

REGULATORY OVERVIEW

LAWS AND REGULATIONS RELATING TO OUR GROUP’S BUSINESS AND OPERATION IN TAIWAN

Forms of Business Organization

From a Taiwan law perspective (including the Company Act (公司法), Income Tax Act (所得稅法), and the associated rulings issued by the Ministry of Economic Affairs (經濟部) and Ministry of Finance (財政部)), the forms of business organization include company limited-by-shares, limited company, unlimited company with limited liability shareholders, and unlimited company. The principal forms of business organization used by foreign entities investing or conducting business in Taiwan include companies incorporated in Taiwan (i.e., subsidiaries) and branch offices of foreign-incorporated companies. Representative offices of foreign companies are not allowed to conduct business and generate revenue in Taiwan. Foreign entities may also conduct business through other types of business relationships with local entities, such as joint ventures, licensing, distributorships, or agency relationships.

The main differences between a subsidiary and a branch office in Taiwan lie in their tax obligations, governance requirements, and legal liability. Both subsidiaries and branch offices are subject to a 20% corporate income tax (“CIT”) on their worldwide income and may enjoy a 10-year loss carry-forward. However, a branch office generally bears a lighter overall tax burden than a subsidiary, as it is not subject to the 21% withholding tax on earnings repatriated to its head office and is exempt from the 5% undistributed earnings tax, both of which apply to subsidiaries unless limited exemptions apply. From a corporate governance perspective, a branch office involves fewer administrative formalities and lower maintenance costs, as it is not required to establish a board of directors or hold board and shareholder meetings, which are mandatory for a subsidiary under Taiwan law. In terms of legal status, a branch office is considered a part of its parent company and not an independent legal person. Consequently, if a branch office’s assets in Taiwan are insufficient to pay off its liabilities, the liabilities will extend to its foreign parent company. By contrast, a subsidiary is an independent legal entity, and, unless otherwise stipulated by law or contract, its liabilities do not extend to its foreign parent company.

Tax

Business Tax

Sales of goods and services in Taiwan and the importation of goods into Taiwan are subject to business tax, which is governed by the Value-added and Non-value-added Business Tax Act (加值型及非加值型營業稅法) (“**Business Tax Act**”). Value-added tax (“VAT”), levied on the value added at each stage of the provision of goods or services, is applicable to general industries, while non-value-added tax is levied on the gross value of the goods or services and applicable to specified industries, such as small businesses and financial institutions. According to the Business Tax Act and the Taiwan Executive Yuan’s announcements, the current applicable VAT rate is 5% for most businesses. With very few exceptions, VAT is applied to the sale of most kinds of goods and services by a business entity. A business entity that sells goods or services is required to report and pay VAT within the statutory period; however, in practice, the tax burden is ultimately passed on to the purchaser. The VAT rate is 0% on the export of goods and services. For imported goods, VAT at 5% is levied on and shall be paid by the consignee or holder of the imported goods.

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Income Tax

Under the Income Tax Act (所得稅法), CIT applies to any type of profits-seeking enterprise (“PSE”) regardless of the form of business, except for partnerships and sole proprietorships. A Taiwan PSE is subject to CIT on all income derived both within and outside Taiwan, while a foreign PSE is subject to CIT only on income sourced from Taiwan. In addition, according to the Income Basic Tax Act (所得基本稅額條例), a Taiwan PSE, with certain exceptions, shall pay the difference between the amount of its ordinary CIT and its Basic Tax should the latter exceed the former. The calculation of Basic Tax is based on the basic income amount, which is the sum of taxable income and certain tax-exempt income, less a deductible amount (currently NT\$500,000, subject to adjustment as determined by the competent authority), and is currently subject to a 12% tax rate. The Income Basic Tax Act does not apply to foreign PSEs without a fixed place of business or a business agent in Taiwan.

Withholding Tax

According to the Income Tax Act (所得稅法), a foreign PSE without a fixed place of business or a business agent in Taiwan is subject to withholding tax on various income derived within Taiwan, with rates varying by income types. Under the Standards of Withholding Rates for Various Incomes (各類所得扣繳率標準), most interest income and royalty income received by a foreign PSE are subject to a 20% withholding tax, while dividend payments from Taiwan companies to a foreign PSE are subject to a 21% withholding tax. A preferential withholding tax rate may apply to certain types of income in the event that there is an applicable tax treaty between Taiwan and the foreign PSE’s country of residence.

