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

Author(s): Kien Trung Trinh, Hien Thi Thu Vu, Mai Thi Le, Thao Thi Bui and Vu Thien Tran

Firm: Tilleke & Gibbins

kien.tt@tilleke.com; thuhien.v@tilleke.com; mai.lt@tilleke.com; thao.b@tilleke.com; vu.t@tilleke.com

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?

Pharmaceutical regulations

The main law is the Law on Pharmacy (Law No. 105/2016/QH13, amended by Law No. 44/2024/QH15).

Detailed implementation rules are provided in Decree No. 163/2025/ND-CP, covering drug import/export, business operations, practice certificates, recalls, advertising and pricing management.

Additional rules on labelling, packaging, drug quality, clinical trials and marketing authorisation (MA) are regulated through ministerial circulars.

Medical device regulations

The main framework is provided by Decree No. 98/2021/ND-CP, amended by Decree No. 07/2023/ND-CP.

Circular No. 19/2021/TT-BYT, amended by Circular No. 10/2023/TT-BYT, provides details on the relevant forms and reporting requirements under Decree 98.

Circular No. 05/2022/TT-BYT provides details on certain provisions in Decree 98.

Regulatory authorities

The Ministry of Health (MOH) oversees pharmaceuticals and medical devices. Among the MOH's divisions, the Drug Administration of Vietnam (DAV) is responsible for pharmaceutical products, while the Infrastructure and Medical Device Administration (IMDA) and provincial health departments manage medical devices.

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 the conclusion of a premarket review and approval process required by a competent authority?

Pharmaceutical products

The applicable trading and marketing requirements depend on whether the drug is classified as prescription (Rx) or over the counter (OTC). Rx drugs require a prescription for dispensing, selling and use, while OTC drugs can be sold and used based on MOH criteria for products that do not need a prescription. Advertising is prohibited for Rx drugs and restricted OTC drugs. Only unrestricted OTC drugs may be advertised.

Drugs are further classified according to origin and type (chemical, herbal, traditional, vaccines, biologicals and special-control drugs). The registration requirements vary by category, with special-control drugs subject to strict management (such as manufacturing, importation and distribution, including separate coding, mandatory documentation and periodic reporting on import/export activities and inventory). All drugs require premarket evaluation and approval by the DAV through the marketing authorisation of registration dossiers.

Medical devices

Devices are classified into Classes A (lowest risk), B, C and D (higher risk/invasiveness). Classes A and B require self-declaration. No comprehensive premarket review or approval is required by the authority. Compliance is monitored through post-market inspections. Classes C and D require comprehensive premarket review and marketing authorisation from the authority before import or sale.

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?

Pharmaceutical products

Drug wholesalers are required to obtain a certificate of eligibility for wholesale distribution and comply with good distribution practice (GDP) standards

Wholesale establishments must have appropriate premises and warehouses for storing medicines, storage equipment and means of transportation, a quality management system, technical and professional documentation and personnel who are responsible for meeting the GDP requirements for medicines.

Not only wholesalers, but also drug manufacturers and importers are permitted to carry out activities related to the wholesale of drugs produced or imported by their own facilities.

Similar to wholesalers, drug manufacturers and importers must obtain a certificate of eligibility for manufacturing or importing drugs and comply with the good manufacturing practice (GMP) or good storage practice (GSP) requirements applicable to wholesalers.

Drug manufacturers must have a designated location, production workshop, testing laboratory, storage warehouse for drugs and raw materials, auxiliary systems, production and testing equipment, a quality management system, technical documentation and qualified personnel who are responsible for meeting the GMP standards.

Drug importers must have a designated location, drug storage warehouse, storage equipment, means of transportation, a quality management system, technical documentation and qualified personnel who are responsible for meeting the GSP standards.

Vietnamese law does not generally impose mandatory insurance, minimum capital or financial-guarantee requirements specifically for pharmaceutical wholesalers, beyond general corporate law and any contractual obligations with distributors/eligible pharmaceutical establishments.

