

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

Authors: Frank (Feng) Zhou and Vicky (Zhilian) Huang

Firm: JunHe, Shanghai

zhouf@junhe.com; zhaohl@junhe.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?

In the People’s Republic of China (PRC), the principal rules of the import, wholesale, retail, and export of therapeutic products (including pharmaceuticals/biologics and medical devices) are the PRC Drug Administration Law (2019 revision) and the Regulation on the Supervision and Administration of Medical Devices (2024 revision).

The National Medical Products Administration (NMPA), under the State Council, is the competent authority responsible for product registration, licensing of manufacturers and distributors, and oversight of import/export licensing requirements related to therapeutic products. The State Administration for Market Regulation (SAMR) is responsible for oversight of the wholesale distribution, retail sale and other commercialisation activities in the Chinese market. The General Administration of Customs (GAC) is responsible for supervision over the import and export of commodities.

All core legislation and regulatory standards are set nationally by the central government. Local authorities act as enforcers but may implement local rules which do not contravene the regulations of the central government.

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?

In China, pharmaceuticals are categorised as prescription-only medicines (POM) or over-the-counter (OTC) drugs. POMs may only be sold with a valid prescription from a licensed healthcare professional (HCP). OTC drugs are further divided into Class A (sold only in licensed pharmacies) and Class B (may be sold in supermarkets or convenience stores meeting regulatory conditions). All drugs require premarket approval by the NMPA, including registration certification before market entry.

Medical devices are classified into three risk-based categories: (1) Class I (low risk) devices, which are subject to a simple premarket filing at municipal-level NMPA authority; (2) Class II

(moderate risk) devices, which are subject to premarket registration at provincial-level NMPA authority; and (3) Class III (high risk), which are subject to premarket approval at the NMPA.

Distribution channels must align with classification. For example, unauthorised sales of POMs or unregistered Class III devices constitute illegal operation, triggering penalties such as fines, product seizure, or licence revocation under the PRC Drug Administration Law (2019 revision) and the Regulation on the Supervision and Administration of Medical Devices (2024 revision).

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?

In China, the wholesale distribution of therapeutic products requires specific licences or filings according to product type.

For pharmaceuticals, the wholesale distribution of pharmaceuticals requires a Drug Operation Permit from provincial-level NMPA. Applicants must comply with the following general criteria: (1) employing minimum numbers of licensed pharmacists or other pharmacy technicians; (2) having business premises, equipment, warehousing facilities and hygiene environment corresponding to their drug business; (3) having the quality management setup or staff corresponding to their drug business; and (4) having rules and system to ensure drug quality and comply with the quality management norms and requirements for drug business operation formulated by the NMPA, particularly the Good Supply Practice (GSP).

For the sale of medical devices, the regime is also risk-based: (1) Class I – no filing, permit or licensing is required; (2) Class II – filing with the municipal NMPA authorities is mandatory; and (3) Class III – a Medical Device Operation Permit issued by the municipal NMPA authorities is mandatory. To engage in business operations of medical devices, an enterprise shall satisfy the following requirements: (1) having a quality management body or quality management personnel in line with its business scope and scale, and the quality management personnel shall have the educational background or professional title of a related major; (2) having a business premise corresponding to the business scope and scale; (3) having the storage conditions appropriate for the business scope and scale; (4) having a quality control system corresponding to the medical devices operated; and (5) having a quality management body or staff for specialised guidance, technical training and after-sale service corresponding to the medical devices operated.

In addition to the industry-specific licences or filings above, the following licences may also be relevant to businesses engaging in wholesale distribution of therapeutic products: (1) a business licence, which is required for all businesses operating in China; (2) a road transport licence, which is required for the road transit of therapeutic products; and (3) internet-related licences and filings, if the distribution of therapeutic products is conducted online.

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?

Yes. In China, businesses providing therapeutic products directly to consumers must meet specific licensing and operational requirements.

The retail of therapeutic products is subject to similar regulatory regime to the wholesale of therapeutic products. Our comments regarding the licensing requirements on the wholesale of therapeutic products in our response to Question 3 generally apply to retail, even though there might be minor differences in terms of the level of authorities involved and the specific requirements.

