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

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

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

In the Republic of Korea (South Korea), the principal statutes governing therapeutic products are the Pharmaceutical Affairs Act (PAA) for drugs and biologics and the Medical Devices Act (MDA) for medical devices, together with the Act on Fair Labelling and Advertising. The primary competent authority is the Ministry of Food and Drug Safety (MFDS), which manages marketing authorisations, safety standards and factory/importer inspections. Additionally, the Ministry of Health and Welfare (MOHW) is responsible for the country's overall healthcare policies and national health insurance pricing.

In addition, the Fair Competition Code issued by the Korea Medical Devices Industry Association (KMDIA) and the Korea Pharmaceutical and Bio-Pharma Manufacturers Association (KPBMA) and approved by the Korea Fair Trade Commission applies to the promotion and advertising of medicinal products to medical services personnel.

As South Korea is a unitary state, there is no division of powers between federal and state levels. All central laws apply uniformly across the country, although some administrative tasks are delegated to local municipal governments (public health centres).

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

Drugs are classified into prescription (ETC) and over-the-counter (OTC) medications, based on their safety and usage profiles. ETC drugs require a prescription issued by a physician and are prohibited from being advertised to the general public (PAA Articles 2, 23 and 50). While OTC drugs can be sold to consumers at pharmacies without a prescription from a professional, such as a physician, ETC drugs can only be sold at pharmacies to consumers based on a prescription issued by a professional.

Medical devices are categorised into classes I, II, III and IV, based on their potential risk to the human body (MDA Article 3). For medical devices, the regulatory affairs for manufacturing (import) notification, certification and licensing purposes are processed according to each respective class of devices.

With respect to premarket reviews, a manufacturer who has obtained a pharmaceutical manufacturing licence and/or an importer who has filed a pharmaceutical import business report must obtain a licence (marketing authorisation) or file a report for each individual product they intend to manufacture or import for sale (PAA Articles 31 and 42). Furthermore, the application submitted for such product licence/report must specify whether the drug is categorised as ETC or OTC medication, and the MFDS classifies them based on separate review criteria (Articles 3 and 4 of the Regulation on the Classification Criteria for Drugs).

For medical devices, the MFDS classifies medical devices into four classes, based on their intended use and the degree of potential risk to the human body, following deliberation by the Medical Device Committee. If an application is submitted by an interested party or if the relevant minister deems reclassification necessary, the minister may reclassify the grade of each product after deliberation by the Medical Device Committee (Article 2 [Attached Table 1] of the Enforcement Regulations issued by the MDA).

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 practice, facility standards, personnel-related requirements and insurance or financial guarantees) are attached to them?

Businesses engaged in the wholesale distribution of drugs must obtain a licence from the local municipality and must strictly comply with the Korea Good Supply Practice (KGSP) standards. Key conditions include maintaining specialised storage facilities (eg, cold chain for biologics), ensuring the relevant environmental controls are applied and appointing a licensed pharmacist as a quality manager (PAA Articles 44 and 45).

For medical devices, distributors must report to the local government and adhere to the Quality and Safety Management Standards (GSP), ensuring that the relevant devices are handled appropriately to maintain their quality and that a traceability system is in place (MDA Article 17).

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?

In South Korea, the retail sale of pharmaceuticals is strictly limited to licensed pharmacists who have opened a community pharmacy that is registered with the local authorities (PAA Articles 20, 44). There are no 'drugstore' chains in South Korea in the Western sense that sell drugs without a pharmacist onsite. However, a limited category of 'safety-reserved medicines' (eg, certain pain relievers, digestive aids) can be sold at designated 24-hour convenience stores, provided they meet specific registration and education requirements (PAA Article 44-2).

For medical devices, retailers must file a medical device retail business report. Unlike pharmaceuticals, certain low-risk devices intended for home use (eg, thermometers, pregnancy test kits) may be exempt from the reporting requirement, allowing them to be sold in general retail outlets (MDA Article 17). While a pharmacist licence is not required to sell medical devices, retailers must comply with standards on ensuring device quality and maintaining sales order, and they are prohibited from providing rebates to medical professionals (MDA Article 18).