Exchange Control

Exchange controls in Taiwan are primarily governed by the Foreign Exchange Control Act (管理外匯條例), which is administered by the Central Bank of Taiwan (“CBC”). Under Taiwan’s foreign exchange regime, only banking institutions or other entities as designated by the Financial Supervisory Commission (“FSC”) and/or CBC (such as the insurance companies and securities firms) may be approved to conduct foreign exchange business. The Regulations Governing the Declaration of Foreign Exchange Receipts, Disbursements or Transactions (外匯收支或交易申報辦法) and relevant administrative rules require that each foreign exchange remittance exceeding NT\$500,000 (or its equivalent) shall be declared to the CBC through the banking institutions.

Current regulations favor trade-related foreign exchange transactions and foreign investment approval investments. Consequently, foreign currency earned from exports of merchandise and services may now be retained and used freely by exporters, and all foreign currency needed for the importation of merchandise and services may be purchased freely from the designated banking institutions approved to engage in foreign exchange business.

Trade aside, effective from 1 November 2024, pursuant to Articles 4 and 6 of the Regulations Governing the Declaration of Foreign Exchange Receipts and Disbursements or Transactions and a press release published by the CBC on 30 October 2024, and unless otherwise provided by the CBC, ROC companies and resident individuals may, without foreign exchange approval, remit outside the ROC foreign currency of up to US\$100,000,000 (or its equivalent) and US\$10,000,000 (or its equivalent), respectively, in each calendar year. In addition, effective from 1 November 2024, ROC companies and resident individuals may, without foreign exchange approval, remit into the ROC foreign currency of up to US\$100,000,000 (or its equivalent) and US\$10,000,000 (or its equivalent), respectively, in each calendar year. Notwithstanding the above, CBC may, depending on the economic and financial situation and the need to maintain the order of the foreign exchange market, adjust the settlement limits as it deems necessary.

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In addition, a non-resident person may, subject to certain requirements, but without foreign exchange approval of the CBC, remit outside and into the ROC foreign currencies of up to US\$100,000 (or its equivalent) for each remittance. However, a non-ROC financial institution outside the territory of Taiwan is not permitted to sell foreign exchange through inward remittance. The above limit applies to remittances involving a conversion of NT Dollars to a foreign currency and vice versa.

Under Taiwan law, foreign currency indebtedness with a repayment term exceeding one year remitted into Taiwan are subject to registration with the CBC pursuant to the Directions for the Declaration of Medium- and Long-Term External Debts by Private Enterprises (民營事業中長期外債申報要點). A Taiwan subsidiary or branch receiving such loans is required to declare the contracted loan amount to the CBC and obtain an external debt registration code upon execution of the relevant loan agreement or upon the inward remittance of the loan proceeds, as applicable. Following registration, drawdowns and repayments under the registered loan must be reported to the CBC on a quarterly basis, and information regarding the outstanding balance of the external debt must be submitted by the 10th day of the month following the end of each calendar quarter.

Employment

In Taiwan, the Labor Standards Law (勞動基準法) (“**LSL**”) is the fundamental law that sets up the minimum requirements and standards of employment terms and conditions, such as working hours, overtime pay, leaves and benefits, severance pay, etc. There is a requirement of minimum wage as determined by the Ministry of Labor (勞動部) (“**MOL**”). Effective from 1 January 2026, the minimum wage is NT\$29,500 per month, or NT\$196 per hour. Employers must pay into the following social insurances for its employees (1) the labor pension plan (under either the LSL (the Old Pension Plan) or the Labor Pension Act (勞工退休金條例) (the New Pension Plan, described in more details below); (2) national health insurance (under the National Health Insurance Act (全民健康保險法) (“**NHIA**”); (3) employment insurance (mainly for unemployment subsidy) (under the Employment Insurance Act (就業保險法); and (4) labor insurance (under the Labor Insurance Act (勞工保險條例)).

There are two separate statutory pension plans that now operate in Taiwan – the Old Pension Plan and the New Pension Plan. The New Pension Plan is the scheme created under the Labor Pension Act (勞工退休金條例), which became effective on 1 July 2005, and applies to employees hired after 1 July 2005. Employees hired before 1 July 2005, can either elect to remain in the Old Pension Plan (a scheme under the LSL) or switch to the New Pension Plan.

Whereas the Old Pension Plan was based on centralized pension accounts, the New Pension Plan creates individual retirement accounts (“**IRA**”) and is a defined contribution program: employers contribute at least 6% of employees’ monthly salary to an IRA for each employee, and such IRAs follow employees when they transfer from one employer to another. Employees become eligible for benefits under their IRA upon retirement after reaching the age of 60. When an employee covered by the New Pension Plan changes employment, the amount contributed by the previous employer remains in place under the same IRA. Consequently, the employment transfer has no effect on the pension fund already accrued under the New Pension Plan.

Moreover, Taiwan is protective of employees (no at-will employment). Employers cannot unilaterally terminate an employment agreement unless they can clearly prove certain statutory requirements as set forth in the LSL. In most situations, the employer is required to pay a statutory severance payment to the employee upon termination.