The enterprise which undertakes online sales of pharmaceuticals/medical devices may carry out online sales of pharmaceuticals/medical devices through their own website or a licensed third-party platform for pharmaceuticals/medical devices online trading services. Enterprises carrying out online sales of pharmaceuticals/medical devices through their own website shall also obtain an Internet Pharmaceutical Information Services Qualification Certificate and a Drug Network Sales Filing/Record, have office premises which correspond to their scale of operation, and satisfy technical criteria such as data backup, malfunction recovery, etc.

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

In China, the PRC Drug Administration Law (2019 revision), the Regulation on the Supervision and Administration of Medical Devices (2024 revision), the Administrative Measures for the Supervision of Online Drug Sales and the Administrative Measures on Supervision of Online Sales of Medical Equipment are the principal rules which govern the sale of therapeutic products to consumers over the internet.

The key requirements include: (1) the sale entity shall have appropriate licences and be GSP compliant; (2) the sale of prescription drugs requires valid e-prescriptions from qualified HCPs; (3) the sales platform shall have statutory obligations to verify merchant qualifications, monitor transactions and shall bear legal liabilities for oversight failures; and (4) all information of the therapeutic products shall be truthful and be accompanied by statutory warnings and instructions.

IMPORT

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)?

China’s import-control framework for therapeutic products is centralised and stringent. Other than limited statutory exceptions, all imported drugs and medical devices must first obtain market authorisation: drugs require an Import Drug Registration Certificate from the NMPA, while

medical devices undergo risk-based review – Class I devices are filed, Classes II and III require provincial or NMPA registration. Unregistered products usually cannot be imported.

The exceptions above generally refer to: (1) certain clinically urgently needed products, approved on a case-by-case basis; (2) certain products which have been commercialised abroad, approved on a case-by-case basis for use in designated hospitals (usually in Hainan and Greater Bay Area); and (3) products entering regulated areas supervised by the GAC – such as bonded zones, bonded warehouses or export processing zones.

The importer must be a locally registered legal entity holding a valid Drug Operation Permit or Medical Device Operation Permit. Products are inspected and tariffed according to their tariff classifications.

Border inspections are risk-based: high-risk items often undergo 100 per cent batch testing by the customs authorities, while others are subject to random sampling. Limited exemptions exist for clinical trials or emergency use, but require prior NMPA approval.

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?

Generally, consumers may import a reasonable amount of pharmaceuticals for personal use. The reasonable amount usually refers to seven days’ supply for POM, unless the consumers can provide prescription which can justify a higher amount. Consumers may carry or receive via mail/express small, reasonable quantities deemed for personal use and shall be subject to customs supervision. All items must be truthfully declared to the GAC and shall not be transferred to others for use or sales.

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?

At present, foreign suppliers cannot supply POM or medical devices to Chinese consumers via cross-border e-commerce (CBEC) but can supply a few OTC products falling under the Retail Import Commodity Catalogue to Chinese consumers via CBEC.

Foreign suppliers must register as merchants on licensed CBEC platform and shall bear the primary liability for quality and safety of the goods. They shall entrust an enterprise which has completed industry and commerce registration in China to complete customs registration, be liable to make truthful declaration, subject to regulation by the relevant authorities, and bear civil liability jointly and severally. The therapeutic products shall comply with the standard or technical specifications such as quality, safety, hygiene, environmental protection, label, etc. at the place of origin.

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?

In China, parallel importation of therapeutic products by businesses is very difficult due to stringent regulatory and intellectual property (IP) frameworks: NMPA requires all pharmaceuticals and medical devices to obtain marketing authorisation before importation, and China adheres to national – rather than international – exhaustion of IP rights, meaning unauthorised imports of genuine products sold abroad may still infringe trademarks or patents. Additionally, re-labelling or re-packaging without NMPA approval is illegal and considered unlicensed manufacturing, while strict GSP, traceability, and pharmacovigilance requirements ensure that only authorised marketing authorisation holders can guarantee product quality, safety, and regulatory compliance – making commercial parallel imports non-compliant and subject to customs seizure, administrative penalties, or legal liability.

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?

China generally does not impose quantitative quotas on the export of therapeutic products under normal circumstances. However, the government may temporarily restrict or require permits for exports during public health emergencies, domestic shortages, or national security concerns. For example, during the Covid-19 pandemic, China mandated that exporters of key medical supplies (eg, medical masks, medical protective clothing) have obtained the registration certificates of medical device products in China and meet the quality standard requirements of the importing countries (regions).

