



Taiwan Healthcare Policies and U.S.-Taiwan Relations

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INTRODUCTION

For U.S. companies in both the pharmaceutical and medical device sectors, Taiwan has long been one of the major export markets in the Asia Pacific. Virtually all the leading U.S. manufacturers in these industries are represented in Taiwan by well-established subsidiaries. In 2019, the total value of pharmaceutical imports to Taiwan was US\$3.1 billion, and the Taiwan market for imported medical devices was an estimated US\$1.86 billion.^{1 2}

U.S. companies in both industries believe, however, that business opportunities in Taiwan would be considerably greater if not for government policies that give priority to cost containment. Since 1995, Taiwan has operated under a single-payer national healthcare system managed by the National Health Insurance Administration (NHIA) under the Ministry of Health and Welfare (MOHW). Increasingly, the NHIA has adopted various mechanisms designed to slow or limit entry into the Taiwan market of new and innovative products and technologies – the types of items that American companies are well known for – due to their relative expense.

At the same time, relations between the U.S. and Taiwan have been growing warmer recently due to the mutual realization of their shared interests and values. In recent months both the U.S. Secretary of Health and Human Services and the Under Secretary of State for Economic Growth, Energy and the Environment have visited Taipei. In addition, the two sides recently held a Taiwan-U.S. Economic Prosperity Partnership Dialogue and signed a Memorandum of Understanding on bilateral economic cooperation.

Prospects appear unusually encouraging for resolution of existing trade issues, whether through the established Trade & Investment Framework Agreement (TIFA) process or through negotiations toward a Bilateral Trade Agreement (BTA). The Taiwan government recently moved to relieve a longstanding irritant in the trade relationship when it changed certain import restrictions on American beef and pork products. Taking effect January 1, 2021, these changes were long requested by the United States, and should further improve the bilateral trade environment.

In the healthcare field, Taiwan has also shown its determination to enhance trade and investment conditions by implementing a Patent Linkage system for pharmaceuticals. Modeled after the U.S. Orange Book process, the enabling legislation was enacted in December 2017 and the new system came into force in August 2019. This puts an end to an issue that had been on the bilateral trade agenda for more than a decade.

In line with this atmosphere of cooperation and goodwill, the US-Taiwan Business Council looks forward to bilateral trade negotiations that will enable further progress in resolving outstanding healthcare-related issues. This position paper will examine outstanding matters in the pharmaceuticals and medical device industries, reflecting the concerns of U.S. businesses with interests in Taiwan. It will also look at potential opportunities for additional bilateral cooperation in new, value-added healthcare fields such as digital and remote healthcare, which have grown tremendously in the wake of the COVID-19 pandemic.

¹ “Industrial Economic Statistics Newsletter 369,” *Taiwan Ministry of Economic Affairs*, November 5, 2020, https://www.moea.gov.tw/MNS/DOS/Publish/wHandPublish_File.ashx?pub_id=1685.

² “Taiwan Commercial Guide,” *U.S. Department of Commerce*, November 8, 2019, <https://www.export.gov/apex/article?id=Taiwan-Medical-Devices>.

TAIWAN HEALTHCARE POLICIES

Pharmaceuticals

The Taiwan government's focus on healthcare cost containment keeps Taiwan's patients from receiving the latest treatments and vaccines compared to other developed economies. The Taiwan government's slow approval process for new drugs, new indications, and reimbursement increases the timeline for new drug availability for patients in Taiwan an average of 20 times that of Japan. Streamlining the approval and reimbursement timelines would dramatically increase Taiwan patients' access to new medicines, and would significantly increase Taiwan's profile as a destination for clinical research and investment in innovative pharmaceuticals.

As a corollary consequence, the Taiwan NHIA also attempts to contain costs by issuing arbitrary guidance on the use of certain high-cost drugs. This effectively caps their usage irrespective of global clinical guidelines, label instructions, or a physician's determination of effective treatment options. According to industry experts, the NHIA's guidance criteria can be subjective because they can differ from extensive scientific evidence supporting the use of the product, as approved on the Prescribing Information.

While this situation has obvious implications for patient care, it also has consequences for Taiwan's role in clinical research. With access to 25 years of patient population data and a high integration of information and communications technology into its network, Taiwan's healthcare system is well suited for clinical trials of new drugs. Yet the global standard of care, particularly in oncology, has become increasingly unified globally. When Taiwan adopts its own unique guidelines to regulating drug usage, guidelines that do not conform with global standards, that excludes its patients as a statistically relevant population for future clinical studies. The ultimate result is a series of losses for key stakeholders in Taiwan – including patients, industry, and clinicians – preventing them from accessing new medical technologies.

