TAIWAN

TRADE SUMMARY

U.S. goods exports in 2014 were $26.8 billion, up 5.4 percent from the previous year. Taiwan is currently the 14th largest export market for U.S. goods. Corresponding U.S. imports from Taiwan were $40.6 billion, up 6.9 percent. The U.S. goods trade deficit with Taiwan was $13.7 billion in 2014, an increase of $1.3 billion from 2013.

U.S. exports of services to Taiwan were $11.8 billion in 2013 (latest data available), and U.S. imports were $7.2 billion. Sales of services in Taiwan by majority U.S.-owned affiliates were $7.0 billion in 2012 (latest data available), while sales of services in the United States by majority Taiwan-owned firms were $3.2 billion.

The stock of U.S. foreign direct investment (FDI) in Taiwan was $16.9 billion in 2013 (latest data available), down from $17.7 billion in 2012. U.S. FDI in Taiwan is led by the manufacturing, wholesale trade, and finance and insurance sectors.

TECHNICAL BARRIERS TO TRADE / SANITARY AND PHYTOSANITARY BARRIERS

Technical Barriers to Trade

Food – Mandatory Biotechnology Labeling

In 2014, Taiwan implemented regulations related to biotech products. The United States and U.S. stakeholders have expressed concern about the requirements' potential impact on trade, and noted that some requirements do not appear to be based on science. Taiwan's February 5, 2014 amendments to the *Act Governing Food Safety and Sanitation* mandated additional biotech registration and traceability requirements, as well as expanded the scope of Taiwan's biotech labeling regulation to include all biotech products, and not just corn and soybeans. On December 22, 2014, the Taiwan Food and Drug Administration (TFDA) announced draft regulations reducing the tolerance for the presence of biotech product, including in food additives, from the current 5 percent level to 3 percent. These draft regulations have not been implemented. TFDA subsequently published revised draft regulations on February 26, 2015, which, if implemented in their current form, would significantly increase the burden to exporters and stakeholders, including by expanding the regulatory scope to include highly processed food products, setting a large font for the required labels, and shortening the length of the implementation period.

In August 2014, Taiwan's Council of Agriculture began screening organic soybeans for biotech materials, with no allowance for minimal residues. Effective November 1, 2014, Taiwan customs authorities mandated the segregation of corn and soybean shipments that contained biotech through separate commodity description codes. Finally, in December 2014, Taiwan notified the WTO of additional measures requiring that imported biotech products be accompanied by a list of all approved biotech events in Taiwan, while products that do not contain biotech must be accompanied by an "identity preservation" certificate or laboratory results confirming no presence of biotech. Taiwan's current practices and contemplated stricter policies on biotech labeling do not appear to be based upon science, impose significant burdens on U.S. stakeholders, and may serve to increase costs and cause concern among consumers.

Cosmetics – Labeling and Other Requirements

Taiwan is considering amendments to the *Cosmetic Hygiene Control Act*. It is anticipated that after Taiwan's legislature approves the changes, TFDA will issue draft guidelines that will address requirements for product information files, product notification, good manufacturing practices, product claims, and advertisements. U.S. stakeholders have expressed concerns that trade in medicated cosmetic products, including toothpaste, breath fresheners, and sunscreen, might be adversely affected under the amendments. The United States will continue to engage with Taiwan on issues that arise in 2015 as implementing measures are issued for comment.

Chemical Substances – ECN and NCN Programs

Under Taiwan's *Labor Safety and Health Law* (LSHL), importers and producers of chemical substances must register all chemical substances they sell or utilize in production with the Ministry of Labor (MOL, known prior to February 2014 as the Council of Labor Affairs, or CLA). In December 2009, the CLA started a pre-registration process, the voluntary Existing Chemical Substance Nomination (ECN) program, which ended on December 31, 2010. In 2012, the CLA implemented the first supplementary ECN in order to update the chemical-substance list and give companies that failed to register under the initial ECN an additional opportunity to do so.

Amendments to Taiwan's *Toxic Chemical Substances Control Act* (TCSCA), drafted by the Environmental Protection Agency of Taiwan (EPAT), were passed on December 11, 2013. The amended TCSCA mandates registration with EPAT of existing chemical substances (under a parallel ECN program) or new chemical substances (under a New Chemical Notification, or NCN, program) manufactured in, exported from, or imported into Taiwan.