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

The online sale of pharmaceuticals (including via social media or marketplace platforms) is strictly prohibited in South Korea under the PAA. All drug sales to consumers must occur face-to-face within a registered pharmacy setting (PAA Article 44). This is a strict rule intended to prevent the distribution of counterfeit drugs and ensure the provision of proper medication counselling to consumers. Violations can lead to severe criminal penalties.

Conversely, the online sale of medical devices is generally permitted, provided the seller has filed the necessary medical device distribution business report. However, they must comply with the requirements related to the medical device advertising review system, ensuring that any claims made on social media or other platforms do not exaggerate the product's efficacy or safety (MDA Article 24). In addition, certain high-risk medical devices or those intended for professional use only may be prohibited from being sold directly to consumers online.

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)?

For pharmaceuticals, a legal entity intending to import drugs must first file a pharmaceutical import business report with the MFDS to establish its status as an authorised importer. Once the business registration process is complete, the importer must then obtain a product marketing authorisation or file a product report for each individual item they intend to bring into the country (PAA Article 42). This dual-layered approach ensures that both the importer's facilities and the specific drug's safety and efficacy are verified before market entry.

In the case of medical devices, those who wish to import them must first obtain a medical device import business licence from the MFDS. Following the acquisition of a business licence, a product licence, product certification or product report is required for each individual medical device intended for import (MDA Article 15). Furthermore, importers must comply with the good manufacturing practices (GMPs) for medical devices.

7. To what extent are consumers allowed to 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?

In South Korea, consumers are permitted to import pharmaceuticals for personal use according to limited quantities, generally up to six bottles of medication or a three-month supply, provided the total value is under $150 for duty-free clearance (Customs Act Article 94, Enforcement Rules of the Customs Act Article 45). For prescription drugs, individuals must submit a valid prescription to the customs authorities to prove the medical necessity of the items, even for personal use. The regulations are significantly more rigorous for psychotropic substances. As per Article 3 of the Narcotics Control Act, any individual wishing to bring these types of substances into the country for self-treatment purposes must obtain prior approval from the MFDS before their arrival. Furthermore, it is a critical legal requirement that psychotropic substances must be transported by hand across the border by the individual. Importing psychotropic substances via international post or courier services is strictly prohibited and any attempts to do so will result in the immediate seizure of the goods and potential criminal prosecution.

Regarding medical devices, the import framework for personal use is even more restrictive. Individuals may only import medical devices for personal use in exceptional circumstances, such as for the treatment of a specific disease when no equivalent device is available on the domestic market. To do so, the consumer must obtain an 'import recommendation for medical devices for personal use' (waiving the standard import requirements) from the National Institute of Medical Device Safety Information (NIDS) (Regulations on the Exemption of Import Requirement Verification for Medical Devices Article 3). This is generally limited to one unit per person and requires the submission of supporting documents, including a doctor's diagnosis and the patient's medical records.

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 prohibited from shipping medicinal products directly to Korean consumers via e-commerce, as this constitutes a violation of the PAA. Regarding medical devices, the MDA requires all products distributed in the domestic market to be handled by a registered local entity. Overseas suppliers cannot sell medicinal products or medical devices to consumers unless they have a licensed Korean entity or importer within South Korea.

However, in the case of medicinal products, as detailed in above, consumers may import up to six bottles (or a three-month supply) for personal use. This has created a situation that is difficult to regulate in practice, namely ensuring that Korean consumers purchasing medicines sold by overseas suppliers stay within these limits. Consequently, there have been recent efforts in South Korea to promote legislative amendments that would explicitly prohibit the direct overseas purchase of medicinal products by domestic consumers.

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 medicinal products is prohibited in South Korea due to the imposition of strict safety and quality control requirements. As detailed above, only those entities that have filed a pharmaceutical import business report with the MFDS and, subsequently, obtained a licence or filed a report with the Minister of Food and Drug Safety for each individual drug item they intend to import are permitted to import and sell pharmaceuticals developed overseas (PAA Article 42).