To ensure that Taiwan patients have access new drugs within a similar timeframe as their counterparts in other countries, Taiwan needs to adopt a transparent and science-based standard of treatment that does not overly focus on cost containment. The relevant authorities in the Taiwan government should reach out to industry to establish a joint government-industry working group to plan and review the new drug/new indication budget, as well as the newly implemented Horizon Scanning methodology. Such collaboration will enable the NHIA to identify trends in innovative health technology, and to thereby generate more accurate forecasts for expenditures. Furthermore, the NHIA should plan for substantial growth rates for the new drug/new indications budgets on top of the Global Budget, to enable better access to more advanced treatments and pharmaceuticals.

Moreover, the implementation of the Managed Entry Agreement (MEA) for new drugs/indications needs to be improved. A more predictable, transparent, and sustainable reimbursement system will allow industry participants to better forecast their markets, allowing for greater market participation.

Another issue facing the pharmaceutical industry in Taiwan is the erosion of value in medicines due to the introduction price adjustment mechanisms. In 2013, Taiwan introduced its pilot Drug Expenditure Target (DET) price-adjustment mechanism as a means of re-pricing pharmaceutical products previously approved for reimbursement. This mechanism was an improvement over earlier methods, and the government decided to extend the pilot project through 2021.

However, the current DET methodology needs revision to ensure that innovation can be better rewarded. For example, the DET budgets established at the beginning of the year consistently fall short of actual expenditures. This results in pricing claw-backs that have caused pharmaceutical firms to remove high-value products from the market.

As 2021 will be the last year for the pilot DET, the Ministry of Health and Welfare plans to review the DET methodology and collect suggestions from stakeholders on how a 2022 price cut would be handled under a new round of DET. The US-Taiwan Business Council recommends that the MOHW set the DET baseline in accordance with the actual expenditure from the previous year, rather than at the targeted amount. Recalibrating the baseline will help build a sound DET mechanism to reflect actual drug expenditures, and would prevent cumulatively larger deviations from the real situation year over year.

Also, under DET rules, as soon as a product goes off-patent, it is immediately subject to significant price cuts, regardless of whether a generic competitor exists on the market. This results in significant loss of value to a product, and adversely impacts the competitiveness of the market. A related issue is the narrow definition of patents recognized by the NHIA. Unlike many advanced nations which recognize patents for formulation, manufacturing process, crystal form, and drug combination, the NHIA only recognizes substance/product patents. This prevents international pharmaceutical companies from extending patent protection in Taiwan, and may deter them from continuing to offer their products on the market once the original patent expires.

The Council also recommends that price cuts on off-patent drugs be triggered by the first generic entry, rather than the date when the product went off-patent. Further, for single-sourced products in which the major compound is off-patent or never had a registered patent in Taiwan – and the product is the only source available in this market with no generic substitute – U.S. companies in the industry suggest that the MOHW establish a sound Reasonable-zone (R-zone) mechanism of 15% as a buffer against the impact of price cuts. An R-zone mechanism sets a maximum price reduction for drugs in the single-source category, and without it these drugs would likely be withdrawn from the market far earlier than other drugs, to the detriment of patients' access and care.

Taiwan has an unfortunate track record of steep and sudden price cuts that create uncertainty in the market. Avoiding such price cuts would help ensure the sustained operations and growth of the pharmaceutical industry, and would improve the predictability and transparency of the investment environment in Taiwan.

Medical Devices

U.S. companies face an uneven playing field in introducing their products to the Taiwan market due to changes in how the Taiwan Food and Drug Administration (TFDA) regulates the manufacture and sale of medical devices. Under Taiwan's Good Manufacturing System guidelines, the TFDA requires medical device manufacturers to undergo a Quality System Documentation (QSD) registration to ensure that the manufacturing facilities meet the set standards.

While the TFDA in theory may honor an Establishment Inspection Report (EIR) from the U.S. FDA as part of a simplified QSD registration, in practice the TFDA still requires that the physical manufacturing plant first be registered separately, followed by a registration of the specific products. This combination typically takes at least 9-12 months.

In addition, to qualify for a simplified QSD pathway application, TFDA requires that the EIRs being submitted must have been issued during the past three years. However, given that the U.S. FDA does not conduct facility inspections on a regular basis – instead using a risk-based approach – many U.S. products are unable to apply for the simplified QSD pathway. Meanwhile, European manufacturers benefit from a Technical Cooperation Program (TCP II) that enables them to enjoy the simplified QSD pathway, and thus allows them to compete more effectively in the Taiwan market.