Under Vietnam's World Trade Organisation (WTO) commitments and applicable domestic laws and regulations, foreign-invested enterprises (FIEs) are not allowed to engage in the distribution of pharmaceuticals within Vietnam. However, an FIE may import pharmaceuticals into Vietnam and subsequently resell/wholesale those imported products to local distributors that hold the requisite licences for drug distribution. In order to do so, an FIE is required to obtain, among other licences, a GSP certificate.

Medical devices

No formal licence is required for the wholesale distribution of medical devices. However, distributors of Class B, C and D devices (except for certain special cases) must submit a declaration of eligibility for trading in medical devices to the regulatory authority.

The declaration includes requirements in terms of the warehouse, means of transportation and personnel applicable to entities trading in Class B, C and D medical devices.

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?

Pharmaceutical products

Under the Law on Pharmacy, medicine retailers include pharmacies, drug counters, medicine cabinets at commune health stations and establishments specialising in the retail of medicinal herbs, herbal medicines and traditional medicines.

Retailers must satisfy requirements relating to their personnel (they must hold appropriate pharmaceutical practice certificates), facilities (a fixed location with a storage area that meets good pharmacy practice (GPP) standards and a minimum area of 10 m^2) and equipment (shelves, cabinets and supporting systems). These conditions must comply with the GPP principles issued by the MOH to ensure drug quality and patient safety.

Medical devices

Vietnamese regulations do not distinguish between wholesale and retail activities for medical devices. Establishments trading Class B, C and D devices (except special cases) must declare their eligibility to trade and meet the applicable requirements related to personnel, storage and transportation.

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

Pharmaceutical products

The online sale of pharmaceutical products to consumers in Vietnam is only permitted through e-commerce trading platforms, e-commerce applications and e-commerce websites that are legally registered and have a valid online ordering function. Sales of pharmaceuticals through unlicensed

social media accounts, livestreams or informal marketplace listings are unlawful and have been a focus of recent enforcement action.

Sales of the following goods via e-commerce are not allowed:

- Retail sale of the following drugs: prescription drugs, except for instances of medical isolation when there is an infectious disease of group A that has been declared an epidemic, according to the law on prevention and control of infectious diseases; specially controlled drugs; and drugs on the list of drugs restricted for retail sale.
- Wholesale sale of specially controlled drugs.

Retailers operating through e-commerce channels must meet the same requirements as traditional physical retailers, in addition to fulfilling all of the regulatory requirements applicable to e-commerce businesses, such as data privacy, transparency, regulatory notification and retail pharmacy obligations.

The online channel (website, app or platform store) must be registered or notified as part of the licensed pharmacy's operations and must display mandatory regulatory information (licence number, the name of the pharmacist in charge, contact details).

Medical devices

There are no specific regulations for the sale of medical devices on the internet. Providing information relating to medical device products on the internet for selling purposes may be considered to be advertising and subject to various restrictions.

Advertising, consumer protection and platform obligations

Online sales are also subject to:

- pharmaceutical and medical device advertising restrictions, particularly prohibitions on advertising prescription medicines to the public and on misleading health claims;
- consumer protection, e-commerce and data protection rules; and
- increasing regulatory expectations that platforms cooperate in removing illegal listings and verifying seller eligibility.

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)?

Pre-importation requirements

Pharmaceutical products

Pharmaceutical products must obtain a MA issued by the DAV before they can be imported and circulated in Vietnam.

Medical devices

The products must be registered with the authority (the IMDA or the Department of Health in city/province) to obtain a registration number/authorisation before being circulated in the Vietnam market.

Once a MA/registration number is granted, therapeutic products may be imported freely in accordance with the importer's business plan and do not require an import licence, except in certain

special cases, such as in relation to specially controlled drugs. Products without a MA/registration number may only be imported under specific circumstances, such as drugs imported for non-commercial purposes, orphan drugs or drugs and medical devices imported for research purposes, and an import licence must be obtained from the competent authority in advance.