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All employees in Taiwan are covered by the LSL except those who work in industries or occupations specifically excluded by the MOL. A manager is covered by the LSL unless that he/she is an appointed/mandated manager. To determine whether a manager is an appointed/mandated manager, the core criterion is whether the manager has high authority and autonomy when performing his or her duties. The court would also consider the following three procedural elements: (i) whether the manager has signed an appointment or mandate agreement (instead of an employment agreement); (ii) whether the manager has been appointed by the company’s board of directors to assume a manager’s position under Company Act (公司法), and (iii) whether the manager has been registered as responsible person/manager in the company’s corporate registration form filed with the MOEA.

Fair Trade Law

The Fair Trade Law (公平交易法) (“FTL”) targets restrictive business practices and unfair trade practices. With respect to business practices, the scope of the FTL’s regulations governs the anti-competitive aspects of monopolies, mergers, concerted actions such as business cartels, and resale price maintenance. For unfair trade practices, the FTL seeks to prevent misleading advertising and labeling, misappropriation of trademarks, copying of trade dress, and other anti-competitive practices in the field of intellectual property law. When it comes to the prohibition of abuse of dominance, the FTL regulates companies with monopolistic positions in markets, and the prohibited activities include, for instance, preventing other players from competing by unfair means, improper pricing, preferential treatment to trading counterparts without justification, and other abusive conduct.

Intellectual Property Laws

Trademarks

Under the Trademark Act (商標法), a trademark is any sign capable of distinguishing the goods or services of one entity from those of another and recognized by ordinary consumers. A trademark may consist of words, symbols, devices, colors, sounds, three-dimensional shapes, or any combination thereof. To obtain protection, the mark must be distinctive and registered with the Taiwan Intellectual Property Office (智慧財產局) (“TIPO”). Once registered, the trademark owner has the exclusive right to use the mark and may prevent others from using identical or confusingly similar marks that could mislead the public, including protection against unregistered well-known foreign trademarks.

Copyrights

The Copyright Act (著作權法) protects original works of authorship, including literary, artistic, musical, and audiovisual works, as well as computer programs. Copyright arises automatically upon the creation of the work, without the need for registration. The copyright owner has the exclusive right to reproduce, distribute, publicly perform, and adapt the work, and may enforce these rights against any unauthorized use by third parties. Moral rights, such as the right of attribution and integrity, are also protected under the Copyright Act.

Patents

The Patent Act (專利法) protects inventions, utility models, and designs that meet the statutory requirements of novelty, inventive step, and industrial applicability. To obtain patent protection, an application must be filed and approved by the TIPO. A granted patent confers an exclusive right to exploit the invention for a specified term, and the patent holder may prevent others from making, using, selling, or importing the patented invention without authorization.

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Trade Secrets

The Trade Secrets Act (營業秘密法) protects confidential business information that has economic value and is subject to reasonable measures to maintain its secrecy. Trade secret protection does not require registration, while it arises from the maintenance of secrecy. The holder of a trade secret may seek civil and criminal remedies against any misappropriation, unauthorized disclosure, or use by third parties, thereby ensuring competitive advantage in the marketplace.

Foreign Investment

The Department of Investment Review of the Ministry of Economic Affairs (“**DIR**”) takes charge of the foreign investment in Taiwan. Foreign investment in Taiwan can be divided into two categories: (1) investment by foreign investors or overseas citizen, which is governed by the Statute for Investment by Foreign Nationals (外國人投資條例), the Statute for Investment by Overseas Compatriots (華僑回國投資條例) and Regulations for Verification of Investment by Overseas Compatriots and Foreign Nationals (華僑及外國人投資額審定辦法); and (2) investment from Mainland China, which is governed by Act Governing Relations between the People of the Taiwan Area and the Mainland Area (臺灣地區與大陸地區人民關係條例) and Regulations Governing the Permission of Investment by Nationals in Mainland Area (大陸地區人民來臺投資許可辦法).

Under the Statute for Investment by Foreign Nationals (外國人投資條例) and the Statute for Investment by Overseas Compatriots (華僑回國投資條例), foreign investors’ and overseas citizens’ investments in Taiwan are subject to review and approval by DIR prior to investment. “Foreign investment” generally includes the following types of activities: (1) the acquisition or holding of shares or capital contributions in a company incorporated in Taiwan; (2) the establishment within Taiwan of a branch office, sole proprietorship or partnership; and (3) the provision of loans with a term of one year or more to any enterprise in which the foreign investor has made an investment described in clauses (1) or (2) above. After investment, their injection of funds is subject to DIR’s review and verification in accordance with Regulations for Verification of Investment by Overseas Compatriots and Foreign Nationals (華僑及外國人投資額審定辦法). In the event that a foreign investor or overseas citizen holds more than one-third of the equity in a business in Taiwan, the investment of that business in other businesses is also subject to DIR’s review and approval.