Another issue of concern involves NHIA's plans to move over 2,000 medical devices from their current designation as self-pay into balanced billing coverage. Medical devices fall into three categories under Taiwan law: full coverage, in which the National Health Insurance (NHI) fully compensates for the cost of the device; balanced billing, in which the NHI covers 20 to 40% of the price; and self-pay, in which the consumer pays the full price. Consistent with the NHI's focus on cost-containment, the newest and most expensive devices tend to be among the 30% of the total medical devices on the market within the self-pay category.

Moving these medical devices into coverage by the NHI should be a boon to patients, but the NHIA's pricing mechanism may result in the unintended consequences of reducing choice in the market. This is due to the NHIA's plan to set a ceiling price for such balanced billing items, based on the median purchasing price paid by hospitals without the markup typically charged to the consumer under balanced billing.

This ceiling will result in markedly reduced prices for manufacturers, potentially resulting in products being pulled from the market. In line with revisions to Article 52-4 of the NHI Law in January 2020, the first item, transcatheter aortic valve implantations (TAVI), was moved from self-pay to balanced billing in August 2020 using the hospital median purchasing price to set the ceiling price.

A further challenge is the NHIA's plan to group products into "same function/same price" categories, without regard to the products' technological sophistication or efficacy. U.S. manufacturers see this as favoring local medical device makers, enabling them to sell less sophisticated products for the same prices as high-quality imports. This effectively creates a trade barrier.

To overcome these challenges, the Council recommends two courses of action. First, the TFDA should accept international Medical Device Standard Audit Program (MDSAP) reports as a substitute for EIRs. That would enable American companies in Taiwan to utilize the simplified QSD pathway, thereby leveling the playing field for U.S.-made medical devices. Otherwise, suppliers will increasingly choose European-made products due to their simplified pathway with the 11 EU Notified Bodies under the TCP II.

Instead of simply accepting MDSAP reports, Taiwan has sought to be included in the MDSAP agreement along with the U.S., Australia, Brazil, Canada, and Japan. But as MDSAP is a multilateral arrangement, increasing the membership is not something that is under the control of any one country.

To ensure that Taiwan remains an open and competitive market for the most advanced medical devices, NHIA should reduce the number of products moved from self-pay to balanced billing. Further, for those products that will be moved from self-pay into balanced billing, the NHIA should use the patient price, rather than the hospital median purchasing price, as the ceiling price.

Finally, the grouping of innovative and conventional devices using the “same function/same price” principle does not effectively distinguish among devices of differing levels of technological sophistication and effectiveness. The NHIA should adopt a more refined categorization system that accommodates these different levels into its pricing structure.

FUTURE OPPORTUNITIES FOR U.S.-TAIWAN HEALTHCARE COOPERATION

If the U.S. and Taiwan can move forward on some of these issues surrounding trade in pharmaceuticals and medical devices, they have an excellent opportunity to expand future cooperation in the healthcare sector. Healthcare was one of the key sectors under discussion during the inaugural meeting of the U.S.-Taiwan Economic Prosperity Partnership Dialogue (EPPD) in November 2020. The two sides have expanded their commitments to collaboration on science and technology issues, and plan to use these talks as a mechanism to enhance existing areas of economic cooperation while forging new ties. In August 2020, the U.S. and Taiwan also signed a Memorandum of Understanding (MOU) on health cooperation that formalized greater bilateral collaboration in areas such as global health security; digital health; research, prevention, and treatment of chronic disease; as well as drug and vaccine development.³

In particular, the digital and remote healthcare sector offers opportunities for growing U.S.-Taiwan collaboration. Digital healthcare is the deployment of digital technologies – Artificial Intelligence (AI), Big Data, machine learning, etc. – in the realm of healthcare, with the promise of providing more accurate diagnoses and more effective treatment. Already, AI is helping oncologists scan medical images for signs of cancer, while ingested sensors can send data on heart rate, diet, and exercise to a smartphone application.

Interest in remote healthcare has also grown due to the COVID-19 pandemic. Telemedicine allows doctors to see patients in their homes, minimizing hospital visits and reducing patient waiting time, which also reduces costs. Experts forecast that new digital technologies could also enable the distribution of medical resources more widely in underserved communities.