Customs classification

The Harmonised System (HS) codes for drugs are specified in Circular No. 09/2024/TT-BYT, in which HS codes are assigned in accordance with Vietnam's import–export nomenclature. Similarly, HS codes for medical devices are provided in Circular No. 19/2024/TT-BYT.

Testing

The following drugs must undergo testing by a drug testing facility designated by a competent state authority before being marketed:

- vaccines;
- biological products that are serums containing antibodies; and
- other drugs as prescribed by the Minister of Health, based on risk assessment results regarding drug quality and quality trends of manufactured and imported drugs

An exemption from some or all of the tests at designated drug-testing facilities for vaccines and biological products applies when (1) the products are imported from countries whose test results Vietnam recognises or has a mutual recognition agreement on drug testing laboratories/results, (2) urgent national needs arise (eg, defence, disasters, epidemics or special-treatment needs) or (3) the MOH risk assessment and quality-trend analysis show the product consistently meets quality standards.

With respect to tariff rates, national or regional exemptions and routine or risk-based border inspections, these matters follow general customs schedules. No special treatment applies specifically to therapeutic products.

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?

Pharmaceutical products

Consumers may bring medicines into Vietnam without prior authorisation if they are for the entrant's own treatment and carried as personal luggage, sent under a bill of lading or brought into the country by the entrant. In such circumstances, the following restrictions apply: (1) the quantity must not exceed seven days' use for narcotics or ten days for psychotropics/precursors as per the prescription; (2) the total customs value does not exceed USD 200 per importation (a maximum of three times per year) or up to VND 10m for medicines treating diseases on the official list of serious diseases (a maximum of four times per year); or (3) the quantity does not exceed 30 days' use as per the prescription.

In such cases, the following documents may be required for customs clearance:

- valid prescriptions;
- official letters from the entrant's general practitioner (GP) and psychiatrist confirming the medications and dosages; and
- any other relevant documents (eg, outpatient treatment records).

If the personal-use case does not fall under one of the aforementioned categories above, an import licence will be required prior to bringing such medicines into Vietnam. The relevant prescription and medical records will need to be submitted to the competent authority.

Medical devices

Currently, there are no specific regulations governing the importation of medical devices into Vietnam for personal use. Consequently, such imports are generally interpreted as not permitted under existing legal provisions.

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?

No.

Pharmaceutical products

Medicine retailers must meet location and operational requirements and must be Vietnam-based. Accordingly, foreign suppliers cannot ship pharmaceutical products directly to consumers in Vietnam via e-commerce or mail order.

Medical devices

To trade in Class B, C and D medical devices (except in special cases), entities must declare their eligibility before operating and meet requirements in regard to warehousing, personnel and other conditions. As a result, retailers must be Vietnam-based, and foreign suppliers cannot ship these products directly to consumers via e-commerce or mail order.

Under Decree 98, importers of devices with valid registration numbers must also be the registration-number owner or be authorised by that owner, with the power of attorney submitted to both the licensing and customs authorities. In practice, foreign suppliers cannot meet this requirement when shipping devices directly to customers. Therefore, foreign suppliers are not permitted to deliver such products directly to consumers in Vietnam via e-commerce or mail order.

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?

Vietnamese regulations do not explicitly address the parallel importation of medical devices.

Under Circular No. 11/2015/TT-BKHCN (as amended), importing goods already placed on the market by the intellectual property owner or an authorised party, including under compulsory licences or prior-use rights, without the owner's consent (parallel importation) is not considered to be an infringement. As a result, the parallel importation of legitimately marketed goods is generally permitted, but importers must still ensure the products' original quality, safety and traceability

An import licence from the MOH is required for the parallel importation of medicines. The imported medicines must satisfy the following criteria:

- The medicines must have the same trade name, active ingredient, strength or concentration and dosage form as the original brand-name drug registered for circulation in Vietnam. They must be manufactured either by the original brand-name manufacturer or by an

authorised manufacturer and offered at a lower price than the brand-name drug currently circulating in Vietnam.