There are certain enumerated types of critical business in which investments by foreign investors and overseas citizens are forbidden or restricted due to national security, public order, good morals, national health, or other concerns.

With respect to investment from Mainland China, the types of investment that are subject to DIR’s review and approval are: (1) holding shares or equity interests in a Taiwanese non-public-traded company, sole proprietorship or partnership; (2) holding 10% or more shares in a Taiwanese public-traded company; (3) incorporating a branch, sole proprietorship or partnership in Taiwan; (4) financing businesses invested through the preceding (1) to (3) by granting a loan with a term of one year or more; (5) having control over a Taiwanese non-public-traded company, sole proprietorship or partnership through contractual arrangement or other means; (6) acquiring the business or assets of a Taiwanese non-public-traded company, sole proprietorship or partnership through a foreign entity controlled by the Mainland China investor; and (7) investing in a financial, insurance, securities or futures institution in Taiwan. Separately, Mainland China investors’ investment of less than 10% shares in a Taiwanese public-traded company is subject to the Regulations Governing Securities Investment and Futures Trading in Taiwan by Mainland Area Investors (大陸地區投資人來臺從事證券投資及期貨交易管理辦法).

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Different from the approach to investment by foreign investors and overseas citizens, for Mainland China investors, only certain types of business that are enumerated by the authorities are permitted to be invested in by those investors. Further, for each permitted type of business, there may be a limit on the percentage of the shares held by Mainland China investors.

Medical Services

Medical Services

Definition of Medical Services

Neither the MCA nor its supplementary regulations explicitly define “Medical Services.” Pursuant to the court precedents and explanations issued by the MOHW from time to time, medical service business refers to the medical practice provision, regardless of whether it is the principal business or ancillary business, or whether any remuneration is received for the provision of medical service. As for the scope of “Medical Practice,” the MOHW has illustrated that any act performed with the direct purpose of treating, correcting, or preventing human diseases, injuries, or defects, or for health maintenance, including examination, diagnosis, and treatment, or, based on the results of examination or diagnosis, prescribing or administering medication, whether in whole or in part, should be included.

Medical Service Advertisement

“Medical Service Advertisement” is defined as “the act of advertising medical services by means of propagation for the purpose of soliciting patients,” under the MCA. In addition, advertisements containing content that implies or suggests medical service business should be regarded as advertisements for medical services.

Based on the above, medical contents will be regulated as a medical service advertisement if all of the three features below are found therein: (1) media are used to solicit patients/promote medical services; (2) medical service(s) can be identified directly or indirectly from the medical contents; and (3) the intended purpose of the medical contents/advertiser is to solicit patients. There is no restriction on the types of media, and the medical contents thereon can be images, sounds, text, etc.

A person who is not a medical institution or a physician is prohibited from making advertisements for medical services. The content of advertisements for medical services is restricted to the following: (1) the name, practice license number, address, telephone number, and directions to the medical institution; (2) the name, sex, academic background, professional experience, and physician or specialist physician certificate number of the physician; (3) hospitals or clinics contracted or associated with the NHI or other non-commercial insurances; (4) clinic practices and clinic hours; (5) the year, month, and date of the opening, suspension, closure, resumption, or relocation of practice; and (6) other items approved and announced by the MOHW for publication or broadcast. Advertisements for medical services may be presented orally via broadcast or television media with the approval of the local competent authority. Moreover, information provided by medical institutions through the internet is regulated by the Regulations on the Management of Internet Information by Medical Institutions (醫療機構網際網路資訊管理辦法).

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Separation of Prescribing and Dispensing

Taiwan’s medical system adopts a “separation of prescribing and dispensing” mechanism, under which physicians at medical institutions issue prescriptions and pharmacists perform dispensing separately. In other words, physicians are responsible for diagnosis and prescribing, while pharmacists are responsible for dispensing and providing pharmaceutical services, thereby preventing physicians from selling medications directly and reducing the risk of overprescription or conflicts of interest. The MOHW has established the Operational Guidelines for the Establishment of Pharmacies (藥局設置作業注意事項), which stipulate that medical institutions and pharmacies must maintain a minimum separation in their establishments.

Healthcare Professionals

Under the MCA, “Healthcare Professionals” include physicians, pharmacists, nurses, midwives, medical technologists, therapists (such as physical, occupational, respiratory, and speech), psychologists, dietitians, opticians, dental technicians, and other individuals holding professional medical certificates issued by the central competent authority.

