

Guide to Taiwan's health industries

September 2022



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This report has been compiled by Damian Gilhawley, a Director at PwC Taiwan, and it is based on a mix of desktop research and in-depth interviews with health sector stakeholders and academics. The information contained in the publication is up to date as of August 2022, unless otherwise stated.

Foreword

COVID-19 has considerably challenged health systems worldwide at a time when they are also having to adapt to ageing populations, changes in patient needs and advances in technology. Yet the pandemic has also helped expedite a number of changes which have the potential to reimagine healthcare. Taiwan is a case in point as it looks to build on its response to the pandemic crisis and accelerate transformation of its health ecosystem.

Taiwan is recognised as having one of the top performing health systems in Asia, underpinned by a single-payer national health insurance (NHI) programme which offers universal coverage with affordable and easy access to high-quality care. However, it faces increasing cost and resource pressures to meet the demands of a fast-ageing population. Thus, planning has started for a next-generation NHI to ensure its future sustainability.

Technology will play a key role in transforming the health system through delivery of better patient experiences, with improved outcomes at lower costs. Digital health is already attracting growing attention in Taiwan from firms operating at the intersection of medical science and technology, as well as encouraging alliances and partnerships between medical facilities and businesses involved in innovative areas such as AI, Big Data and IoT.

The government's current initiative to develop Taiwan's biomedical industry into an international hub for innovative biotech and medical R&D and a leader in precision health also offers significant bio investment and collaboration opportunities. Precision health has been targeted as one of six core strategic industries, with a focus on using AI technology and integrating Big Data analytics to create advanced solutions for the biomedical field.

This publication, which is a revised update of the previous 2020 edition, serves as a comprehensive introductory guide to Taiwan's health industries. It provides a compact but detailed analysis of the healthcare system, as well as the biotechnology, pharmaceutical and medical device sectors. It also covers the challenges and opportunities that are expected to influence the current status and future prospects of the health industries market.

PwC Taiwan's health industries practice focuses on the healthcare, pharmaceutical and life science areas. Our experienced professionals, backed by the expertise and resources of our global network, can provide comprehensive advice and solutions to health-focused businesses and organisations. If you need more information or have questions about Taiwan's health industries market and how PwC can be of help, please don't hesitate to contact us.

We hope you will find this guide a useful resource for exploring Taiwan's health industries, and we look forward to being of assistance in the future.



Lily Wong
Health Industries Advisory Leader
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Executive summary

Taiwan's healthcare system

Key features

- Taiwan has a high-performing healthcare system that is internationally recognised for its universal health insurance coverage and the delivery of high-quality, affordable medical treatment and care.
- The government-run, single-payer national health insurance (NHI) scheme provides patients easy access to a large network of contracted hospitals and clinics, most of which are privately owned.
- NHI benefits are comprehensive and uniform, with all medically necessary services covered, and patients face few limits on their choice of provider or doctor, as there is no strict referral system.
- With patients enjoying universal access to high-quality healthcare services and abundant medical facilities, low out-of-pocket costs and short waiting times, public satisfaction with the NHI is high.
- Health expenditure represented 6.7% of GDP in 2020, lower than the OECD average of 8.8%, with the NHI accounting for 53% of all spending, followed by household out-of-pocket spending at 31%.
- The low GDP spend reflects the monopsony power of the government, as the single buyer of and payer for healthcare services, to control expenditures, as well as low-cost administrative efficiency.

Main challenges

- A major challenge for Taiwan's healthcare system is the NHI's 'all-you-can-eat' provisions and weak constraints on demand or supply, which encourages overuse and wastage of medical resources.
- Patients seeking treatment for minor ailments are a key factor behind overcrowding at many hospitals, resulting in poor working conditions for doctors and nurses that in turn is causing retention problems.
- Due to underfunding and fiscal constraints, the adoption of cost-containment measures has led to challenges in balancing costs and medical care, and impacted patient access to innovative drugs.
- Higher costs associated with an ageing population and growth in chronic disease cases will further strain the resources of the healthcare and long-term care systems and impact the NHI's finances.
- The government has already taken steps to address some of these issues, such as curbing costs and reducing waste, but further and deeper reforms will be needed to ensure the NHI's sustainability.
- Healthcare reform is a sensitive topic in Taiwan, so any major changes will be a protracted process. Planning has already begun for a next-generation NHI and will take a number of years to complete.