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. China permits the manufacture and export of therapeutic products not approved for domestic sale under an ‘export-only’ framework. Such products do not require NMPA marketing approval, provided they comply with the laws and standards of the destination country.

Manufacturers must hold valid domestic production licences (eg, Pharmaceutical Manufacturing Permit or Medical Device Manufacturing Filing/Permit). The labelling and instructions of products shall be compliant with the requirements of the importing country/region. Whether dual labelling (eg, Chinese plus foreign language) is needed depends on the requirements of the importing country/region.

Exporters shall establish and preserve archives of export products. The contents shall include purchase contracts, quality requirements, inspection reports, certificates of conformity,

packaging, label samples, customs declaration forms, etc. so as to ensure traceability of the product export process.

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?

In China, imported therapeutic products must comply with stringent local language and traceability requirements before domestic circulation. All labels and package insert for drugs and medical devices must be in simplified Chinese, including product name, registration number, manufacturer, indications, dosage (for drugs), intended use (for devices), batch number, expiry date, and storage conditions. For traceability, all marketed drugs must carry a unique serialised code under China’s national drug traceability system, enabling end-to-end tracking. Medical devices are subject to the Unique Identification System for Medical Devices (UDI) system. These measures support anti-counterfeiting and quality oversight by linking products to the national regulatory platforms operated by the NMPA.

In contrast, products manufactured solely for export are exempt from Chinese labelling, serialisation, and UDI requirements, provided they are clearly marked ‘for export only’ and comply with the destination country’s rules.

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?

China’s price controls, reimbursement rules, public procurement systems, and supply obligations materially influence therapeutic product distribution and availability.

Regarding price-control, the National Healthcare Security Administration (NHSA) enforces strict price discipline through centralised volume-based procurement (VBP) for selected generic drugs and devices, and national negotiations for selected innovative drugs, drastically lowering prices for selected drugs and devices. Winning products gain fast hospital access while non-participants or high-priced alternatives face restricted use in public hospitals.

Regarding reimbursement, only products listed in the National Reimbursement Drug List (NRDL) are covered by public insurance which will affect the distribution channels or availability of therapeutic products.

Regarding public procurement, public hospitals must purchase drugs and devices via provincial centralised bidding platforms. Off-platform procurement is generally prohibited. VBP winners must guarantee supply quality, and default will be delisted and inclusion on a credit blacklist.

The centralised bidding platforms typically have ‘two-invoices’ requirements for POM supplied to public hospitals, meaning that drug manufacturers can only have one layer of distributor before drugs are sold to public hospitals.

Additionally, under the Measures of the State for the Administration of Pharmaceutical Reserves, designated enterprises must undertake reserve task of essential medicines, vaccines, and emergency supplies. The government may requisition during public health emergencies.

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?

Chinese regulators (primarily the NMPA, SAMR, GAC and their local subordinates) have broad enforcement powers. In practice, regulators use unannounced ‘fly-in’ inspections, daily supervision and China’s national drug/medical device traceability system to detect violations. The customary legal consequences of the non-compliance are as follows: (1) administrative penalties include but not limited to warnings, fines, confiscation of products and proceeds, suspension of operations, revocation of licences, and listing on the List of Subjects with Seriously Illegal or Dishonest Acts; (2) civil remedies allow consumers to seek compensation under the PRC laws (eg, PRC Protection of Rights and Interests of Consumers, PRC Product Quality Law), including punitive damages for harm caused by defective products; (3) criminal liability applies in severe case.

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?

Generally speaking, recent geopolitical changes as well as Chinese and foreign laws and policies responding to such changes are significantly impacting the cross-border flow of Chinese therapeutic products.

Escalating tariffs and non-tariff trade barriers, coupled with heightened emphasis on domestic production and national security have far-reaching effects on global supply chain of therapeutic products. Regulatory scrutiny, localisation mandates, and supply chain resilience requirements in key markets increasingly constrain market access and export competitiveness of Chinese exporters of therapeutic products. On the other hand, Chinese authorities introduce various new measures to encourage domestic production of drugs and devices which are currently produced abroad. Increasingly, foreign producers are adopting the ‘in-China-for-China’ strategy to build supply chains specially for China.