While the U.S. is already an obvious leader in digital innovation, Taiwan likewise brings several compelling advantages to digital and remote healthcare. The island is renowned for its prowess in semiconductors and information technology component manufacturing, and has been able to collect more than 20 years of medical data through the NHI. The current government prioritizes the development of digital technology industries through policy initiatives and programs throughout a large network of research centers, universities, and government ministries.

In August 2020, Taiwan's flagship telecom company Chunghwa Telecom signed an MOU with National Yang-Ming University and National Chiao Tung University to collaborate on strengthening medical innovation. In addition, the 5+2 Industrial Innovation policy - central to President Tsai Ing-wen's efforts to modernize Taiwan's economy - includes developing Taiwan into a center of excellence for biomedicine as one of its key goals. Taiwan's high education levels and relatively low salaries is an added attraction for U.S. investors in the sector.

Taiwan startups, many created by medical professionals and researchers, are leveraging Taiwan's strengths in digital technology into innovative products, services, and business models. For example, medical pathology diagnostic imaging startup aetherAI was founded by a physician, Joe Yeh, and uses AI in its diagnostic imaging technology that enables more accurate diagnoses.

³ "AIT and TECRO Sign Memorandum of Understanding on Health Cooperation," *American Institute in Taiwan*, August 10, 2020, <https://www.ait.org.tw/ait-and-tecro-sign-memorandum-of-understanding-on-health-cooperation/>

The use of computer assisted imaging software has been available for a decade, but aetherAI's opportunity to feed vast troves of NHI imaging data into its algorithm enables even greater accuracy.

While the NHI's pool of existing data offers an opportunity for Taiwan firms, data privacy rules limit its use to research centers and universities, where much of the exciting research in digital healthcare is being done. The Industrial Technology Research Institute, Taiwan's public/private research center, has developed a tool to help diagnose diabetic retinopathy – a common consequence of diabetes that can cause blindness - by incorporating 10,000 images of patients with the disease. The software can be installed in a smart funduscope – the scanning device used to diagnose retinopathy – and will enable ophthalmologists to diagnose the disease and prescribe treatment more easily.

National Yang-Ming University has also joined National Chiao Tung University and Academia Sinica to form the "Digital Medicine Alliance" to promote development and adoption of individualized, advanced precision medicine. Digital medicine falls within the broader digital healthcare sector, and involves ingestible sensors that can relate key diagnostic and monitoring data to physicians continuously and remotely. The alliance is developing remote diagnostic tools for patients at risk of stroke, Taiwan's fourth leading cause of death.

Collaboration between U.S. and Taiwan research institutes, universities, and companies is ongoing. Microsoft is teaming up with privately funded research organization Taiwan AI Labs to leverage data available on Microsoft's Azure cloud to develop precision medicine. This is a quickly developing field with many opportunities for cooperation between U.S. companies, Taiwan startups, and Taiwan research institutions. The Taiwan government should encourage domestic companies to collaborate with international partners in these emerging fields, focusing on innovation and quality.

CONCLUSIONS & RECOMMENDATIONS

Taiwan's healthcare system continues to earn global accolades for providing high-quality, accessible care to its citizens at affordable prices. This reputation is also being burnished by its exemplary and effective handling of the COVID-19 challenge starting in 2020.⁴ Despite Taiwan's exclusion from relevant international institutions such as the World Health Organization, its healthcare system has increasingly been recognized for the efficiency of the NHI program, its high-quality healthcare-related infrastructure, its technological innovation, and its affordability.⁵

Nearly 90% of Taiwan residents surveyed in 2019 expressed satisfaction with their healthcare.⁶ Ezekial Emanuel, a globally renowned Harvard-educated oncologist who helped develop the Affordable Care Act in the U.S., actually includes Taiwan as the answer to the question posed in the title of his new book: *Which Country Has the World's Best Healthcare?*⁷

Key to Taiwan's success in healthcare was the pioneering establishment of the single-payer NHI scheme in 1995. Since then, Taiwan has seen marked improvements in public health, with average life expectancy rising from 74.5 years in 1995 to 80.9 in 2019, and with infant mortality falling from 9 per thousand in 1995 to 3.6 per thousand in 2019.^{8 9}

Yet despite these advances, Taiwan seems to have plateaued. Infant mortality has not improved over the past few years and remains 33% higher than in South Korea (2.7 per thousand) and a whopping 176% higher than Hong Kong (1.26 per thousand).^{10 11} Taiwan likewise trails its neighbors in longevity.