Taiwan's biomedical industry

- The biomedical industry (including applied biotechnology, pharmaceuticals and medical devices) is a priority policy focus for the Taiwan government under its six core strategic industries initiative.
- A long period of investment has produced a solid foundation, with an ecosystem spanning the entire biomedical value chain, from research, discovery and development to manufacturing and marketing.
- Total industry revenue (excluding exports) amounted to US\$19.9bn in 2021, with the pharmaceutical sector representing the largest share at 43%, followed by medical devices (34%) and biotech (23%).

Biotechnology sector

- Strong policy support has been a key contributory factor to the growth of Taiwan's biotechnology sector, which has almost doubled in market size over the past decade to reach US\$5bn in 2021.
- Clinical research capacity has progressed rapidly, supported by abundant talent, good research infrastructures, ample clinical trials experience, and cost-competitive R&D and manufacturing.
- Growth momentum remains strong, supported by the continued promotion of innovative biomedical R&D, a robust biotech IPO market and the maturation of company pipelines and service offerings.

Pharmaceutical sector

- High pharmaceutical per capita spending and a robust medical infrastructure supports the market growth of pharmaceutical drugs in Taiwan, with the domestic market reaching US\$8.6bn in 2021.
- The tight-budgeted hospital market accounts for 80% of total drug sales, which limits profits for drug-makers, and this is further compounded by a long reimbursement timeline and annual price reviews.
- Demographic and epidemiological trends will drive up future demand for medicines, but the continued use of drug-price controls to contain healthcare spending will limit rates of increase in market value.

Medical device sector

- A rapidly ageing population and related higher demand for healthcare products and services has supported growth in Taiwan's medical device sector, with domestic sales of US\$6.7bn in 2021.
- Imports account for 60% of domestic demand, mostly for high-end devices used in hospitals, while local companies rely on exports of mid-to-low-end medical equipment for 60% of their revenues.
- The new Medical Device Management Act, which took effect in May 2021, will support regulatory efficiency and innovation, as the government looks to move the sector up the value-added chain.



Healthcare system

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Healthcare in Taiwan

Taiwan has one of the top healthcare systems in the world, according to a number of international healthcare index rankings. The main reason is its National Health Insurance (NHI) scheme, which provides universal and affordable health coverage and care to all citizens and residents. With patients enjoying easy access to a comprehensive range of subsidised and high-quality medical services, and facing few limits on their choice of healthcare provider or doctor, the level of public satisfaction with the NHI is consistently high at about 80%-90%.

Some of the very best features of Taiwan's healthcare system were on display during the COVID-19 pandemic crisis in 2020-2022. The virus outbreak had a much more moderate impact in Taiwan than in other areas across the world due in large part to the experience and capabilities of the local health sector. Besides taking advantage of the lessons learnt from the 2003 outbreak of SARS, Taiwan's early response to COVID-19 was made possible through integrating innovative health information technology and a robust healthcare infrastructure.

Its many achievements notwithstanding, the NHI, like many other healthcare systems around the world, has encountered myriad challenges over the years, including serious financial deficits. The government has managed those issues through successive policy adjustments and reforms, most notably the launch of a second-generation NHI in 2013. However, the NHI still faces several critical challenges, as reflected by the recent return of deficits, which will necessitate further substantive reforms in order to secure its longer-term viability.

The main structural issue is the 'all-you-can-eat' provisions of the NHI system and relatively weak constraints on demand or supply, which leads to overuse and wastage of resources. For instance, the lack of a gatekeeper referral system enables easy access to care, with per capita outpatient visits twice the OECD average. Also, widespread overprescribing is common since prevailing fee-for-service reimbursement mechanisms and lack of proper prescribing and dispensing separation enables providers to profit from patient treatment.

A rapidly ageing population and growth in chronic diseases, together with rising costs of new health technologies and surgical advances, are putting an additional strain on the healthcare system. With Taiwan forecast to become a super-aged society by 2025, healthcare spending on the elderly will grow sharply in the coming years. Besides driving the NHI's costs higher, an ageing population will also lead to a shrinking workforce and a reduced premium base, which will in turn exacerbate the long-term sustainability issues facing the system.

The government is already taking steps to address some of these challenges, such as the launch of an initiative in 2018 to reduce the total number of outpatients at large hospitals by 2% annually until a 10% reduction has been achieved in five years, and greater use of cloud data-sharing systems to reduce waste. Further and deeper reforms will be needed over the longer term as demographic and epidemiological trends add growing pressure on the NHI's finances. However, any major policy changes will most likely be a protracted process.