- The expected wholesale price must be at least 20 per cent lower than the winning bid price of the brand-name drug registered for circulation in Vietnam.
- The medicines must be licensed for circulation and export to Vietnam by the country of manufacture or by a country that is an International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) member or Australia.
- The medicines must not be radiopharmaceuticals, vaccines or biological products.

EXPORT

10. Are there any 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?

Under the Law on Pharmacy, drugs and medicinal ingredients manufactured exclusively for export purposes may be exported without obtaining a drug MA. However, this exemption does not apply to products under special control, including controlled narcotic, psychotropic and precursor substances; herbal ingredients classified as rare or specially controlled; and radioactive substances listed by the Vietnamese government. When dealing with such products, exporters must comply with the regulatory requirements of the importing country.

Drugs under special control must be accompanied by a valid MA in Vietnam and can only be exported with an export licence, with the quantity strictly limited to the amount specified in the licence. Establishments exporting these products must report each export shipment to the competent authorities and comply with the required semi-annual and annual reporting regimes, including providing reports on the export of combination drugs containing controlled substances, as well as radioactive and toxic drugs, as required under the relevant regulations.

Under Decree 98, medical devices that are manufactured in Vietnam and are for export purposes only are generally exempt from obtaining a registration number. The export quantity is set according to demand, without any quantity restrictions and without requiring approval from the MOH.

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?

Vietnam effectively permits the manufacture and export of 'export-only' therapeutic products.

As described in the response to Question 10, drugs produced solely for export purposes may be exported without obtaining a domestic MA from the MOH, except for certain categories of products under special control. These specially controlled products must meet domestic MA and licensing requirements before export.

Also mentioned in the response to Question 10, medical devices that are manufactured in Vietnam for export purposes only are generally exempt from obtaining registration numbers from the MOH.

In terms of labelling, exported goods must comply with the labelling laws of the importing country. Vietnamese regulations additionally require that export labels must not contain images or information relating to sovereignty disputes or other sensitive content that could adversely affect national security, politics, the economy, society, diplomatic relations or cultural traditions.

Record-keeping obligations follow the general requirements for export activities, including maintaining manufacturing and export documentation and, for special-control products, complying with mandatory reporting regimes on export quantities and inventory.

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?

Products circulating in Vietnam market

All imported therapeutic products must display mandatory Vietnamese-language information before circulating in Vietnam. Before customs clearance, the original label must at least show the product name, origin and the details of the manufacturer or responsible overseas entity. If the original label lacks full details, the accompanying documents must provide them. Anti-counterfeiting and traceability features (eg, stamps, barcodes, quick response (QR) or DataMatrix codes) may be added voluntarily.

Exported products

Goods labels of exports shall be presented according to the law in the importing country, provided that the information provided does not contravene the laws and must be truthful, precise and true to the substance of goods and may not represent any picture or information relating to a sovereignty dispute and other sensitive information which may affect national security, politics, the economy, society, diplomatic relations and cultural traditions of Vietnam.

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?

Price control mechanisms

Methods to manage drug prices include:

- Tendering for national reserve medicines and medicines at medical facilities.
- Tendering, placing orders or assigning tasks to supply medicines for national target programmes, defence, security, disaster recovery, natural calamities and epidemic prevention and control.
- Publication or re-publication of the projected wholesale price for prescription medicines, except in cases that are exempt in regard to domestically produced medicines or imported medicines not intended for commercial purposes.
- Recommendations regarding the projected wholesale price already published or re-published during the circulation of medicines on the market when the MOH detects any of the following cases:

- The projected wholesale price is higher than the highest price of similar medicines already published or re-published without prior recommendation from the MOH, except where the establishment provides an explanatory report and supporting documents on the price fluctuations. If the medicine has a different strength or concentration per dosage unit compared to similar medicines, the price comparison will be made on an equivalent conversion basis;

- The difference between the projected wholesale price and the winning bid price of the same medicine exceeds the maximum difference stipulated by the government, except where the establishment provides an explanatory report and supporting documents on price fluctuations; and
- The medicine with a projected wholesale price published or re-published has no similar medicine circulating in Vietnam and its published or re-published price is higher than the selling price in the country of origin or other countries, except where the establishment provides an explanatory report and supporting documents on price fluctuations.

