will need to cooperate with health facilities/retail pharmacies that holds the relevant licence to sell therapeutic products in order to sell such products from its platform. The PSEF itself may not sell therapeutic products.

All telemedicine applications providing health services, including selling therapeutic products, must be registered with the MoH.

Only over-the-counter therapeutic products may be sold through general e-commerce marketplaces.

Regarding the selling of products through social media platforms, generally, under the Minister of Trade Regulation No. 31 of 2023 on Business Licence, Advertisement, Training, and Supervision of Business Actors through Electronic Systems, social media platforms are prohibited from facilitating any e-commerce activity on their platforms, and therefore, the sales of therapeutic products through social media platforms are banned. However, the advertisement of therapeutic products through social media is still possible.

Therapeutic product advertising through social media is subject to BPOM Regulation No. 2 of 2021 on the Guidelines for the Supervision of Drugs Advertisements (BPOM Reg 2/2021). Under this regulation, only non-prescription medicines (over-the-counter products and limited over-the-counter products) are allowed to be advertised through social media, and such medicines must have obtained a distribution licence from the BPOM.

Before launching the advertisement, the contents of the advertisement must first be approved by the BPOM by submitting an application to BPOM's online systems.

There is no regulation that specifically governs the sale of medical devices to consumers over the internet. Generally, according to MoH Regulation No. 1191/MENKES/PER/VIII/2010 on the Distribution of Medical Devices, the retail of medical devices may only be conducted by medical device stores with a medical device store licence, as well as drugs retailers and pharmacists in a limited amount. These retailers may sell their products over the internet through a telemedicine applications by cooperating with PSEF.

The advertising of medical devices through social media is permitted, provided the use of the advertised device does not require medical professional assistance. The following additional requirements apply when advertising medical devices in electronic media such as social media:

- advertisements featuring dramatizations must include the disclaimer – ‘This scene is dramatized’, and those featuring dangerous scenes, must include the warning ‘Dangerous scene, do not imitate.’;
- scenes unsuitable for infants and children must be labelled ‘Parental Guidance Required’ or show a symbol meaning the same meaning;
- text visualisations must meet the legibility and clarity requirements; and
- advertisements for medical devices and household health supplies must not feature children under the age of five, unless the medical devices and household health supplies are intended for this age group.

<p>Before launching the advertisement of medical devices, their contents must first be approved by MoH by submitting an application to MoH's online systems.</p>
<p><b>IMPORT</b></p>
<p><b>6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?</b></p>
<p>The import regulation for therapeutic products is governed under BPOM Regulation No. 24 of 2017 on the Criteria and Governance of Drugs Registration, as amended (BPOM Reg 24/2017). A distribution licence (<i>izin edar</i>) must be obtained from the BPOM to distribute imported therapeutic products in Indonesia. For the product registration with the BPOM, the applicant must first receive written approval from the foreign pharmaceutical manufacturer, unless the applicant is an affiliate of the foreign pharmaceutical manufacturer.</p> <p>The foreign pharmaceutical manufacturer must also have: (1) pharmaceutical manufacturing licence from its local authority; (2) a valid Good Drugs Manufacturing Practices certificate or its equivalent certification issued by the local drugs supervisory authority; and (3) latest inspection results and the relevant changes for not more than two years as issued by the local drugs supervisory authority.</p> <p>The import and distribution of medical devices falls under MoH Reg 62/2017. Under Article 10 of MoH Reg 62/2017, a distribution licence (<i>izin edar</i>) is required to distribute medical devices in Indonesia. A distribution licence for imported medical devices can only be applied for by a:</p> <ul style="list-style-type: none"><li>• sole agent/sole distributor/exclusive distributor;</li><li>• medical device distributor with an appointment letter from the principal and a power of attorney to register the medical devices in Indonesia;</li><li>• medical device distributor with an agreement with the manufacturer;</li><li>• medical device distributor that assembles the devices; or</li><li>• medical device distributor that repackages them.</li></ul> <p>MoH Reg 62/2017 only permits medical equipment sold under one trade name/brand from the same principal to be distributed by one distributor. In addition, medical devices may only be imported by a company that holds a medical device distributor's licence (<i>Izin Penyalur Alat Kesehatan</i>) and a distribution licence for the imported medical devices.</p> <p>The customs classifications, tariff rates and import restrictions applicable to therapeutic products and medical devices will depend on the HS code of each product.</p>
<p><b>7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?</b></p>

