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?

Malaysia is a federal state. Pursuant to Article 74 of the Federal Constitution, legislative powers are divided between the federal government, the state governments and matters of concurrent jurisdiction. Matters relating to medicine and health fall within the federal legislative sphere under the Federal List and Concurrent List in the Ninth Schedule, resulting in the creation of a centralised national regulatory framework for therapeutic products.

The key legislation governing therapeutic products includes:
• the Sale of Drugs Act 1952;
• the Control of Drugs and Cosmetics Regulations 1984;
• the Poisons Act 1952;
• the Dangerous Drugs Act 1952;
• the Medical Device Act 2012; and
• the Medical Device Regulations 2012.

The principal competent authorities governing therapeutic products are:
• the Ministry of Health Malaysia (MOH);
• the Drug Control Authority (DCA);
• the National Pharmaceutical Regulatory Agency (NPRA); and
• the Medical Device Authority (MDA).

Pharmaceuticals and biologics are primarily regulated under the Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984, with retail supply and dispensing restrictions largely governed by the Poisons Act 1952. Medical devices are regulated under the Medical Device Act 2012 and Medical Device Regulations 2012.

Where a product comprises two or more regulated components, the product is treated as a combination product. In such cases, the registration and regulatory process involves regulatory endorsement and/or registration with both the NPRA and the MDA.

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 are attached to each classification with respect to trade and distribution? In particular, is the conclusion of a premarket review and approval process required by a competent authority?

In Malaysia, therapeutic products are classified under separate regulatory regimes for pharmaceuticals, on one hand, and medical devices, on the other.

Pharmaceuticals are primarily classified under the Poisons Act 1952, which categorises poisons into Group A, B, C and D. Under the Poisons Act 1952 and the Poisons Regulations 1952, the sale and supply of poisons are regulated according to their classification. The different categories of poisons are defined under the Poisons Act 1952, as follows:

- Group A poisons may only be sold by a licensed wholesaler to a pharmacist, to another licensed wholesaler or for immediate export outside Malaysia. Retail sale to the public is not permitted.
- Group B poisons may only be supplied pursuant to a valid prescription issued by a registered medical practitioner, dentist or veterinary surgeon, as applicable, and must be dispensed by a pharmacist in accordance with the prescription requirements.
- Group C poisons may only be sold as dispensed medicines, and every supply must be recorded in the Prescription Book, in accordance with the regulatory requirements.
- Group D poisons may only be sold as dispensed medicines, and every supply must be recorded in the Poisons Book, in accordance with the regulatory requirements.
- Part II poisons (P2) may only be sold in a retail context by poison licence holders.
- Non-scheduled poisons (NP) refer to products that may be sold over the counter without a prescription.

Each classification determines the extent of control over the storage, sale, dispensing, record keeping and distribution of the substance. These classifications directly affect who may trade in the products, the conditions of sale and the licensing obligations imposed on wholesalers, pharmacists and retailers.

Any person selling poisons in contravention of the Poisons Act 1952 shall be guilty of an offence and punishable by a fine not exceeding MYR 50,000 or imprisonment for a term not exceeding five years, or both.

Medical devices in Malaysia are classified according to risk into Classes A to D. A medical device shall be classified by an establishment based on the level of risk it poses, its intended use and the vulnerability of the human body, in accordance with the manner in which it is prescribed. Each classification determines the level of regulatory control applicable to the manufacturing, import, distribution and retail supply of such devices, including requirements relating to licensing, storage, record keeping, advertising and dispensing. For all classes, medical devices may only be manufactured, imported, distributed or supplied by licensed establishments, and only registered medical devices may be placed on the Malaysian market, unless a specific statutory exemption applies. Any person who trades in or distributes a medical device without prior registration and the requisite establishment licence commits an offence and is liable, upon conviction, to a fine not exceeding MYR 200,000 or imprisonment for a term not exceeding three years, or both.

LICENSING, AUTHORISATIONS AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations or other official permissions are required for businesses to engage in the wholesale distribution of therapeutic products, and what key conditions (such as good distribution practices, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

Businesses engaged in the wholesale distribution of therapeutic products in Malaysia must obtain the appropriate establishment licences and ensure that the products they handle are duly registered with the competent authorities.