On July 3, 2013, Taiwan's legislature passed amendments to the LSHL and renamed it the *Occupational Safety and Health Act* (the OSH Act), which became effective on July 3, 2014. The Executive Yuan commenced drafting regulations to implement a NCN program, as mandated by the OSH Act. To pave the way for implementation of the obligatory NCN program, on May 26, 2014, OSHA announced the second supplementary ECN program, with the nomination window open from June 1, 2014 to July 31, 2014. As with the 2010 and 2012 programs, the 2014 ECN program was also voluntary.

On September 8, 2014, Taiwan notified the WTO of its draft "Regulation of New and Existing Chemical Substances Registration", enacted pursuant to the amended TCSCA. This regulation covers existing chemical substances that are listed on EPAT's ECN inventory, as well as new chemical substances which are not listed on the ECN inventory. This regulation became effective on December 11, 2014. On October 28, 2014, Taiwan notified the WTO of its draft "Regulation of New Chemical Substances Registration", enacted pursuant to the OSH Act and covering any new chemical substances not listed on the existing MOL chemical inventory. This regulation became effective on January 1, 2015. While previous ECN and NCN programs implemented on a voluntary basis, the separate ECN/NCN registrations under the TCSA and OSH Act implementing regulations both became mandatory from the dates of their respective entries into force. As of March 2015, EPAT and OSHA maintained separate listings. Stakeholders have urged both agencies to move towards a consolidated single registration window to reduce the burden of submitting duplicative registrations.

The United States has raised questions regarding the operation of the notification systems, the protection of confidential business information, and the scope of coverage of the regulations. The United States will continue to engage with Taiwan authorities on these issues in 2015 as implementation of the regulations proceeds. The United States will also engage with MOL and EPA to discuss ways to harmonize the two regulatory systems to the extent possible.

Toys – Mandatory Inspections for Formamide and Phthalates

On July 7, 2014, Taiwan notified the WTO of new inspection requirements for formamide in foam toys and phthalates in children's products, subsequent to measures implemented on March 1, 2014. The Bureau of Standards, Metrology and Inspection (BSMI) announced that, pursuant to the December 4, 2012 revision of Chinese National Standard (CNS) 4797, the limitation on formamide in foam toys would be set at less than 2 ppm. The total amount of DMP, DEP, DEHP, DBP, BBP, DINP, DIDP, and DNOP in phthalates in children's products would be limited to less than 0.1 percent.

The United States is concerned that standards restricting the amount of certain phthalates contained in non-mouthable children's products do not appear to correspond to international practice.

The United States has also raised a concern that Taiwan's 2 ppm total limit on formamide in certain foam toys does not appear to correspond to international practice. Accordingly, the requirement that manufacturers test for formamide in toys where it is likely not present is an onerous and costly task for manufacturers. Raising the limit to 200 ppm, by contrast, would harmonize Taiwan requirements with other major markets.

Sanitary and Phytosanitary Barriers

Beef and Beef Products

Taiwan banned imports of U.S. beef and beef products following the detection of an animal with bovine spongiform encephalopathy in the United States in 2003. In 2006, Taiwan began allowing imports of U.S. deboned beef derived from animals under 30 months of age. In October 2009, the United States and Taiwan reached agreement on a Protocol expanding market access for U.S. beef and beef products (for human consumption). The Protocol provided for a full re-opening of the market, but Taiwan's legislature adopted an amendment to the *Food Sanitation Act* in January 2010 that banned imports of U.S. ground beef, internal organs and eyes, brains, spinal cord, and skull meat, contrary to Taiwan's Protocol obligations. Taiwan also announced additional border measures, including a licensing scheme for permitted offals, and imposed stricter inspection requirements for certain "sensitive" beef offals (*e.g*., tongue) that discourage trade. In July 2014, Taiwan confirmed market eligibility for U.S. beef lips, ears, backstrap and tunic tissue, though other barriers still prevent trade in these products. The United States will continue to urge Taiwan to open its market fully to U.S. beef and beef products based on science, the OIE guidelines, and the United States' negligible risk status.