Individuals may import therapeutic products for personal use under special access scheme, either by taking the products across the border or receiving them by mail. The quantitative limits is determined under Annex III of BPOM Regulation No 27 of 2022 on the Supervision of Drugs and Food Entry to Indonesia Territory (BPOM Reg. 27/2022). The following limits apply for carrying products across the border,:

- solid supply (tablets/caplets/capsules/pills etc.) – 30 pcs per person for every product type/item;
- semisolid supply (cream/ointment/gel/suppository etc.) – 3 pcs per person for every product type/item;
- aerosol supply – 3 pcs per person for every product type/item; or
- in the quantity as prescribed by a doctor in the prescription for up to 90 days of treatment.

When crossing the border, individuals must declare that they are carrying these products by filling out a customs form.

The permitted quantity for prescription-only medicines for receiving therapeutic products by mail, is based on the prescribed quantity by a doctor in the prescription for up to 90 days of treatment. Individuals may also import non-prescription medicine for personal use using mail order in a limited amount of up to three days' use.

Narcotics and psychotropics may neither be carried across the border nor sent through the post/mail. Psychotropics may only be carried across the border by non-Indonesian citizen based on the prescribed quantity by a doctor in the prescription for up to 60 days of treatment.

The import of medical devices for personal use is governed by MoH Regulation No. 51 of 2014 on Medical Devices Entry Through Special Access Scheme, as amended (MoH Reg 51/2014). Contrary to BPOM Reg. 27/2022, bringing medical devices for personal use is not explicitly mentioned under MoH Reg. 51/2014; instead, MoH Reg 51/2014 only mentions special use on doctor's request.

For importing medical devices under this basis, a non-donation SAS permit must first be obtained by either: (1) the head of the relevant health institution; (2) the patient; or (3) the relevant doctor. The medical device imported under this method must be registered in the country of origin, be new (not a used product), and have a life period of at least two years from the date of SAS approval.

**8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification, or labelling obligations – if any – must they satisfy?**

The same rules and restrictions mentioned in the response to Question 7, above apply to foreign suppliers who ship directly to consumers. For mail order, only prescription-only medicine is allowed. While the regulation remains silent on shipment based on e-commerce platform orders, the requirement for mail order should presumably apply as the rule covers any delivery through shipment services or postal services.

No local presence, platform registration, verification or labelling obligation applies to personal use products (either therapeutic or medical devices), as their entry to the Indonesian territory is based on a special access scheme.

**9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual-property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?**

Generally, every imported therapeutic product and medical device must have been given a distribution licence (*izin edar*) prior to its distribution in Indonesia, regardless of whether it is part of a parallel import.

For therapeutic products, the requirements for obtaining a distribution licence explained in the response to Question 6, above, will apply to the registration of a parallel import products. For product re-labelling or re-packaging as well as maintaining original quality, safety and traceability, Good Drugs Distribution Practices (CDOB) must be followed.

MoH Reg. 62/2017 only allows medical devices sold under one trade name/brand from the same principal to be distributed by one distributor. To obtain the distribution licence for medical devices, the applicant must show that the medical device has obtained a Certificate of Free Sale (CFS) issued by the relevant authority in the country of origin, for the distribution in that country. The CFS must at least contain: (1) the trade/brand name; (2) the type of product; (3) the name and address of the manufacturer; and (4) the validity period. The importer may also conduct re-labelling and re-packaging of the imported products, provided that the importer has the production certificate of the product and power of attorney from the manufacturer to do so.

**EXPORT**

**10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public health emergencies), and how are such measures administered and enforced?**

The management of therapeutic product and medical device supplies under normal condition or public-health emergencies is governed by GR 28/2024. Under GR 28/2024 the planning, provisions and distribution of therapeutic products and medical devices for their supply resilience is supervised by the MoH through a National Health Information System. However, the government has not issued further implementing regulations relating to this, so the administration and enforcement for this matter remains to be seen.

In terms of quantitative quotas or other measures restricting the export of therapeutic products and medical devices, we are not aware of any specific regulation governing such restrictions. Generally, exporters must obtain a Certificate of Exportation from the MoH for exporting therapeutic products and medical devices.