The parallel importation of medical devices is also prohibited in South Korea for the same reasons as medicinal products. As detailed above, anyone wishing to import medical devices must first obtain a medical device import business licence from the MFDS and then they must obtain a product licence, product certification or file a product report for each individual medical device intended for import into the country (MDA Article 15).

EXPORT

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

South Korea generally encourages the export of therapeutic products, such as by enacting the Act on Fosterage of the Medical Device Industry and Support for Innovative Medical Devices. There are no measures, such as quantitative quotas, permits or others, that restrict or place conditions on the export of medical devices.

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

In the case of medicinal products and medical devices for export, export-only product marketing authorisation can be obtained from the MFDS. This allows manufacturers to produce and export products that are not authorised for sale on the domestic market. The primary condition is that the product must meet the regulatory requirements of the importing country. However, only those entities who have obtained a pharmaceutical manufacturing licence or a medical device manufacturing licence from the MFDS are eligible to be granted export-only product authorisations (PAA Article 31, MDA Article 6).

For medicinal products and medical devices, labelling must, in principle, be in Korean. However, Chinese characters or foreign languages of the same size as Korean text may be included. For products granted export-only marketing authorisation, labelling may be written solely in the language of the importing country (Regulation on Safety of Pharmaceuticals Article 77; Enforcement Regulations of the Medical Devices Act Article 44).

Meanwhile, pharmaceutical or medical device manufacturers must ensure that export-only products do not enter the domestic supply chain. Violations of this requirement may give rise to criminal penalties (PAA Article 93, MDA Article 51).

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 are allowed to circulate domestically or before therapeutic products may be exported?

All therapeutic products circulated in Korea must have Korean-language labelling. However, as detailed above, Chinese characters or foreign languages of the same size as Korean text may be included (Regulation on Safety of Pharmaceuticals Article 77, Enforcement Regulations of the Medical Devices Act Article 44). For medicinal products, container and outer packaging labels must additionally include, among other mandatory items, the name and address of the manufacturer or importer, the product name, manufacturing number and expiration date, quantity or dosage information, storage instructions, active ingredients and their amounts, and a clear indication of whether the product is an ETC or OTC item. Package inserts must also be provided and must set out the directions for use, dosage, precautions and any other statutorily required information, all in Korean. False or misleading statements or unapproved efficacy claims are strictly prohibited.

In the case of medicinal products, it is mandatory to assign serial numbers using barcodes or radio-frequency identification (RFID) tags to ensure the product's traceability from manufacturing to the point of dispensing. Relevant data is reported to the Korea Pharmaceutical Information Service (KPIS) (PAA Article 56, Regulation on Safety of Pharmaceuticals Article 69 and the Guidelines for the Use and Management of Pharmaceutical Barcodes and RFID Tags).

These serialisation and traceability requirements operate in parallel to the labelling and package insert obligations and are intended to support anti-counterfeiting measures and post-market surveillance.

For medical devices, the inclusion of unique device identification (UDI) data on the product labelling and the registration of integrated information have been introduced in stages and are now applied to all classes of devices. Importers and manufacturers must attach UDI codes to products and report the distribution data to the Medical Device Information & Technology Assistance Centre (MDITAC) (MDA Articles 2 and 20; Article 54-3 of the Enforcement Regulations of the MDA).

In addition, containers or outer packaging of medical devices must bear, in Korean, the manufacturer's or importer's name and address, the country of origin for imported devices, the licence or certification number, the product or model name, the manufacturing number and date or use by date, quantity and a clear indication that the product is a medical device, with single-use devices specifically labelled as such. Package inserts must describe the method of use, precautions and any required maintenance or inspection instructions, and must not include false or misleading information or claims that go beyond the approved or certified scope of the licence.

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?