The health ministry confirmed as much in 2017, when it said that planning had begun for a third-generation NHI and would take about 6-8 years to complete. Meanwhile, insurance premium rates were raised in 2021 to bolster the NHI's revenues. Controlling costs and waste also remains a priority, with provider and patient behaviours scrutinised more closely, and the likely imposition of further constraints such as through higher co-payments. Moreover, efforts to shift some of the burden of primary care away from big hospitals will continue.

The rest of this chapter will look more closely at the key elements of Taiwan's healthcare system—including its regulatory framework, delivery infrastructure and workforce, patient demand and resource utilisation, and healthcare expenditure and financing trends—and analyse the challenges facing the government as it plans and prepares to revamp the NHI for a long-term sustainable future.

Regulatory framework

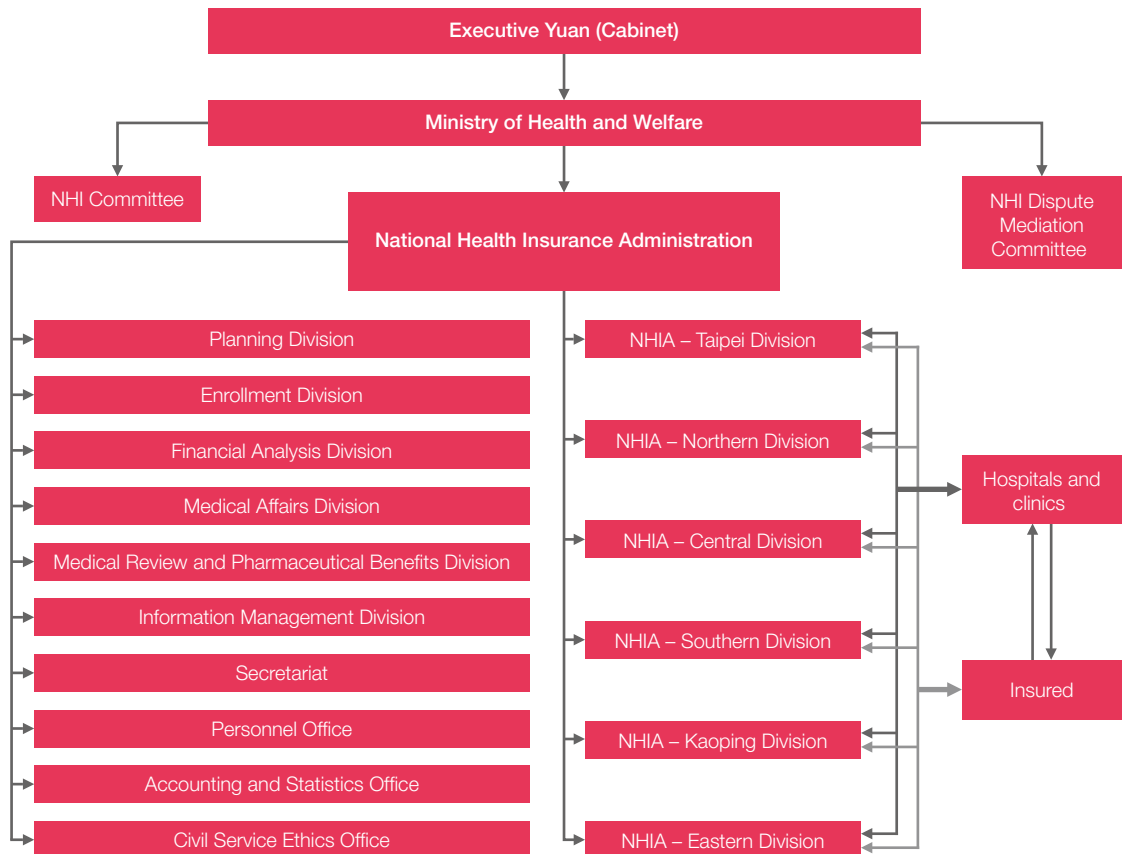
The Ministry of Health and Welfare (MOHW) is the principal regulatory authority for health and social welfare matters in Taiwan, and its mission is to promote the health and well-being of all citizens. The ministry is responsible for health promotion, disease prevention and control, food safety and drug management, medical care, social insurance, social welfare, social assistance and protective services. It also administers the operations of 26 public hospitals and 13 social welfare institutions.