Beta-agonists

In September 2012, Taiwan adopted and implemented an MRL for ractopamine in beef muscle cuts consistent with the Codex standard. However, Taiwan has not implemented an MRL for ractopamine in other beef products (*i.e*., offal) or pork, despite notifying the WTO in 2007 of its intent to do so. Taiwan authorities state that pressure from the local pork industry and consumer groups currently prevent the establishment of an MRL for pork. Apart from ractopamine, Taiwan has also not established MRLs for other beta-agonist compounds, such as zilpaterol, or provided science to support its policy. The United States will continue to urge Taiwan to implement the remaining proposed MRLs for ractopamine without further delay, and accept and approve new applications for MRLs for beta-agonists based upon science in a timely manner.

Maximum Residue Limits for Pesticides

Taiwan's slow process for establishing MRLs for pesticides, limited number of approved MRLs, and zero tolerance policy for pesticides that do not have established MRLs has resulted in stopped shipments at the port of entry and restrictions on U.S. agricultural exports to Taiwan. In May 2014, the United States provided Taiwan authorities with an MRL priority list which included more than 250 chemicals. The United States will continue to work with Taiwan authorities to swiftly establish MRLs for pesticides that do not currently have an approved MRL in Taiwan and find ways to further reduce the risk of rejected or delayed shipments in the future.

IMPORT POLICIES

Tariffs

When Taiwan became a WTO Member in January 2002, the authorities implemented tariff-rate quotas (TRQs) on small passenger automobiles and 24 agricultural products. Taiwan subsequently eliminated TRQs for eight of those agricultural products. TRQs remain on 16 agricultural products, including rice, peanuts, bananas, and pineapples.

Taiwan maintains Special Safeguards (SSGs) for a number of agricultural products covered by TRQs. SSGs, which are permitted under Article 5 of the WTO Agreement on Agriculture, allow Taiwan to impose additional duties when import quantities exceed SSG trigger volumes or import prices fall below SSG trigger prices. Because Taiwan previously did not import many of these products, its SSG trigger volumes are relatively low. Currently, Taiwan applies SSG provisions to 15 agricultural product categories, including poultry meat, certain types of offal, and milk.

U.S. stakeholders continue to request that Taiwan lower or eliminate tariffs on many goods, including large motorcycles, agricultural products, and soda ash.

Agriculture and Fish Products

Prior to joining the WTO, Taiwan banned or restricted imports of 42 agriculture and fish products. At the end of 2007, Taiwan phased out TRQs for persimmons, mackerel, carangid, and sardines. As noted above, 16 agricultural products still are subject to TRQs.

Beef and Pork

Despite administrative measures to improve market access for U.S. beef muscle cuts previously restricted due to ractopamine, the United States remains concerned about Taiwan's import requirements. Specifically, Taiwan's import requirements include an excessively strict import licensing regime, unscientific bans on meat products, and box-by-box inspections, that affect U.S. meat exports, including beef offal and pork.

Rice

Upon accession to the WTO in 2002, Taiwan committed to lifting the ban on rice imports and opened an import quota of 144,720 metric tons (MT) on a brown rice basis under a "special treatment" regime. Taiwan's annual WTO TRQ is divided into two portions: 35 percent or 50,652 MT for private sector imports, and 65 percent or 94,068 MT for public sector imports. The amount allocated to public sector imports is divided by both country of origin and tender type (*i.e.*, the simultaneous buy-sell (SBS) scheme and normal tenders). The SBS scheme is attractive to U.S. exporters because private importers bear all costs of importing, storing and distributing the rice.

In 2003, based on input from the United States and WTO members, Taiwan implemented a public sector import quota based on a country-specific quota (CSQ) regime, with the U.S. quota of 64,634 MT accounting for the largest share. However, in certain years Taiwan has rejected bids for U.S. rice under its WTO CSQ, arguing that high U.S. prices had exceeded Taiwan's ceiling price. U.S. exporters have raised concerns that Taiwan's ceiling price mechanism, which is not made public, arbitrarily sets prices lower than the levels bid by U.S. exporters, causing the tenders to fail.

In 2014, out of the total CSQ allotted to the United States, only 46,100 MT were successfully awarded for U.S.-origin rice. One reason for this shortfall is that multiple tenders failed due to low ceiling prices. The remaining 18,534 MT (28.6 percent of Taiwan's total U.S. CSQ commitment) were then retendered on a global basis. Taiwan reported that a 2013 tender of 2,000 MT of rice, allotted under the SBS tender, was not filled, will not be re-tendered. The United States continues to press Taiwan to fulfill its obligations based not on import licenses issued but on actual import figures and to address disruptions in rice trade stemming from Taiwan's ceiling price mechanism.