South Korea operates a national health insurance (NHI) system, which includes a 'positive list' for reimbursement purposes. Under this system, the MOHW publishes notifications listing reimbursable prescription drugs and treatment materials, together with the approved maximum prices, and only products included on these lists are broadly accessible through the insurance scheme. As a result, the pricing and reimbursement status directly impacts whether and how therapeutic products are distributed and prescribed in practice.

In addition, for reimbursable prescription drugs, patients generally pay a contribution of the cost of approximately 30 per cent, with the remaining 70 per cent reimbursed by the National Health Insurance Service (NHIS), while treatment materials are subject to copayment ratios specified in the relevant ministry notifications, with the balance paid by the NHIS. The drug price negotiation process involving the NHIS, together with the reimbursement and pricing evaluations conducted by the Health Insurance Review and Assessment Service (HIRA), therefore, materially influence the relevant market access, pricing and distribution channels, even though these mechanisms are not trade measures per se.

The government also mandates supply obligations for 'essential medicines' to prevent shortages. Such obligations may be accompanied by policy measures, including price adjustments or other incentives, aimed at ensuring the continued production and stable distribution of such medicines by private manufacturers and distributors, thereby further shaping the availability of therapeutic products on the Korean market.

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?

Regulators possess broad investigative powers, including the ability to conduct on-site inspections and the authority to seize non-compliant products. Sanctions include administrative fines, the suspension of business licences, the revocation of licences and criminal prosecution (imprisonment or high fines) (PAA Articles 76, 79, 81, 81-2, 93, 94, 95, 95-2, 96, 97, 97-2, 97-3 and 98; MDA Articles 36, 38, 38-2, 51, 52, 53-2, 54, 55 and 56).

The MFDS's Special Judicial Police are particularly active in investigating illegal online sales, false or exaggerated advertising and the distribution of unapproved products.

Recently, the 'Pharmaceutical Supply Chain Transparency' initiative has increased the frequency of audits conducted on distribution data. Compliance with anti-corruption laws (the Kim Young-ran Act) and the 'K-Sunshine Act' (the reporting of economic benefits provided to healthcare practitioners) are also a critical part of the regulatory landscape for distributors.

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

In light of the limitations of South Korea's existing Medical Service Act framework in regard to regulating new technologies developed alongside the advancement of digital healthcare, the Digital Medical Products Act was enacted on 23 January 2024 and took effect on 24 January 2025. This Act establishes the requirements related to the handling, management and support of digital medical products, such as their manufacturing and importation, to ensure their safety and efficacy, while promoting quality improvement. The Korean government expects that by establishing a system for the authorisation and safety management of medical products that are integrated with advanced digital technologies (eg, artificial intelligence (AI), robotics, virtual reality (VR) and augmented reality (AR)), this Act will keep pace with technological advancements and contribute to the improvement of public health.

The Digital Medical Products Act includes regulations concerning manufacturers of digital medical devices, digital-converged pharmaceuticals and digital medical/health support devices. Manufacturers of these digital medical products may be subject to administrative sanctions if they fail to meet specific security guidelines and quality management systems (QMSs) standards. Therefore, thorough prior preparation is deemed necessary in this context. To this end, it is crucial for the relevant entities to respond proactively to the procedures for the conformity assessment of quality management standards by the MFDS, as well as the procedures for proving the safety and efficacy of such products using real-world evidence (RWE) evaluations and to faithfully address any issues identified during these processes.

Meanwhile, the rules for the legal management of contract sales organisations (CSOs), which were previously used as channels for the provision of indirect illegal kickbacks, became fully effective in October 2024. All CSOs are now legally required to register with local governments. Unregistered CSOs are prohibited from operating (Article 46-2 of the Pharmaceutical Affairs Act). Similar to pharmaceutical companies, CSOs are now mandated to submit and disclose expenditure reports, making all of the economic benefits provided to healthcare professionals transparent (Article 47-2 of the Pharmaceutical Affairs Act).

The implementation of these regulations has significantly increased the likelihood of illegal kickbacks being detected, and the contractual relationship between pharmaceutical companies and distributors has been restructured within a more formal and transparent framework.