Pharmaceuticals
Wholesalers of pharmaceutical products must hold a wholesale licence issued by the NPRA pursuant to the Control of Drugs and Cosmetics Regulations 1984. The holders of such licences are only allowed to distribute products registered with the DCA. Wholesale activities must also comply with the requirements set out in the Sale of Drugs Act 1952 and the Poisons Act 1952, where applicable.

Medical devices
Wholesalers of medical devices are required to obtain an establishment licence from the MDA pursuant to the Medical Device Act 2012 (Act 737). Only registered medical devices may be imported, exported, manufactured or distributed, unless a statutory exemption applies.

Good distribution practice (GDP) requirements
The wholesale distribution of both pharmaceuticals and medical devices is subject to mandatory compliance with GDP or good distribution practice for medical devices (GDPMD), as applicable. GDP compliance is a condition of all import, wholesale and manufacturing licences and applies to:
• manufacturers;
• importers;
• wholesalers; and
• authorised representatives (for medical devices).

GDP obligations govern the full supply-chain process, including storage, transportation, security, record keeping, product traceability and the handling of returns or recalls. The purpose of these obligations is to ensure that the quality, safety, efficacy, integrity and performance of registered products are preserved during distribution and that they are maintained until the product reaches the end user.

Compliance monitoring and enforcement
Compliance with the respective GDP/GDPMD obligations is verified through inspections conducted by the NPRA or by recognised conformity assessment bodies (CABs). In addition, both the NPRA and MDA conduct post-market surveillance to monitor the therapeutic products available in the market and ensure ongoing compliance with the statutory and regulatory requirements.
Non-compliance may lead to enforcement action, including:
• the imposition or amendment of licence conditions;
• the suspension, non-renewal or revocation of establishment licences;
• the seizure of non-compliant products; and
• the imposition of administrative sanctions or prosecution for regulatory offences.

4. Are there any 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 are attached to them?

Malaysia imposes specific licensing and regulatory requirements on businesses that supply therapeutic products directly to consumers.

Pharmaceuticals and poisons
The retail supply of pharmaceuticals and scheduled poisons may only be carried out from licensed premises, such as community pharmacies or licensed poison premises, in accordance with the

Poisons Act 1952 and its subsidiary legislation. Retail activities must be supervised by a registered pharmacist or a poison licence holder, depending on the category of product involved.

The type of products that may be supplied is determined by their statutory classification, as follows:
• Prescription-only medicines (Group B poisons) may only be dispensed upon the presentation of a valid prescription issued by a registered medical practitioner, dentist or veterinary surgeon.
• Pharmacy medicines (Group C and D poisons/P2) must be supplied under the supervision of a pharmacist or poison licence holder, in accordance with the applicable licence conditions.
• Non-scheduled products (NPs) may be sold over the counter without the need for a prescription.

Retailers must comply with mandatory requirements relating to storage, record keeping, labelling, advertising and dispensing, and may only supply products that are duly registered with the DCA.

Medical devices
Retailers of medical devices must be licensed as establishments pursuant to the Medical Device Act 2012 (Act 737). Only registered medical devices may be sold, supplied or advertised to consumers, unless a statutory exemption applies. Retail establishments must comply with the GDPMD obligations, including in regard to storage, traceability and post-market monitoring.

Online pharmacies and e-commerce retailers
Internet pharmacies and online retailers are subject to the same regulatory controls as physical retail premises. Only registered pharmacies or establishments licensed pursuant to the Medical Device Act may engage in the online sale of therapeutic products.

The online sale of prescription-only medicines without a valid prescription and the sale of unregistered products is prohibited. All online advertising and promotional statements must comply with the Medicine Advertisements Board's requirements and other statutory controls.

Key retail compliance obligations
Retail and direct-to-consumer supply of therapeutic products must comply with rules related to the following:
• the relevant GDP or GDPMD obligations;
• proper storage and environmental controls;
• supervision by qualified personnel;
• accurate record keeping and documentation;
• product traceability for recall purposes; and
• compliance with the relevant advertising and promotion restrictions.

Non-compliance may result in enforcement action, such as licence suspension or revocation, product seizure, compoundable offences or criminal prosecution, depending on the nature of the breach.

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

The online sale and supply of therapeutic products in Malaysia, whether carried out through websites, mobile applications, social media channels or marketplace platforms, is permitted only within the scope of the regulatory frameworks established by the Online Healthcare Services (OHS) Guideline 2025 and the e-Pharmacy Guideline 2022.