Since our operations primarily involve healthcare professionals, such as physicians and nursing personnel, we will focus below on the regulations relevant to these two groups.

Physicians

Physician Qualifications

Citizens of Taiwan who have passed a physician examination and hold a physician certificate in accordance with the Physicians Act (醫師法) may work as a physician. Further, under the MCA, “Physicians” include physicians, Chinese medicine doctors, and dentists.

A person meeting any of the following conditions may not work as a physician. If such a person has worked as a physician, his/her physician certificate must be revoked or cancelled: (1) upon a final and binding judgment, being found to have committed an offense under the Narcotics Elimination Act or Narcotics Control Act; (2) upon a final and binding judgment, being found to have committed an offense under the Drug Control Act; or (3) having his/her physician certificate revoked according to law.

Physicians may apply for a diplomate certificate upon completion of diplomate training and examination by the central competent authority. The Diplomate Specialization and Examination Regulations (專科醫師分科及甄審辦法) stipulate the relevant requirements.

Physician Practices

Physicians may practice medicine only after registering their practice with the local competent authority where they intend to practice and obtaining a practice license. Practicing physicians are also required to join the local medical association.

A practice license will not be issued, and any practice license already issued will be revoked or cancelled, under any of the following circumstances: (1) the physician certificate has been revoked or cancelled; (2) the physician’s practice license was cancelled within the past year; or (3) the physician has been determined by a team of specialist physicians and scholars/experts invited by the local competent authority to be unable to practice due to objective facts. Once the disqualification cause is removed, the physician may reapply for a practice license.

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Physicians must practice in a medical institution, long-term care service institution, or psychiatric rehabilitation institution approved and registered with the local competent authority or approved by the MOHW, unless one of the following conditions applies: (1) performing first aid; (2) consulting with or supporting other medical institutions; (3) being called out to visit patients by request; (4) providing emergency or public health medical services assigned by competent authorities of all levels; or (5) engaging in other matters reported to and approved by the local competent authority.

Medical Ethics

The Taiwan Medical Association (中華民國醫師公會全國聯合會) has established the Code of Medical Ethics for Physicians (醫師倫理規範) as an industry standard for its members, incorporating relevant provisions from the World Medical Association Code of Medical Ethics. Physicians who violate medical ethics in their professional practice are subject to disciplinary action by the Taiwan Medical Association or the competent authority.

Nursing Personnel

Nursing Personnel Qualifications

Citizens of Taiwan who pass the national examination for nursing personnel and obtain a nursing personnel certificate in accordance with the Nursing Personnel Act (護理人員法) (“NPA”) may serve as nursing personnel. Under the NPA, “Nursing Personnel” includes professional registered nurses and registered nurses.

A person who falls under any of the following circumstances may not serve as nursing personnel. If such a person has served as nursing personnel, his/her nursing personnel certificate must be rescinded or revoked: (1) upon a final and binding judgment, being found to have committed an offense under the Narcotics Elimination Act or Narcotics Control Act; (2) upon a final and binding judgment, being found to have committed an offense under the Drug Control Act; or (3) having his/her nursing personnel certificate revoked under the NPA.

A person who does not hold a professional registered nurse or registered nurse certificate may not use the title of professional registered nurse or registered nurse. Similarly, a person who does not hold a nurse practitioner certificate may not use the title of nurse practitioner. A professional registered nurse may apply for a nurse practitioner certificate after completing nurse practitioner training and passing the review conducted by the MOHW. The Regulations Governing Specialties and Examination of Nurse Practitioner (專科護理師分科及甄審辦法) stipulate the relevant requirements.

Nursing Ethics

The Taiwan Union of Nurses Association (中華民國護理師護士公會全國聯合會) has established the Taiwan Code of Ethics for Nurses (臺灣護理倫理規範) as an ethical guideline for nursing practice.

Pharmaceutical Products, Medical Devices, Cosmetics, Food, and Health Foods

Pharmaceutical Products

The Pharmaceutical Affairs Act (藥事法) (“PAA”) governs the manufacture, importation, distribution, and sale of pharmaceutical products in Taiwan.

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Under Articles 6 to 10 of the PAA, “Drugs” are generally referred to as active pharmaceutical ingredients and pharmaceutical preparations intended for diagnosis, treating, or alleviating disease of human beings, and include those sufficient to affect the body structure and physiological functions of human beings. All drugs must undergo a registration and approval process with the competent authority before they may be marketed or sold in Taiwan. No manufacture or import should be allowed until such approval is granted, and a drug license is issued.

The PAA also prescribes requirements that drug containers or packages bear labels specifying statutory particulars, such as the product name, ingredients, and dosage.