In 2012, Taiwan authorities decided to shift a larger percentage of the U.S. CSQ to SBS tenders. Although the SBS tenders have been working well, U.S. stakeholders are concerned that relatively low default penalties create a situation in which a successful bidder can decline a purchase for any reason, leaving the quota unfilled. In response to U.S. concerns about the adequacy of the performance bond under the SBS scheme, Taiwan replaced the 10 percent bond with a higher-value NT$2000 ($66) per ton bond for 2013 rice CSQ imports under the SBS scheme. Nevertheless, the United States is concerned that the performance bond price may be too low, especially in years with high rice prices. The U.S. Government continues to monitor the situation to ensure that the SBS scheme functions well and that no barriers impede fulfillment of all the rice quotas.

Distilled Spirits

Differential taxation for domestic and imported distilled spirits has been a contentious issue between Taiwan and a number of its important trading partners in the past, and it was the subject of negotiation during Taiwan's WTO accession process. Taiwan categorizes cooking wine into two subgroups, one group with a salt content requirement, and the other under "cooking alcoholic products" for products with alcohol content no greater than 20 percent and labeled "exclusively used for cooking." Based on these specifications, *mijiu* rice wine under these categories is taxed at NT$9 ($0.30) per liter, a much lower tax rate than that applied to non-cooking alcoholic products, NT$2.5 ($0.08) per liter per degree (percentage) of alcohol content.

The United States and other trading partners continue to express their strong concerns to the Taiwan authorities that steps should be taken to ensure that the domestic *mijiu* rice wine is not marketed to compete with, or substitute for, like imported alcoholic beverages, and that imported alcoholic beverages should not be taxed at a higher rate than like domestically produced alcoholic beverages.

The distilled spirits industry also continues to face challenges in the Taiwan market stemming from unclear regulations, excessive restrictions, and burdensome labeling requirements.

EXPORT SUBSIDIES

Taiwan provides incentives to industrial firms in export processing zones and to firms in designated emerging industries. Taiwan has notified the WTO of these programs. The Ministry of Finance (MOF) in October 2011 resumed tax rebates for customs duties on certain components and raw materials that are imported into Taiwan and then used to produce goods for export. On January 1, 2013, the program was expanded to cover a total of 1,751 products in categories including electronics, textiles, machinery, chemicals, mineral products, basic metal products, and plastics. On January 29, 2013, MOF announced that tax rebates would be expanded to include all components and raw materials that are imported into Taiwan and then used to produce goods for export, with the exception of 51 items identified on a negative list. The rebates were effective retroactively from January 1, 2013.

INTELLECTUAL PROPERTY RIGHTS PROTECTION

Taiwan was not included in the Special 301 Watch List in the 2014 Special 301 Report. Nevertheless, intellectual property (IP) rights holders continue to express concerns, including with respect to trade secret misappropriation, illegal textbook copying, end-user software piracy, cable TV signal theft, and infringement of copyrighted material on the Internet. Such infringement of copyright material on the Internet takes various forms, including file sharing and the use of media box hardware that may contain or facilitate the user's access via the Internet to pirated content. The importation and trans-shipment of counterfeit products is also a problem, as is the involvement of some Taiwan companies in supplying components to factories in China that produce counterfeit goods.

Although *Taiwan's Copyright Act* was amended in 2009 to require Internet service providers (ISPs) to undertake specific and effective notice-and-takedown actions against online infringers as a condition of avoiding liability for infringing activities of users on their networks, Taiwan has yet to effectively implement the *Copyright Act* amendments. Furthermore, meetings convened by the Taiwan Intellectual Property Office (TIPO) between ISPs and rights-holders aimed at producing a consensus on specific measures to address repeat infringement have not yet reached successful conclusion. TIPO has also increased outreach to law enforcement bodies on media box piracy in an attempt to mount an effective response to this new form of infringement, but serious concerns remain, particularly with regards to media box devices that facilitate infringement via internet links to pirated content.