The e-Pharmacy Guideline 2022 governs the online retail supply of pharmaceutical products containing poisons and requires full compliance with the Poisons Act 1952, the Sale of Drugs Act 1952 and their subsidiary legislation. The OHS Guideline 2025 regulates platform-based healthcare services, including medication supply as a support service following a legitimate online consultation.

Permitted online supply under the e-Pharmacy Guideline
The online supply of pharmaceutical poisons is restricted to the following circumstances:
• supply pursuant to an e-prescription issued by a registered medical practitioner or dentist;
• supply based on an uploaded physical prescription, with the original prescription subsequently presented to the pharmacy; and
• retail supply of Group C poisons by a licensed pharmacist without an e-prescription, consistent with the Poisons Regulations 1952.

All dispensing activities must be carried out exclusively by registered pharmacists operating from a licensed physical pharmacy premises. Remote or off-premises dispensing is not permitted.

Regulatory obligations for online pharmacy platform operators
Platform operators providing e-pharmacy services must, among others:
• be Malaysian-incorporated companies with a physical presence in Malaysia;
• ensure that the e-pharmacy operations are conducted only by pharmacists holding a Type A Poison licence;
• have at least one registered pharmacist as part of its senior management team or on the board;
• use secured and controlled digital systems, which must not utilise external sales links distributed via WhatsApp, Telegram, social media or similar messaging applications;
• ensure that their platforms are hosted on local servers and protected by appropriate cybersecurity measures; and
• maintain robust systems for identity verification, prescription validation, documentation and traceability.

Prohibitions under the e-Pharmacy Guideline
The e-Pharmacy Guideline imposes strict prohibitions, including:
• the advertising of pharmaceutical poisons on any media platform;
• the display of product names, images, stock-keeping units or any information that enables consumers to self-select medicines without intervention by a pharmacist; and
• the promotion or advertisement of prescription-only medicines, except where expressly exempt by the Medicines Advertisement Board pursuant to the Medicine (Advertisement and Sale) Act 1956.

IMPORT

6. What requirements are set as part of 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)?

Malaysia adopts a comprehensive import control framework for therapeutic products, combining product registration, establishment licensing, customs control and post-market regulatory oversight.
For pharmaceuticals, including drugs and medicinal products containing poisons within the scope of the Sale of Drugs Act 1952 and the Poisons Act 1952, all products must be registered with the DCA pursuant to the Control of Drugs and Cosmetics Regulations 1984 and assigned a MAL

registration number prior to importation. Importers must hold a valid importer's licence issued by the NPRA. The importation of unregistered products is only permitted if limited statutory exemptions apply, such as for clinical trials, personal use, government-approved programmes or other specific regulatory authorisations.

For medical devices, products must be registered pursuant to the Medical Device Act 2012, following a conformity assessment conducted through an appointed CAB. Importers must hold a valid establishment licence issued by the MDA. Only registered medical devices imported by licensed establishments may be placed on the Malaysian market, unless a specific exemption applies.

All therapeutic products must be declared, together with the supporting regulatory approvals and establishment licences. Import duties and tariff rates depend on the applicable customs classification. At the border, imports are subject to routine and risk-based inspections by the Royal Malaysian Customs Department, in coordination with health regulators. Products that are unregistered, improperly labelled or suspected of non-compliance may be detained, rejected or seized.

Following importation, therapeutic products remain subject to post-market surveillance, pharmacovigilance or vigilance reporting, recall obligations and regulatory enforcement action in the event of non-compliance.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by post), and what quantitative limits, prescription requirements, customs declarations, duties or other restrictions apply?

Malaysia operates a comprehensive import control regime for therapeutic products, integrating product registration requirements, establishment licensing, customs controls and post-market regulatory oversight.

Pharmaceuticals and poisons

For pharmaceuticals, including drugs and medicinal products containing poisons regulated under the Sale of Drugs Act 1952, the Poisons Act 1952 and their subsidiary legislation, all products must be registered with the DCA pursuant to the Control of Drugs and Cosmetics Regulations 1984 before they may be imported. Each registered product is assigned a MAL registration number.

Importers must hold a valid importer's licence issued by the NPRA and may only import products that have been duly registered.