In addition, pharmaceutical firms, including drug dealers and drug manufacturers, must obtain approval and complete registration with the competent health authority in accordance with the PAA. Only entities that have been duly licensed may engage in the manufacture, import, export, or sale of drugs.

Holders of drug licenses bear statutory responsibilities under the PAA, including reporting supply shortages of essential drugs, monitoring product safety, reporting serious adverse reactions, and recalling products that pose risks or fail to comply with regulatory standards. These obligations ensure product quality, safety, and compliance throughout the product lifecycle.

Furthermore, advertisements for drugs are strictly regulated under the PAA, which defines such advertisements as communications promoting medical efficacy and restricts their publication to approved pharmaceutical firms. Prescription drugs and those designated by the competent authority may only be advertised in academic medical journals, and all advertisements must comply with statutory requirements to avoid false, exaggerated, or misleading claims. In addition, under Article 70 of the PAA, interviews, news reports, or promotional content that imply or suggest medical efficacy are also deemed as drug advertisements and are therefore subject to the same regulatory restrictions.

Medical Devices

The Medical Devices Act (醫療器材管理法) (“MDA”) governs the design, manufacture, import, sale, and supply of medical devices in Taiwan. Under Article 3 of the MDA, “Medical Devices” include instruments, apparatus, materials, software, and reagents intended to achieve, by non-pharmacological means, purposes such as (1) diagnosis, treatment, or prevention of human diseases; (2) modification of body structure or function; or (3) control of conception. Medical devices must be registered or approved by the competent authority before being marketed.

The MDA sets forth labeling and instruction requirements to ensure proper identification and safe use of medical devices. Labels must be affixed to the device or its packaging, and instructions must include essential safety and usage information.

The MDA also governs the registration and permitting of medical device firms, including manufacturers and dealers. Only companies established under Taiwan law or branches of foreign companies in Taiwan may register as medical device firms. These businesses must obtain approval and a permit from the competent authority, and any changes require updates to the registration.

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Advertising of medical devices is strictly regulated under the MDA. Only registered firms may advertise, and all advertisements require prior approval from the local competent authority. Approved advertisements may not be altered during their validity, and violations may result in suspension or correction orders; in particular, unauthorized modifications to the originally approved content of a medical device advertisement without prior approval from the competent authority are subject to administrative fines ranging from NT\$200,000 to NT\$5,000,000 under Article 65 of the MDA.

Cosmetics

The Cosmetic Hygiene and Safety Act (化粧品衛生安全管理法) (“CHSA”) governs the manufacture, import, sale, labeling, and safety management of cosmetics in Taiwan. Under Article 3 of the CHSA, cosmetics are defined as products applied to the human body’s surface, such as skin, hair, nails, lips, or oral cavity, for cleansing, beautifying, altering appearance, or maintaining good condition, without affecting human health through pharmacological action.

Cosmetic products cover a wide range of categories, including cleansing products, skincare products, hair care and styling products, perfumes, deodorants, lip products, makeup products for face and eyes, nail products, and non-medicated oral care products, such as toothpaste and mouthwash.

Under the CHSA and the Regulations Governing Notification of Cosmetic Products (化粧品產品登錄辦法), manufacturers and importers must complete product notification and establish product information file before the supply, sale, giveaway, public display, or consumer trial offer of cosmetics. Cosmetic businesses are required to comply with Good Manufacturing Practice (“GMP”) standards to ensure consistent manufacturing and compliance with quality and safety requirements. In addition, they must maintain a Product Information File (“PIF”) that includes essential documentation, such as ingredient details, manufacturing processes, safety assessments, and relevant test reports, in accordance with the Regulations for Cosmetic PIF Management (化粧品產品資訊檔案管理辦法). Starting 1 July 2024, PIFs have been required for sunscreens, hair dyes, perm agents, antiperspirants, and home-use tooth whitening products containing peroxide. From 1 July 2025, cosmetics for babies, lips, eyes, as well as general toothpaste and mouthwash, must also comply. Finally, beginning 1 July 2026, all cosmetic products—except handmade solid soaps produced by entities exempt from factory registration—must have a PIF established before being marketed, sold, or provided for consumer use.

Labeling requirements under the CHSA mandate that cosmetics clearly indicate product name, function, net weight, volume, or amount, full ingredient names, manufacturing date and expiration date (or shelf life), usage and storage instructions, precautions/warnings, manufacturer or importer information (name, address, phone number), country of origin of imported product, batch (lot) number, and any other information required to be labeled by the competent authority. Labels must not be false, exaggerated, misleading, or suggest medical efficacy.