Taiwan has a two-level administrative structure of healthcare governance. At the central level, the MOHW is the responsible body for overall health administration, including policy development and regulations, and the guidance, supervision and coordination of regional health bureaus. At the local level, each of Taiwan's municipal, city and county governments operate public health bureaus, which are responsible for managing health and medical care matters within their respective jurisdictions.

The MOHW has six affiliated agencies that look after different areas of health and social welfare: the Centers for Disease Control; Food and Drug Administration; Health Promotion Administration; National Health Insurance Administration (NHIA); National Research Institute of Chinese Medicine; and the Social and Family Affairs Administration. The NHIA is in charge of the compulsory national health insurance programme, known as the NHI, which provides universal coverage to all residents.

The MOHW closely supervises all NHI initiatives and policies. Its NHI Committee helps plan and monitor NHI tasks, and its NHI Dispute Mediation Committee handles disputes concerning health insurance. As a single-payer insurer, the NHIA bears responsibility for the operations of the NHI, healthcare quality and information management, research and development, and human resource training. Administrative funding is provided by the central government through a budgetary process.

Figure 1: Organisation of the NHI system in Taiwan



Source: The Commonwealth Fund, 2020 International Profiles of Health Care Systems.

Healthcare delivery infrastructure

Providing equal access to healthcare services is a foundational pillar of Taiwan's NHI programme, and so patients have complete freedom of choice among different healthcare providers. They also enjoy easy access to doctors, including hospital-based specialists, as there is no requirement to register with a primary care physician. The NHIA ensures that access by maintaining an extensive network of contracted care providers, which is a mixture of public and private hospitals and clinics, dentists, pharmacies and other health facilities.

In general, the provider licensing by local health authorities and hospital accreditation by the Joint Commission of Taiwan are trusted to assure an acceptable standard of care, and serve as the basis for contracting with the NHIA. Based on accreditation standards, medical care institutions are classified as medical centres (more than 500 beds), regional hospitals (250-500 beds), district hospitals (20-249 beds), and basic-level clinics. Also, medical treatment and care is divided into Western and traditional Chinese medicine (TCM).

Figure 2: Status of medical institutions in Taiwan, 2020-2021

Medical care institutions (2021)	23,278	Other medical institutions	4,604
Hospitals	478	Midwifery practices	24
Clinics	22,800	Medical laboratories	359
Pharmacies	8,234	Medical radiological institutions	49
Pharmacies	8,234	Physical therapy practices	352
Home care practices	1,587	Occupational therapy practices	128
General nursing homes	553	Denture clinics	29
Psychiatric nursing homes	47	Mental counselling clinics	121
Home care practices	708	Psychotherapy clinics	74
Post-natal nursing institutions	279	Speech therapy centres	76
Blood donation institutions	18	Dental technology centres	941
Blood donation centres	5	Hearing centres	23
Blood donation stations	13	Home respiratory care practices	8
Pathology institutions	10	Optometry practices	2,389
Pathology institutions	10	Nutrition advisory organisations	31

Source: Ministry of Health and Welfare

Note: The data on hospitals and clinics is for 2021 and all other data is for 2020.

Hospitals and clinics

In 2021, Taiwan had a total of 23,278 medical care institutions, which consisted of 478 hospitals and 22,800 clinics, the vast majority of which were contracted with the NHIA (see Table 1 below). Most of the hospitals (83%) and an even greater proportion of the health clinics (98%) are privately owned, and many are small. Western medicine is the predominant form of treatment, representing 53% of all registered care providers, followed by dentistry clinics (30%) and TCM institutions (17%).

The closure or mergers of small hospitals has seen the total number of hospitals drop from 669 in 2000 to 478 in 2021. District hospitals in particular have struggled to survive in the face of increasing competition from the larger and better-resourced regional hospitals and medical centres. Existing facilities have grown in size and opened more beds in a bid to boost efficiency and revenues—the total number of hospital beds increased from 114,179 in 2000 to 138,442 in 2021. Taiwan currently has 5.9 hospital beds per 1,000 population, above the OECD 2019 average of 4.4, with two-thirds of all beds owned by privately-operated health facilities.

As for primary care clinics, their total number grew from 17,413 in 2000 to 22,800 in 2021, consisting of 11,835 Western medicine clinics, 6,922 dental clinics and 4,043 TCM clinics. The rise has been boosted, in part, by more cosmetic and aesthetic medicine clinics, and the government's efforts to reduce patient reliance on hospitals for provision of primary care services. Around 40% of Taiwan's doctors work as private practitioners in their own clinics, and 80%-90% of clinics are solo practices.