The importation of unregistered pharmaceuticals is strictly prohibited unless a specific statutory exemption applies, including in regard to:

- clinical trial materials;
- personal-use exemptions;
- government-initiated or government-approved programmes; and
- other exemptions expressly authorised by the DCA or the MOH.

Medical devices

For medical devices, importation is governed by the Medical Device Act 2012 (Act 737) and the Medical Device Regulations 2012. A medical device may be imported only if:

- the device has undergone a conformity assessment conducted by a recognised CAB;
- the device is registered with the MDA; and

• the importer holds a valid establishment licence issued by the MDA.

Only registered medical devices imported by licensed establishments may be placed on the Malaysian market unless a specific statutory exemption applies (eg, special access, investigational devices or personal-use exemptions).

Customs declarations and border controls
All therapeutic products must be declared upon importation together with:
• proof of product registration (MAL number or device registration certificate);
• valid establishment or importer licences; and
• other supporting regulatory approvals, permits or exemption letters.

Customs duties and tariff rates are determined based on the harmonised system (HS) classification applicable to each product. At the border, the Royal Malaysian Customs Department, in coordination with the NPRA and the MDA, conducts both routine and risk-based inspections. Products that are any of the following may be detained, rejected, seized or forfeited:
• unregistered;
• improperly declared or labelled; or
• suspected of non-compliance.

Post-importation regulatory oversight
Once imported, therapeutic products remain subject to ongoing regulatory controls, including:
• post-market surveillance;
• pharmacovigilance (for pharmaceuticals and biologics);
• vigilance reporting (for medical devices);
• quality defect reporting; and
• mandatory recall obligations when safety or compliance issues arise.

The failure to comply with post-market obligations may result in enforcement action, including suspension or cancellation of the product registration, revocation of establishment licences, administrative sanctions or prosecution under the applicable governing legislation.

8. Are foreign suppliers allowed to 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?

Foreign suppliers are generally prohibited from shipping therapeutic products directly to Malaysian consumers for commercial purposes unless the supply is channelled through a properly licensed Malaysian establishment and the products are registered with the competent regulatory authority.

Pharmaceuticals and poisons
Foreign suppliers may not sell or supply pharmaceutical products directly to Malaysian consumers unless:
• the products are registered with the DCA pursuant to the Control of Drugs and Cosmetics Regulations 1984; and
• the supply is conducted through a licensed Malaysian entity, such as a registered importer, wholesaler, community pharmacy or approved e-pharmacy operator.

The direct cross-border sale or shipment of prescription medicines, poisons or pharmacy-only products to consumers is not permitted in circumstances where the Malaysian intermediary does not hold the requisite NPRA licences.

The online supply of such products must fully comply with the e-Pharmacy Guideline 2022 and the OHS Guideline 2025, including the requirements related to:
• pharmacist supervision and dispensing from licensed premises;
• prescription verification and record keeping;
• patient counselling and documentation; and
• platform design controls, data security and restrictions on medicine self-selection.

Foreign entities must also establish a Malaysian legal presence, either through local incorporation or by appointing a licensed local responsible party, in order to hold importer or wholesaler licences. Foreign suppliers operating without such a licence risk product seizure, detention, refusal of entry or enforcement action.

Medical devices
Foreign suppliers may not commercially supply medical devices directly to Malaysian consumers unless:
• the devices are registered under the Medical Device Act 2012 (Act 737); and
• the supply is made through a licensed Malaysian establishment (authorised representative, importer or distributor) that holds the appropriate establishment licence issued by the MDA.

The importation of medical devices requires a valid establishment licence, and foreign manufacturers must either appoint a Malaysian authorised representative or establish a local entity to obtain the necessary regulatory approvals.

Direct-to-consumer shipment of unregistered medical devices is generally prohibited. An exemption is available only where the import qualifies strictly as a personal-use medical device under the Medical Device (Exemption) Order 2024. This exemption applies solely to personal use by the importer and does not permit commercial supply, distribution or resale.

9. How is the 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 the product's original quality, safety and traceability?

The parallel importation of therapeutic products by businesses is not prohibited per se in Malaysia, but it is subject to stringent controls under both intellectual property law and sector-specific health regulation. Whether parallel importation is lawful depends on (1) the trademark proprietor's consent, (2) regulatory registration and (3) the preservation of product quality, safety and traceability throughout the supply chain.