**11. Is there any form of ‘export-only’ or ‘dual-labelling’ authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling, or record-keeping obligations apply?**

Yes, the MoH will issue a Certificate of Exportation for export-only products which are not marketed and registered in Indonesia,. In order to obtain the Certificate, the applicant will need to submit: (1) an application letter; (2) a valid production certificate; (3) product information covering the product’s name, distribution licence number, raw/active materials and use, type/size, specification, packaging, labelling and country of destination; and (4) a written statement that the export product will not be marketed in Indonesia.

**LABELLING, TRACEABILITY, AND PRODUCT INFORMATION**

**12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?**

Under the Head of BPOM Decree No. 279 of 2024 on Standard Information for Drugs (BPOM Decree No. 279/2024), the labelling and product information for both therapeutic products and medical devices must be provided in Indonesian, Latin characters and Arabic numerals, unless they are intended for export. The use of other languages is permissible as long as the word has no direct equivalent in Indonesian. In addition to the Indonesian text, product information may also be provided in English subject to approval from the BPOM.

The contents of product information and label must comply with the requirements set out under Annex X and XI of BPOM Reg. No. 24/2017.

Regarding the unique device identification, serialisation, anti-counterfeiting, or traceability, both therapeutic products and medical devices will have a distribution licence number (*Nomor Izin Edar – NIE*). This NIE is unique to each product and will be assigned when obtaining the distribution licence prior to their circulation.

**PRICING, REIMBURSEMENT, AND MARKET ACCESS**

**13. Are there any price-control, reimbursement, public procurement, or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?**

Generally, GR 28/2024 grants the central government the authority to regulate and control the price of health supplies, particularly for drugs and medical devices. Price control on therapeutic products is governed by MoH Regulation No. 98 of 2015 on the Provision of Information on the Maximum Retail Price of Drugs (MoH Reg 98/2015). Maximum Retail Price of Drugs (*Harga Eceran Tertinggi – HET*) is defined as the highest retail price of drugs in pharmacy, drugs store, hospital and clinics. Pharmaceutical manufacturers must provide HET information in their

products label. The HET information may be in the form of: (1) nominal value in Rupiah denomination; or (2) HET formula.

Pharmacy, drugs store, hospital and clinics may only sell drugs in the same price as or lower than the HET, unless the HET stated in the label is no longer relevant. In such a case, the pharmacy, drugs store, hospital and clinics must provide an explanation to the public.

## **ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS**

### **14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?**

Non-compliance with the distribution provisions of therapeutic products under BPOM Reg. No. 24/2017 may result in BPOM imposing administrative sanctions in the form of: (1) a written reprimand; (2) the termination of products' registration process; (3) the suspension of the product's distribution licence; (4) the revocation of the product's distribution licence; and/or (5) a prohibition from submitting product registration for two years.

For medical devices, under MoH Reg. 62/2017, the MoH has the authority to oversee distribution activities by: (1) performing audit on technical and clinical information; (2) inspecting the production and distribution facilities; (3) conducting sampling and testing; and (4) supervising the labelling and marketing of medical devices. For non-compliance with distribution rules under the regulation, the MoH may impose administrative sanction in the form of: (1) a written reprimand; (2) the suspension of business activities; and (3) the revocation of distribution licence. In addition to administrative sanctions, if the non-compliance causes serious injury, disability or death, and/or involves counterfeiting or distributing medical devices without a valid distribution licence, the offender may be subject to criminal sanctions.

Further to the sanctions above, therapeutic products and medical devices which do not meet the required standard could also be recalled based on the instruction of BPOM or MoH, according to their respective authority. The recalling of therapeutic products and medical devices is conducted based on, among others, sampling and testing, public's complaint and findings during inspection.

### **15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of trade, distribution, or cross-border movement of therapeutic products in the future?**

In February 2026, the BPOM issued BPOM Regulation No. 4 of 2026 on the Implementation of Pharmacovigilance (BPOM Reg 4/2026). This regulation replaces the previous regulation in place for the implementation of pharmacovigilance under BPOM Regulation No. 15 of 2022 on the Pharmacovigilance Application, which focuses pharmacovigilance implementation on drug manufacturers.

One of the main highlights in BPOM Reg. 4/2026 is that the BPOM now requires drug distributors, importers and exporters to exchange safety data with the distribution licence holder for pharmacovigilance purposes. This enables a more comprehensive and timely collection of

information on adverse events, quality issues, and potential risks across the supply chain, including cross-border distribution.