The average Taiwan life expectancy in 2019 was 80.9, compared to 82.92 in South Korea, 84.43 in Japan, and 84.76 in Hong Kong.^{12 13 14} Taiwan's cancer mortality rate is also higher than its peers. In lung cancer, Taiwan's mortality rate in 2017 was 27.5, well above Japan's at 20.2 and South Korea's at 22.9.¹⁵

⁴ Zakaria, Fareed. "On GPS: Learning from Taiwan's Covid-19 Response," *CNN*, September 13, 2020, <https://edition.cnn.com/videos/tv/2020/09/13/exp-gps-0913-chen-on-taiwan-covid-response.cnn>

⁵ Taiwan Emerges as Pioneer in Strengthening Global Healthcare," *Bio Spectrum Asia*, December 21, 2020, <https://www.biospectrumasia.com/news/55/15136/taiwan-emerges-as-pioneer-in-strengthening-global-healthcare.html>

⁶ "Poll Finds Most Taiwanese Satisfied with NHI Service," *Taipei Times*, November 28, 2020, <http://www.taipetimes.com/News/taiwan/archives/2019/11/28/2003726623>

⁷ Oshinsky, David. "Health Care: The Best and the Rest," *The New York Review*, October 22, 2020, <https://www.nybooks.com/articles/2020/10/22/best-health-care/>

⁸ "Chinese People Live Longer! Average Life Expectancy is 80.9 Years Old and Hit a New High," *Ministry of the Interior*, August 5, 2020, https://www.moi.gov.tw/chi/chi_news/news_detail.aspx?type_code=02&sn=18453

⁹ "Taiwan Infant Mortality Rate 1950-2020," *Macrotrends*, <https://www.macrotrends.net/countries/TWN/taiwan/infant-mortality-rate>

¹⁰ Plecher, H. "South Korea: Infant Mortality from 2009-2019," *Statista*, October 20, 2020, <https://www.statista.com/statistics/939359/infant-mortality-in-south-korea/>

¹¹ "Hong Kong Infant Mortality Rate 1950-2020," *Macrotrends*, <https://www.macrotrends.net/countries/HKG/hong-kong/infant-mortality-rate/>

¹² "South Korea Life Expectancy 1950-2020," *Macrotrends*, <https://www.macrotrends.net/countries/KOR/south-korea/life-expectancy/>

¹³ "Life Expectancy for Japanese Men and Women Rises in 2019," *Nippon*, August 17, 2020, <https://www.nippon.com/en/japan-data/h00788/>

¹⁴ "Hong Kong Life Expectancy 1950-2020," *Macrotrends*, <https://www.macrotrends.net/countries/HKG/hong-kong/life-expectancy/>

¹⁵ "Global Burden of Disease 2017," *Institute for Health Metrics and Evaluation, University of Washington*, <http://ghdx.healthdata.org/gbd-2017>

Among the myriad factors contributing to these diverging outcomes, many healthcare experts point to Taiwan's overarching focus on cost containment instead of a focus on investment and reward for innovation. National healthcare expenditures in Taiwan equal 6.6% of GDP, compared to a 9-10% level for most developed nations.¹⁶ Its per capita healthcare spending came to only US\$1,697, less than half that of Britain, which has the lowest per capita healthcare expenditure among advanced European nations.¹⁷

Emanuel includes Taiwan at the top of his list of successful healthcare systems primarily for its low costs for consumers, particularly for pharmaceuticals. This focus on cost containment over investment, however, can lead to long delays in the introduction of innovative new drugs and indications to Taiwan, denying patients treatments that could lead to better outcomes and longer, better-quality lives. Further, certain policies adopted by Taiwan's government might amount to non-tariff trade barriers.

The US-Taiwan Business Council urges immediate resumption of the TIFA process and the start of negotiations toward a Bilateral Trade Agreement. The Council calls on the Office of the U.S. Trade Representative (USTR) to respond in kind to the unilateral moves that Taiwan has taken to liberalize its market and to remove some of the impediments to expanded bilateral trade. Negotiations on a U.S.-Taiwan Bilateral Trade Agreement would be the most effective way to tackle these and other remaining issues that have obstructed U.S. companies from gaining fully effective access to the Taiwan healthcare market.

The Council recommends expanded future bilateral cooperation in the healthcare sector – potentially focusing on the emerging fields of digital and remote healthcare. The U.S.-Taiwan economic relationship would be elevated to a new level of cooperation, and would help ensure mutual prosperity and an even more effective healthcare environment for the Taiwan populace.

¹⁶ "Insurance Statistics," *National Health Insurance Agency*, https://www.nhi.gov.tw/Content_List.aspx?n=BC0498EE81BDCBB6

¹⁷ Oshinsky, David, op.cit.