Trademark law requirements
Malaysia adopts a consent-based international exhaustion regime under the Trademarks Act 2019. Parallel importation is lawful only where the trademark proprietor has expressly or implied that they consent to the goods entering the Malaysian market.

The Federal Court's decision in *Guangzhou Light Industry & Trade Group Ltd v Lintas Superstore Sdn Bhd* [2022] 6 MLJ 836 clarified the following principles:
• The mere fact that goods are genuine is no longer sufficient to avoid infringement.
• Parallel importation without the trademark owner's consent may constitute trademark infringement under Sections 54 and 56 of the Trademarks Act 2019.
• Territorial restrictions imposed by the trademark proprietor are legally effective and may

prevent the product's resale in Malaysia.
• The burden lies on the importer to show that consent (express or implied) was given.

Accordingly, businesses must ensure that the rightsholder has authorised the goods' entry into Malaysia before proceeding with parallel importation.

Regulatory compliance for therapeutic products
Satisfying the relevant trademark requirements does not exempt parallel importers from the need to comply with Malaysian public health regulation. Parallel-imported pharmaceuticals, biologics and medical devices remain fully subject to:
• mandatory product registration with the DCA (pharmaceuticals) or the MDA (medical devices);
• labelling and packaging requirements prescribed by the NPRA or the MDA;
• GDP/GDPMD obligations to ensure product quality, safety and integrity;
• compliance with storage, transportation, traceability and recall requirements; and
• the requirement for the importation to occur solely through a licensed establishment holding the appropriate NPRA or MDA licence.
Products that are unregistered, improperly labelled or not traceable to an approved supply chain may be detained, seized or rejected at the border, regardless of their trademark status.

EXPORT

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

The Malaysian government possesses broad statutory authority to restrict, condition or prohibit the export of goods, where necessary, to protect public health, ensure national security or maintain essential domestic supply. The key legal bases for such controls include:
• Section 31 of the Customs Act 1967 – empowers the Minister of Finance to prohibit, restrict or impose conditions on the export of any goods or class of goods through an order published in the Official Gazette.
• Section 26 of the Sale of Drugs Act 1952 – authorises the Minister of Health to regulate or prohibit the export of drugs and medicinal preparations.
• The Control of Supplies Act 1961 – enables the government to control, ration or restrict the supply, movement and export of specified goods during shortages, emergencies or situations affecting essential supplies.

During the Covid-19 pandemic, the government exercised these powers by imposing export restrictions on face masks under the Customs (Prohibition of Exports) (Amendment) (No. 2) Order 2020, issued pursuant to Section 31 of the Customs Act 1967, to preserve domestic availability and support public health response measures.

Sector-specific regulatory controls on exports of therapeutic products
In addition to general export control laws, exports of therapeutic products are subject to sector-specific regulatory conditions administered by the NPRA (pharmaceuticals) and the MDA (medical devices). These controls operate as regulatory prerequisites rather than quantitative export quotas.

Pharmaceuticals
The NPRA regulates export scenarios primarily through product registration status and documentation requirements, including:
• the For Export Only (FEO) pathway, which allows the manufacture and export of pharmaceutical products intended exclusively for foreign markets and not for local sale;

• issuance of a Certificate of Pharmaceutical Product (CPP) or other supporting documentation required by the importing country; and
• compliance with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) standards to ensure exported products meet international regulatory expectations.

Medical devices
For medical devices, the MDA administers an export framework that includes:
• the Export-Only Medical Device Exemption Letter, issued under the Medical Device Act 2012, which authorises the export of devices not intended for domestic sale;
• provision of export certification services (eg, free sale certificates or certificates of status), where required by foreign regulators; and
• compliance with the GDPMD and post-market traceability obligations for export-only 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?

Malaysia provides formal export-only regulatory mechanisms that allow therapeutic products to be manufactured domestically and exported without first obtaining Malaysian marketing approval. These mechanisms ensure that exported products meet the appropriate quality, safety and traceability standards, while preventing unauthorised circulation in the local market.