- Declaration of wholesale and retail prices for medicines on the list of essential medicines.
- Posting of wholesale and retail prices of medicines.
- Price stabilisation for medicines.
- Price negotiation for medicines.
- Price negotiation for medicine procurement packages where the price negotiation method is applied.
- Regulation of the maximum retail markup for medicines sold at retail outlets located within medical examination and treatment facilities.

Medical device price management requires manufacturers and traders to post device prices at locations mandated by the Law on Prices or on the MOH's electronic portal.

Reimbursement system

Vietnam's reimbursement framework finances pharmaceuticals and medical devices mainly through social health insurance (SHI), private insurance and patient self-payment. Drug coverage is governed by Circular No. 20/2022/TT-BYT (as amended by Circular No. 37/2024/TT-BYT). The SHI fund reimburses medication costs based on actual use and within the scope of the health insurance law.

For medical devices, Circular No. 04/2017/TT-BYT and Circular No. 22/2024/TT-BYT regulate direct reimbursement for drugs and devices. Reimbursable items include those on the list of rare drugs and Class C or D medical devices, except certain exclusions such as in vitro diagnostic devices, personalised devices and items traded as regular goods, provided specific conditions, such as a lack of availability or an inability to refer patients, are met.

Public procurement mechanisms

Public procurement in Vietnam is tightly regulated and significantly shapes how therapeutic products reach the market. Drug procurement financed by the state budget, national reserves, health insurance funds or public hospitals must comply with the Law on Bidding. The system relies heavily on concentrated bidding and price negotiations, with Circular No. 05/2024/TT-BYT governing negotiated procurement for more than 600 originator drugs and selected devices. As public hospitals are the country's main purchasers, suppliers must meet the relevant bidding requirements to access the market.

Stock/supply obligation mechanisms

Vietnam's system also incorporates supply-related obligation measures. Medicines procured for national reserves, epidemic response, national defence and disaster recovery must follow dedicated public-service procurement rules to ensure their uninterrupted supply.

Essential drug lists and MOH/Health Insurance Department procurement lists guide purchasing decisions, influencing which therapeutic products remain consistently available.

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?

Competent authorities (primarily the MOH, the DAV and provincial Departments of Health) may:

- conduct routine and ad hoc inspections of licensed premises, warehouses, vehicles and records;
- require the production of documents, samples and electronic data;
- take and test product samples;
- suspend operations or seal goods where there is a risk to public health; and
- coordinate with customs, market surveillance authorities and police in cross-border or criminal cases.

Inspections may be risk based or complaint driven and may be announced or 'extraordinary' (unannounced), particularly where safety concerns arise.

The legal consequences are categorised into three levels of severity:

(1) Administrative measures (most common)

Administrative enforcement, primarily governed by Decree No. 117/2020/ND-CP dated 28 September 2020 (as amended in 2021, 2023 and 2025), is the primary mechanism in practice. Sanctions include:

- warnings and formal compliance orders;
- monetary fines, which are scaled based on the violation (eg, selling without a certificate of eligibility for pharmacy business (CEPB), violating GDP/GPP standards or incorrect labeling);
- confiscation and destruction of non-compliant goods;
- license suspension: temporary revocation of the CEPB or the pharmacy practice certificate for one to 24 months; and
- mandatory withdrawal of non-compliant products from the market at the business's expense.

Sanctions are often accompanied by publication of the violations and orders to remediate the deficiencies within fixed deadlines.