The Legislative Yuan amended Taiwan's Trade Secrets Law in January 2013 to provide more deterrent, enhanced penalties for trade secrets misappropriation. Under January 2014 amendments to Taiwan's *Communications Protection and Surveillance Act,* law enforcement bodies were also given additional enforcement tools to deal with trade secret theft. Additionally, May 2014 amendments to the *Intellectual Property Case Adjudication Act* oblige defendants in lawsuits concerning trade secrets to submit substantive defenses. Finally, as of December 2014, draft amendments to the *Witness Protection Act* that would extend coverage to witnesses in trade secrets cases were pending review by the Legislative Yuan. Despite these positive steps, it remains difficult to pursue civil trade secret actions in Taiwan courts, in part due to continuing challenges in developing and securing access to evidence that is critical to plaintiffs.

In 2014, Taiwan authorities also took positive steps in the direction of enhancing patent and test data protections for innovative pharmaceutical products in certain respects by committing to establish a patent linkage system and study expanding the scope of regulatory data protection to cover a broader scope of innovations in pharmaceuticals and biologics. However, additional concrete steps are needed to implement these reforms.

Taiwan's Intellectual Property Rights Police completed a restructuring on January 1, 2014, with the stated intent of improving operational capacity coordination and cooperation with other enforcement agencies. The IPR Police report increased seizure values since the restructuring. However, rights holders have raised concerns over reduced staffing and smaller numbers of enforcement actions

SERVICES BARRIERS

Banking Services

In 2013, Taiwan's banking regulatory body, the Financial Supervisory Commission (FSC) indicated that it would allow foreign banks in Taiwan to keep both their subsidiary and branch operations, but asked that foreign banks' branches limit their primary business scope to areas that do not overlap with those of the subsidiaries, including corporate finance and derivatives services for large companies.

Taiwan authorities implemented the "Regulations Governing Internal Operating Systems and Procedures for the Outsourcing of Financial Institution Operation," on May 6, 2014, that lifted previous requirements that both local and foreign banks establish standalone onshore data centers.

Securities Services

In December 2012, the FSC announced that it would adopt a differential management approach and provide preferential licensing procedures for foreign trust fund companies that meet FSC's localization standards. In November 2014, FSC announced new measures to promote long-term investment in the Taiwan market by lowering the ceiling for the Taiwan investors' share of an offshore fund from 70 percent to 50 percent. This lower ceiling would apply if the offshore fund does not meet certain qualifications for the preferential management scheme, which include establishing a local presence, investing an average of NT$4 billion (US$127.5 billion) in onshore funds and recruiting a certain number of Taiwan staff.

Pay Television Services

Taiwan's *Cable, Radio, and Television Law* restricts foreign investment in pay-TV services to a total equity share of 20 percent for direct investment, or 60 percent for direct plus indirect investment. Effective July 27, 2012, the National Communications Commission (NCC) relaxed geographic restrictions on cable franchises for new and incumbent operators that agreed to use digital signals. The cable digital TV (DTV) penetration rate rose from 30.9 percent in June 2013 to 70.9 percent in December 2014. Experts point to continuing caps of NT$600 ($20) on monthly cable TV fees as hampering public access to a broader range and higher quality of programming. The NCC has announced plans to remove the cap on monthly fees and allow for differential payment by consumers by 2017.

INVESTMENT BARRIERS

Taiwan prohibits or restricts foreign investment in certain sectors, including agricultural production, chemical manufacturing, bus transportation, and public social services (including public education, health, child care, sewage, and water services).

Direct foreign ownership of wireless and wire line telecommunications firms is limited to 49 percent, with additional indirect foreign investment permitted up to 60 percent. Separate rules exist for Chunghwa Telecom (CHT) – the legacy carrier still partially owned by the Ministry of Transportation and Communications. CHT controls 97 percent of the fixed line telecommunications market. For CHT, the cap on foreign direct investment is 49 percent, with additional foreign direct investment permitted up to 55 percent. The total foreign ownership limit on cable TV broadcasting services is 60 percent, of which up to 20 percent can be through direct investment.

Foreign ownership in satellite TV broadcasting services, power transmission and distribution, piped distribution of natural gas, and high speed railways is limited to 49 percent of the total shares issued. The foreign ownership ceiling on airline companies, airport ground handling companies, forwarders, air cargo terminals, and catering companies is 49.99 percent, with each individual foreign investor subject to an ownership limit of 25 percent.