Pharmaceuticals –FEO registration
Pharmaceutical products manufactured in Malaysia exclusively for export must be registered with the NPRA under the FEO category. FEO registration is mandatory, whether for:
• new pharmaceutical products developed solely for export; or
• locally registered products being converted to export-only status, in which case the existing MAL number is retained and annotated to reflect the relevant export-only approval.
Although evaluated under an abridged assessment pathway, FEO applications must still comply with minimum NPRA requirements, including:
• producing Certificates of Analysis (CoA);
• providing stability data appropriate to the intended markets;
• full GMP compliance; and
• validated production, batch release and traceability documentation.

Pharmaceuticals approved as FEO cannot be supplied, sold or marketed in Malaysia under any circumstances.

Medical devices – the export-only exemption framework
For medical devices, Malaysia adopts an exemption-based model. Devices intended solely for export may be exported without undergoing Malaysian device registration, provided that the manufacturer or exporter:

- submits a Notification for Export-Only Medical Device to the MDA; and
- obtains an Export-Only Medical Device Exemption Letter issued under the Medical Device Act 2012.

This exemption authorises export activities only. It does not permit the device to be supplied, advertised or placed on the Malaysian market.

Labelling requirements for export-only products

Malaysia does not recognise a standalone dual-labelling authorisation. Export-only pharmaceuticals and medical devices:
• are exempt from Malaysian domestic labelling requirements;
• must comply with the labelling and regulatory standards of the importing country; and
• may carry different destination-specific labels, provided that all of the labels remain accurate, traceable and consistent with the approved product identity and specifications.

For regulatory completeness, the NPRA or the MDA typically requires copies of export labels to be submitted as part of the FEO registration or export-only notification file to ensure traceability and regulatory compliance.

LABELLING, TRACEBILITY 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?

Before imported therapeutic products may be supplied or placed on the Malaysian market, they must comply with statutory and regulatory requirements on labelling, patient information, anti-counterfeiting measures and traceability, as administered by the NPRA (for pharmaceuticals) and the MDA (for medical devices).

Pharmaceuticals – labelling and patient information requirements
All imported pharmaceutical products must comply with the Control of Drugs and Cosmetics Regulations 1984 and the NPRA labelling standards. Labels and package inserts must be provided in Bahasa Malaysia or English, and must clearly include:
• the product name;
• the active ingredient(s) and strength;
• the dosage form and pack size;
• the batch or lot number;
• the expiry date;
• the storage conditions;
• the name and address of the manufacturer;
• the name and address of the Malaysian product registration holder; and
• the assigned MAL registration number.

Package inserts must set out:
• the indications and dosing information;
• contraindications, warnings and precautions;
• possible adverse reactions;
• instructions for use and administration; and
• special population considerations, where applicable.

Anti-counterfeiting controls include the NPRA-approved security hologram, batch or lot identification and other traceability elements to support recall, quality defect reporting and pharmacovigilance obligations.

Medical devices – labelling and instructions for use
Medical devices must comply with the Medical Device Act 2012, Medical Device Regulations 2012 and relevant MDA guidance documents. The labelling requirements include:

• the device name, model or catalogue number;
• the registration number;
• the manufacturer's name and address;
• the Malaysian authorised representative's details;
• the batch number, lot number or serial number;
• the date of manufacture and the expiry date (where applicable);
• intended use and performance claims;
• storage or handling conditions; and
• warnings, precautions and contraindications.

Labelling is required in English and, for home-use medical devices, Bahasa Malaysia labelling is mandatory. Home-use devices must be accompanied by paper instructions for use (IFU), while professional-use devices may provide electronic IFUs, where permitted by MDA guidance.

Traceability identifiers must be preserved, including serialisation and unique device identification (UDI), where applicable.

Anti-counterfeiting, traceability and post-market controls
Malaysia's anti-counterfeiting and traceability regime builds on:
• compliance with GMP and GDP/GDPMD obligations;
• batch, lot or serial number identification;
• distribution, supply, and recall records maintained by licensed establishments; and
• post-market surveillance, product testing and enforcement conducted by the NPRA and MDA.

These mechanisms ensure that imported products can be traced through the supply chain and that any defective or falsified products can be promptly identified and removed from the market.

Export-only therapeutic products
Therapeutic products manufactured solely for export are exempt from Malaysian domestic labelling requirements. Export-only pharmaceuticals (FEO) and export-only medical devices must instead comply with the labelling standards set by the importing country. Nevertheless, the NPRA and MDA typically require copies of export labels to be submitted as part of the regulatory file for documentation and identification purposes.