(2) Civil liability

Businesses may incur civil liability for:

- breach of contract;
- product liability for defective or harmful products (eg, if a non-compliant product causes health issues, the distributor may be sued for medical costs and loss of income); and
- consumer protection claims for misleading information or unlawful sales.

Civil claims may be brought by affected consumers or business partners.

(3) Criminal liability

Serious violations (such as trading in counterfeit medicines, large-scale illegal imports or conduct causing serious harm to health) may constitute criminal offences under the Penal Code 2015 (as amended in 2017), including:

- fines and imprisonment for the responsible individuals;
- criminal liability of the commercial legal entities; and

- confiscation of the proceeds and instrumentalities of the offence.

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?

Many legal documents relating to the pharmaceutical field have been issued in Vietnam recently, specifically the following: (1) Law No. 44/2024/QH15 amending and supplementing some articles of the Law on Pharmacy; (2) Circular No. 12/2025/TT-BYT on the registration of drugs and medicinal ingredients; (3) Decree No. 163/2025/ND-CP providing detailed guidance on the implementation of the Law on Pharmacy; (4) Circular No. 31/2025/TT-BYT further detailing the implementation of the amended Law on Pharmacy and Decree 163; and (5) Circular No. 28/2025/TT-BYT, on regulations for GMP for drug and medicinal ingredients. All of these legal documents have been in effect since 1 July 2025.

Through these updated and revised regulations, significant advancements have been made in terms of enhancing the management system for pharmaceutical products, from registration to importation to circulation. The updated regulations simplify some procedures applicable to the pharmaceutical field and enhance the drug registration procedure, as well as the rights and responsibilities of certain types of pharmaceutical businesses in Vietnam.

For example, the updated regulations allow trading in pharmaceutical products through e-commerce, including e-commerce trading floors, e-commerce sales applications and e-commerce sales websites with online ordering functions. Accordingly, the retail of non-prescription drugs through e-commerce is permitted if the drugs are neither specially controlled drugs nor drugs included in the list of drugs restricted for retail sale, and the wholesale of drugs and drug materials via e-commerce is also permitted, as long as the products being sold are not specially controlled drugs.

For medical devices, the transition period set by Decree 98 officially ended on 30 June 2025. As of early 2026, all Class B, C and D (high-risk) devices must possess a full MA licence to be imported or traded, ending the era of transitional permits.

Noteworthy enforcement trends: 'the digital watchdog'

Regulators have moved from reactive inspections to proactive digital surveillance. National Steering Committee 389 and the DAV have launched a 'peak enforcement' campaign running, which ran throughout March 2026. This campaign specifically focused on:

- ensuring every unit sold is logged in the national digital system;
- cracking down on 'livestream' sales of prescription drugs and unverified health supplements on platforms like TikTok and Shopee; and
- strict monitoring of the new requirement for importers to announce 'expected wholesale prices' before market launch to prevent price gouging.

Anticipated reforms and future outlook

Looking towards 2027, the medical sector is bracing for several key shifts.

In a move to align the country with international standards, Vietnam is implementing Circular No. 57/2025/TT-BYT. While the Circular takes official effect on 15 February 2026, the specific classification of medical devices into technical and quality groups for procurement purposes will

officially commence on 1 January 2027. This regulation significantly favours medical devices and drugs that hold certifications granted by stringent regulatory authorities (SRAs) such as the United States Food and Drug Adminitration, the European Medicines Agency, Japan's Pharmaeucticals and Medical Devices Agency and Australia's Therapeutic Goods Administration, by placing them into higher-tier bidding groups (like Group 1).

As of 1 January 2026, under Resolution No. 261/2025/QH15 and subsequent implementation guidelines, Vietnam has officially raised the health insurance reimbursement rate to 100 per cent for near-poor households and seniors aged 75 and older. This policy shift is expected to significantly increase patient volumes within the public healthcare system by removing the financial barriers related to co-payments for these vulnerable groups.