Cosmetics that pose safety risks or violate statutory requirements are subject to recall and disposal in accordance with the Regulations Governing Cosmetic Product Recall (化粧品回收處理辦法). Competent authorities may conduct on-site inspections and random testing, and businesses must cooperate and provide samples as required. Where violations are found, the competent authority may order suspension of operations, sealing of products, and implement recall, correction, confiscation, or destruction of offending products. Depending on the circumstances of the offense, the extent of harm, and the scope of impact, the competent authority may also publicly disclose the violator’s name, address, and product details.

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Food

The Food Safety and Sanitation Act (食品安全衛生管理法) (“FSSA”) and its enforcement rules govern the manufacture, processing, import, sale, labeling, and advertising of food products in Taiwan. Under Article 3 of the FSSA, “Food” includes goods for eating, drinking, or chewing and their raw materials. Food additives are substances added to foods for purposes such as coloring, seasoning, preservation, emulsification, or oxidation prevention, and only additives approved by the central competent authority may be used, each with an approval number; processing aids are substances used during food processing for technological purposes, with residues that must not perform any function in the final product. Permissibility of additives and processing aids is further governed by the Standards for Scope, Application and Limitation of Food Additives (食品添加物使用範圍及限量暨規格標準) and the Sanitation Standards for Processing Aids (加工助劑衛生標準).

Packaged foods must bear labels indicating product name, ingredients, expiration date, and nutrition information in accordance with the Regulations on Nutrition Labeling for Prepackaged Food Products (包裝食品營養標示應遵行事項) and Regulations on Nutrition Claim for Packaged Food Products (包裝食品營養宣稱應遵行事項), while bulk foods must comply with separate labeling requirements prescribed by the competent authority.

Under the FSSA and the Regulations Governing the Registration of Food Businesses (食品業者登錄辦法), food business operators designated by the central competent authority, including manufacturers and processors, catering businesses, importers, retailers, logistics providers, and businesses engaged in the manufacture, processing, import, or sale of food additives should register and are required to regularly confirm the registration details to the competent authorities. For imported foods, the importer of record or designated distributor must act as the domestic responsible company and is primarily responsible for compliance and reporting obligations.

Food business operators must establish food safety monitoring plans and recall procedures. If products pose sanitation or safety risks or violate labeling or advertising rules, operators must report to local regulators and follow the Regulations Governing Recall and Disposal of Food and Related Products (食品及其相關產品回收銷毀處理辦法).

Food labeling, promotion, and advertising must not be false, exaggerated, misleading, or claim medical efficacy. Media outlets must retain advertiser information for six months and provide it upon request by regulators.

Health Foods

The Health Food Act (健康食品管理法) (“HFA”) and FSSA govern the manufacture, import, sale, labeling, and advertising of health foods in Taiwan. Under Article 2 of the HFA, “Health Foods” are products intended to provide specific health benefits and require approval by the central competent authority. Health foods must undergo registration and verification before they may be marketed, and only products that have passed inspection and obtained a health food license may be labeled as health foods.

REGULATORY OVERVIEW

Health foods must comply with labeling requirements under the HFA and the FSSA, including a clear indication of product name, ingredients, net weight, volume or quantity, name of food additives, expiration date, method and conditions of preservation, name and address of the responsible business operator or the importer (if the health food is imported), the approved health claims, permit number, the legend of “health food” and standard logo, recommended intake and important message for consumption of the health food, possible health risks, and other necessary warnings, nutritional components and their content, and any other information designated by the central competent authority. Health food labeling and advertising must not be false, exaggerated, or misleading, and must not suggest medical efficacy beyond the scope approved by the competent authority. References to therapeutic or medical efficacy are strictly prohibited.

Businesses that manufacture, process, import, or sell health foods must register as food business operators under the FSSA and the HFA. For imported health foods, the importer of record or designated distributor should bear primary responsibility for compliance and reporting obligations.

Under the HFA, health food business operators are subject to inspection and enforcement by the competent authorities, including on-site audits and random testing of products. Operators must cooperate with inspections and comply with orders to suspend, seal, recall, or destroy products that violate statutory requirements.

Privacy Law

Taiwan’s privacy protection framework is primarily governed by the Personal Data Protection Act (個人資料保護法) (“PDPA”), which applies broadly to the collection, processing, and use of personal data. Other laws also contain privacy-related provisions, but these generally apply only in specific contexts or circumstances. Below is an overview of the PDPA and other relevant legal provisions.