PRICING, REIMBURSEMENT AND MARKET ACCESS

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

Malaysia does not impose direct trade restrictions on therapeutic products through statutory price controls or a national reimbursement system. However, several domestic policy mechanisms materially influence distribution channels, pricing behaviour and product availability.

Private sector pricing – transparency over direct price control
In the private sector, there are no statutory price caps on medicines. Prices are generally market determined, subject to the Price Control and Anti-Profiteering Act 2011, which prohibits unreasonable profiteering, but does not set specific price ceilings. Product quality, safety and regulatory approval remain under the jurisdiction of the MOH.

Malaysia has traditionally relied on price transparency initiatives, rather than price regulation, to moderate pricing, including:

• the Consumer Price Guide (CPG); and
• the MyPriMe (Malaysian Price Monitoring) platform.

These initiatives have historically been voluntary and non-binding.

A notable shift occurred with the introduction of the Price Control and Anti-Profiteering (Price Marking for Drug) Order 2025, which requires private healthcare facilities and community pharmacies to display medicine prices or maintain accessible price lists. Although the Order does not impose price caps, it:
• enhances price comparability;
• curbs opaque mark-up practices;
• encourages competitive pricing; and
• indirectly influences stocking, substitution and distribution decisions.

Public sector procurement – de facto determinant of availability
Public sector procurement by the MOH is a major determinant of therapeutic product availability. Medicines and medical devices are procured through:
• national concession arrangements;
• centralised national tenders;
• Approved Products Purchase List (APPL) mechanisms; and
• e-tender platforms for facility-level procurement.

Products awarded through these channels achieve extensive distribution coverage across government hospitals and clinics. Conversely, products not selected for public procurement may only be available through private sector supply chains, thereby influencing:
• patient access patterns;
• the commercial priorities of the supplier; and
• overall market pricing dynamics.

Malaysia does not operate a universal national reimbursement scheme or statutory reimbursement list for private sector medicines. As a result, reimbursement does not function as a nationwide price-setting or distribution-control mechanism outside the public sector.

Emergency powers – temporary supply and export controls
Malaysia does not impose general statutory stockholding obligations in normal conditions. However, during public health emergencies or supply disruptions, to implement temporary controls, including domestic supply prioritisation, stock rationing or export restrictions, the government may invoke the Control of Supplies Act 1961 and Section 31 of the Customs Act 1967.

These powers were notably exercised during the Covid-19 pandemic.

Combined effect on market behaviour
While these instruments are not trade measures in terms of their form, they collectively exert significant influence over:
• how therapeutic products are priced;
• which products are stocked and distributed;
• the relevant procurement and supply-chain priorities; and
• availability across public and private sectors.

In practice, public procurement patterns, mandatory price display and emergency supply powers operate alongside regulatory approval requirements to shape the Malaysian therapeutic product landscape.

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?

From an enforcement and investigative perspective, Malaysian regulators possess broad statutory powers under the Sale of Drugs Act 1952, the Poisons Act 1952 and the Medical Device Act 2012 to investigate, inspect and take action against unlawful activities involving therapeutic products.

Investigative and inspection powers
Authorised officers are empowered to:
• enter and inspect premises;
• examine, copy and seize records, documents and digital data;
• take samples for analysis;
• detain, seal or seize products suspected to be unregistered, counterfeit, adulterated or non-compliant;
• require the production of licences, prescriptions and supporting documentation;
• investigate advertising, promotion, online sales and distribution activities; and
• trace supply chains and direct laboratory testing.

These powers are routinely exercised through:
• planned market-surveillance inspections of licensed premises;
• targeted raids on suspected illegal operators;
• investigations into online platforms and e-commerce sellers; and
• border operations in coordination with the Royal Malaysian Customs Department.

Forfeiture powers
Under Section 43 of the Medical Device Act 2012, any seized medical device, related article, record, equipment or data is liable to forfeiture, whether or not a prosecution is instituted.

For pharmaceuticals:
• upon conviction under the Sale of Drugs Act 1952, the court must order forfeiture of the offending drugs and any similar drugs found in the offender's possession, including packaging and containers, for disposal as directed by the authorities; and
• analogous forfeiture powers apply under the Poisons Act 1952 for offences involving poisons and unlicensed supply.