Taiwan authorities notably proposed amendments to the *Statute for Investment by Foreign Nationals* that aim to enhance Taiwan's inward investment, including by eliminating pre-investment approval requirements for investments under $1 million USD. Taiwan also proposed amendments to the *Business Mergers and Acquisitions Act* that seek to clarify criteria and review procedures affecting foreign investment in Taiwan companies. As of January 2015, these amendments were still pending approval by the Legislative Yuan. The United States will continue to engage with Taiwan authorities to increase the transparency and predictability of Taiwan's investment regime.

Portfolio Investment

Foreign portfolio investors are required to register and can do so via the Internet. Up to 30 percent of funds remitted for purposes of portfolio investment may be held in money market or other similar instruments. Funds for futures trading, however, must be remitted to Taiwan specifically for that purpose and are segregated from funds remitted for equity investment. The cap on the balance of a foreign investor's New Taiwan Dollar (NTD) omnibus account resulting from profits gained from futures trading in Taiwan is NT$300 million ($10 million). If the balance exceeds the limit, the foreign investor is required to convert the NT dollars into U.S. dollars within 5 working days, with the new NTD balance below NT$10 million ($333,000).

Foreign hedge funds are permitted to trade in Taiwan's stock market, subject to Taiwan authorities' surveillance. Foreign individual investors are subject to an investment limit. Onshore foreign individuals and institutional investors are also subject to annual inward and outward limits of NT$5 million and NT $50 million respectively.

OTHER BARRIERS

Pharmaceuticals

Stakeholders continue to underscore the need to create a more predictable market for pharmaceuticals, including innovative pharmaceuticals, in Taiwan's health care system. Concerns include whether Taiwan health authorities will take steps to provide greater consistency in the treatment of patented pharmaceutical products, how to calculate annual drug expenditure targets, and how to clarify what actions will be taken if targets are exceeded.

The United States encourages Taiwan to continue to consult with relevant stakeholders in implementing policies that will facilitate the private sector's development of innovative products and improve patients' access to such products.

Medical Devices

Concerns persist over Taiwan's product license approvals and pricing review mechanisms. Manufacturing facility (Quality Systems Documentation, QSD) registration is mandatory in Taiwan, regardless of whether a medical device is already on the market or new to Taiwan's market; and re-registration is required every three years. Some have called for the removal of QSD and replacing the registration standard by either accepting ISO standards and certificate or applicable U.S. GMP requirements and Establishment Inspection Reports (EIR).

Self-pay and balance-billing are two mechanisms that have been introduced by Taiwan authorities to allow Taiwan patients to have the option of choosing medical devices that are not paid in-full by the authorities. At present, however, NHIA does not provide reimbursement for implanted devices under either fee scheme. Implants, in addition to a range of other commonly used devices not approved for reimbursement, must instead be issued a self-pay code. Industry estimates some 2,000 devices regularly used by hospitals must apply for self-pay codes under the NHIA guidelines, and stakeholders report that hospitals that ask patients to self-pay for devices without a code are subject to administrative penalties by NHIA. To expedite code issuance, in April 2014, NHIA began assigning temporary self-payment codes for urgent or high-demand medical devices within two months of application. Reform of these procedures could speed patient access to medical devices.

The balance billing mechanism, introduced in January 2013, allows partial patient self-pay for high-end devices or new technologies. NHIA has the authority to introduce price caps that apply ceilings on what patients pay on new balance billing items. Transparency and due process mechanisms are critical in this process and the balance billing system may not effectively distinguish among devices of differing effectiveness. In a positive development, in 2014, NHIA established a website used to help consumers compare the cost of devices at different hospitals as a way to address a consumer concern without resorting to setting a balance billing cap.

U.S. stakeholders and trade officials have encouraged Taiwan to adopt a flexible mechanism that would: (1) reduce the stringency regarding which products may enter the market as self-pay or balance-billing devices, (2) provide Taiwan consumers a greater choice of advanced medical devices, and (3) provide clear self-payment guidelines to allow earlier access to new devices prior to the establishment of a reimbursement price.

Medical device stakeholders has proposed modifying Taiwan's Price Volume Survey system to address its lack of transparency in reimbursement procedures, including its single purchase price policy, and ineffectiveness in reaching its intended goal of reducing budgetary waste. The policy does not appear to take into account differences in therapeutic value, which may discourage the introduction of newer and more effective devices into the Taiwan market.