Personal Data Protection Act (“PDPA”)

The PDPA applies to all natural persons, non-government agencies, and government agencies. According to the PDPA, personal data can only be collected, processed, and used when (1) the data collector has specific purpose(s) to do so; (2) at least one of the statutorily specified circumstances (e.g., there is a contractual relationship between the parties) exists; (3) the data collecting agency provides adequate notice to the data subject. The personal data collected must be processed and/or used within the necessary scope of the specific purpose(s) identified upon collection, and may only be used for other purposes if one of the following conditions is met: (1) it is expressly required by law; (2) it is necessary to promote the public interest; (3) it is necessary to prevent harm to the life, body, freedom, or property of the data subject; (4) it is necessary to prevent material harm to the rights and interests of others; (5) it is necessary for statistical or academic research conducted by a government agency or academic institution for the public interest, provided that the data is processed or disclosed in a manner that does not identify any specific data subject; (6) the data subject has given consent; or (7) the use benefits the rights and interests of the data subject.

REGULATORY OVERVIEW

In cases where the data includes special categories of personal data as defined in Article 6 of the PDPA (“**Sensitive Personal Data**”), such as medical records, healthcare information, genetic data, sex life, or other health-related details, stricter requirements apply. These include obtaining the data subject’s explicit written consent, implementing appropriate security and maintenance measures, and ensuring that the Sensitive Personal Data is used only within the necessary scope of the specific purposes identified at the time of collection. The PDPA further requires that non-government agencies refrain from using such Sensitive Personal Data for any purpose beyond the original scope unless a statutory exception applies or otherwise provided by laws. These provisions are particularly relevant to the aesthetic medicine services, where Sensitive Personal Data may be routinely collected and processed as part of service delivery.

Other Relevant Privacy-Related Legal Provisions

Medical Care Act (醫療法) (“MCA”)

According to the MCA, medical institutions and their personnel must not, without legitimate reason, disclose any information concerning a patient’s illness or health acquired in the performance of their professional duties.

Physicians Act (醫師法)

According to the Physicians Act, physicians must not, without legitimate reason, disclose any information concerning a patient’s illness or health acquired in the performance of their professional duties, except for responding to inquiries or performing appraisals requested by competent authorities, which include health authorities, judicial authorities, and judicial police agencies.

Nursing Personnel Act (護理人員法) (“NPA”)

Under the NPA, nursing personnel, as well as nursing institutions and their staff, must not disclose the confidential information of others acquired in the performance of their professional duties, unless permitted by law or in writing by the patient or the patient’s legal representative. Disclosure is also permitted when responding to inquiries from competent authorities.

Criminal Code (刑法)

Article 316 of the Criminal Code applies to certain professionals, including physicians, their business assistants, and individuals who have previously engaged in such occupations. Under this provision, any such person who, without a legitimate reason, discloses another person’s confidential information acquired in the performance of their professional duties should be subject to criminal liability.

Civil Code (民法)

Article 195(I) of the Civil Code provides that if a person wrongfully causes damage to another’s privacy or severely infringes upon another’s personality, the injured party may claim reasonable monetary compensation even if the injury does not result in purely pecuniary loss.

Regulatory Authorities for Medical Institutions, Healthcare Professionals, and Healthcare Services

The regulatory framework in Taiwan is primarily overseen by two levels of health authorities: the central health authority, the MOHW, and the local health authorities, the Departments of Health of municipal and county/city governments.

REGULATORY OVERVIEW

Ministry of Health and Welfare (“MOHW”)

The MOHW serves as Taiwan’s central regulatory authority for medical institutions, healthcare professionals, and healthcare services. It is responsible for formulating national laws, regulations, and policies governing the establishment and operation of medical institutions, as well as setting standards for healthcare quality and patient safety. MOHW oversees the licensing and credentialing of healthcare professionals, including physicians and nurses, and administers disciplinary measures when applicable and necessary. In addition, it develops nationwide healthcare programs, supervises hospital accreditation systems, and manages health insurance reimbursement policies. Through these functions, MOHW ensures consistency in healthcare standards and provides strategic direction for the country’s medical system.

Departments of Health of Municipal and County/City Governments

Departments of Health at the municipal and county/city level serve as local enforcement agencies. They implement MOHW’s regulations and policies within their jurisdictions, ensuring compliance among medical institutions and healthcare professionals. Their duties include inspecting healthcare facilities, monitoring service quality, investigating complaints, and imposing administrative penalties for violations. These departments also manage local public health programs, including vaccination campaigns, disease surveillance, and emergency medical response. By addressing case-specific issues and operational oversight, they serve as the frontline regulators, translating national healthcare policies into practical, localized actions.

We have been advised by our Taiwan Legal Advisers that during the Track Record Period and up to the Latest Practicable Date, based on the information provided by us and certain compliance letters issued by the competent authorities in Taiwan, we had complied with the relevant laws and regulations in all material respects that are material to our business and operations in Taiwan, and there were no material breaches or violations of the laws or regulations applicable to us that would have a material adverse effect on our business, financial condition or results of operations.