Criminal sanctions
Criminal offences arise under:
• the Sale of Drugs Act 1952;
• the Control of Drugs and Cosmetics Regulations 1984;
• the Poisons Act 1952;
• the Medical Device Act 2012; and
• applicable subsidiary legislation.

Penalties may include fines, imprisonment, or both, with enhanced penalties applicable to repeat offenders and offences involving counterfeit or adulterated products.

In practice, criminal prosecution is commonly pursued against:
• the sellers of unregistered or falsified medicines;
• illegal online operators supplying poisons without prescriptions;
• distributors of counterfeit, adulterated or substandard therapeutic products; and
• unlicensed importers and intermediaries.

Administrative and remedial measures
In addition to criminal enforcement, the NPRA and MDA routinely deploy administrative actions, including:
• mandatory product recalls;
• suspension, non-renewal or revocation of establishment or import licences;
• the seizure and destruction of non-compliant products;
• the issuance of warning notices, compound offers and administrative penalties;
• the issuance of public advisories and alerts; and
• the imposition of requirements to amend labelling, advertising or promotional materials.

These measures allow regulators to act swiftly to protect public health by removing unsafe or illegal products from the market, while longer-term investigations or prosecutions continue.

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

Malaysia's regulation of therapeutic products has, in recent years, been shaped by intensified enforcement action, policy modernisation and structural regulatory reforms. Several notable trends are reshaping compliance expectations across the sector.

Enforcement and compliance trends
Enforcement activity has increased significantly, particularly against the sale of unregistered, counterfeit and adulterated therapeutic products via online marketplaces, social media-based sellers and informal distribution networks.

In 2024, the MOH reported seizures of 21,571 illegal health products valued at MYR 37.5m, with nearly 70 per cent of enforcement cases originating from complaints about online sales.

This trend demonstrates a sustained regulatory focus on:
• e-commerce platforms and third-party sellers;
• storage hubs and courier fulfilment centres;
• cross-border shipments and small parcel consignments; and
• unlicensed intermediaries involved in the domestic supply chain.

The clear message is that online and cross-border distribution channels will continue to face heightened, data-driven surveillance and enforcement activities.

Anti-counterfeiting, verification and traceability initiatives
Malaysia is strengthening its supply chain security and authentication mechanisms, particularly for pharmaceuticals. Key initiatives include:
• the Pharmaceutical Track and Trace System (PTTS); and
• the introduction of mandatory NPRA security hologram labels.

The Pharmaceutical Services Programme announced that from 1 October 2025, a new contractor will administer the supply of security labels and the PTTS for all registered pharmaceutical products.

These developments signal a shift toward technology-enabled traceability, with increased emphasis on:
• batch identification and serialisation;
• end-to-end movement and distribution records;
• supply-chain integrity and anti-counterfeiting verification; and
• rapid recall and quality defect response capabilities.

Manufacturers, importers, and distributors should expect tightened compliance obligations and more structured documentation requirements as part of these traceability reforms.

Medical device regulatory and trade control reforms
Significant regulatory changes are underway in the medical device sector, including:
• The Medical Device (Amendment) Regulations 2025 revise the fee framework for Class A medical device applications, effective 1 January 2026.
• The MDA has confirmed the introduction of a Medical Device Import Permit (MDIP) regime, which will require pre-import documentation submission through a centralised electronic system.

Although mandatory enforcement of the import permit regime has been moved from 2 January 2026 to 1 July 2027, a voluntary transition phase will commence in June 2026.

This reform represents a shift towards:
• pre-border regulatory screening of medical devices;
• closer operational alignment between customs controls and the device registration status; and
• enhanced traceability and documentation oversight for imported devices.

The changes will materially affect importers, authorised representatives and distributors, and should be factored into supply chain planning for 2026–2027.

Strengthened inter-agency coordination
Malaysia has also enhanced its inter-agency enforcement cooperation, especially in regard to border control and anti-smuggling operations. The MOH now works closely with:
• the Malaysian Border Control and Protection Agency;
• the Royal Malaysian Customs Department; and
• security and intelligence units.

This coordinated approach enables more integrated monitoring of imports, exports, e-commerce shipments and distribution networks, supporting faster detection and enforcement activity targeting illegal therapeutic products.