As Taiwan's public health infrastructure was not capable of meeting the jump in demand triggered by the launch of the NHI in 1995, the programme was designed from the start to attract non-public investment. Private hospitals currently outnumber public facilities by more than five to one. Many are organised as foundations in order to enjoy the tax benefits afforded not-for-profit medical institutions. And yet most of them behave as if they were for-profit, as reflected in their annual financial reports.

In 2020, 86.3% of medical institutions that claimed more than NT\$200m (US\$7m) in reimbursements from the NHI reported a profit. In general, hospitals generate revenue from reimbursement payments, co-pays and registration fees, and proceeds from sales of services and devices not covered by the NHI. Many also depend on non-healthcare income (such as from food courts, convenience stores and parking lots) to balance fiscal gaps from shrinking NHI reimbursements for services performed. As a result, hospitals are under increasing pressure to be more efficient, to compete for patient volume, and to provide more services with higher margins.

This heightened competition for patients creates a supply-induced demand for medical care services under the predominantly fee-for-service payment system, and is a major contributory factor to the high utilisation of healthcare resources in Taiwan. However, weak constraints on service demand or supply, provider reimbursement mechanisms, and the ability of hospitals to gain profit from the sale of drugs and other services all serve to encourage overtreatment, which is a driver of NHI spending.

Table 1: Number of NHI-contracted hospitals and clinics, 2021

	Total	Western medicine hospitals	Chinese medicine hospitals	Dental hospitals	Western medicine clinics	Chinese medicine clinics	Dental clinics
Medical care institutions	23,278	473	4	1	11,835	4,043	6,922
Contracted hospitals and clinics	21,679	469	4	1	10,591	3,820	6,794
% of contracted health facilities	93.1	99.2	100.0	100.0	89.5	94.5	98.2

Source: Ministry of Health and Welfare and National Health Insurance Administration.

Figure 3: Number of hospitals and hospital beds in Taiwan, 2001-2021

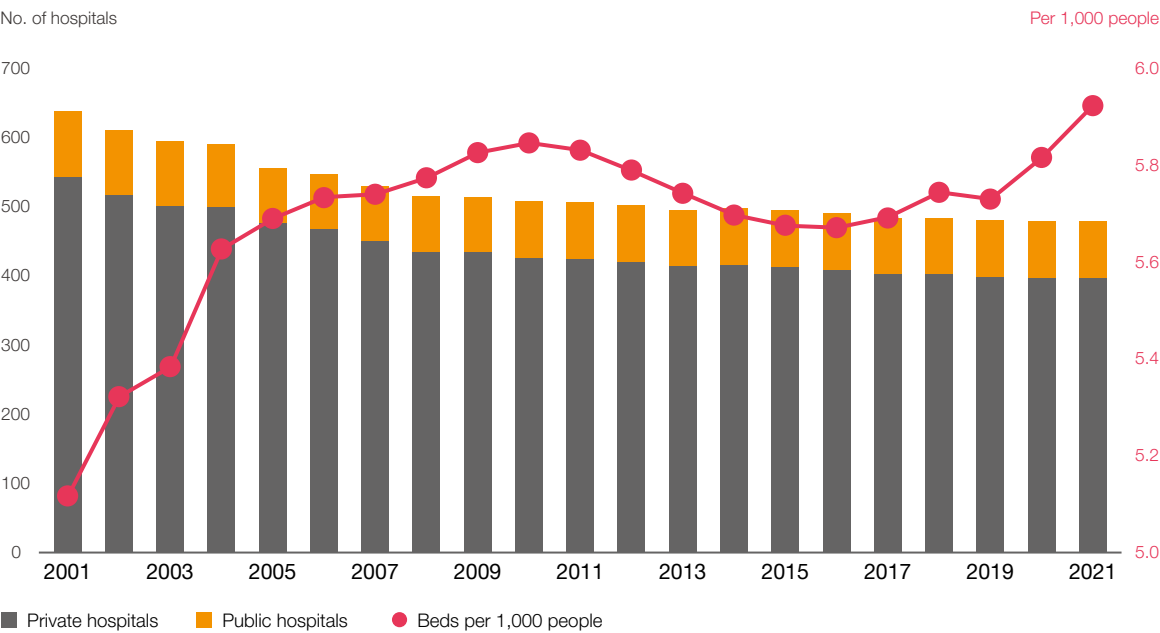
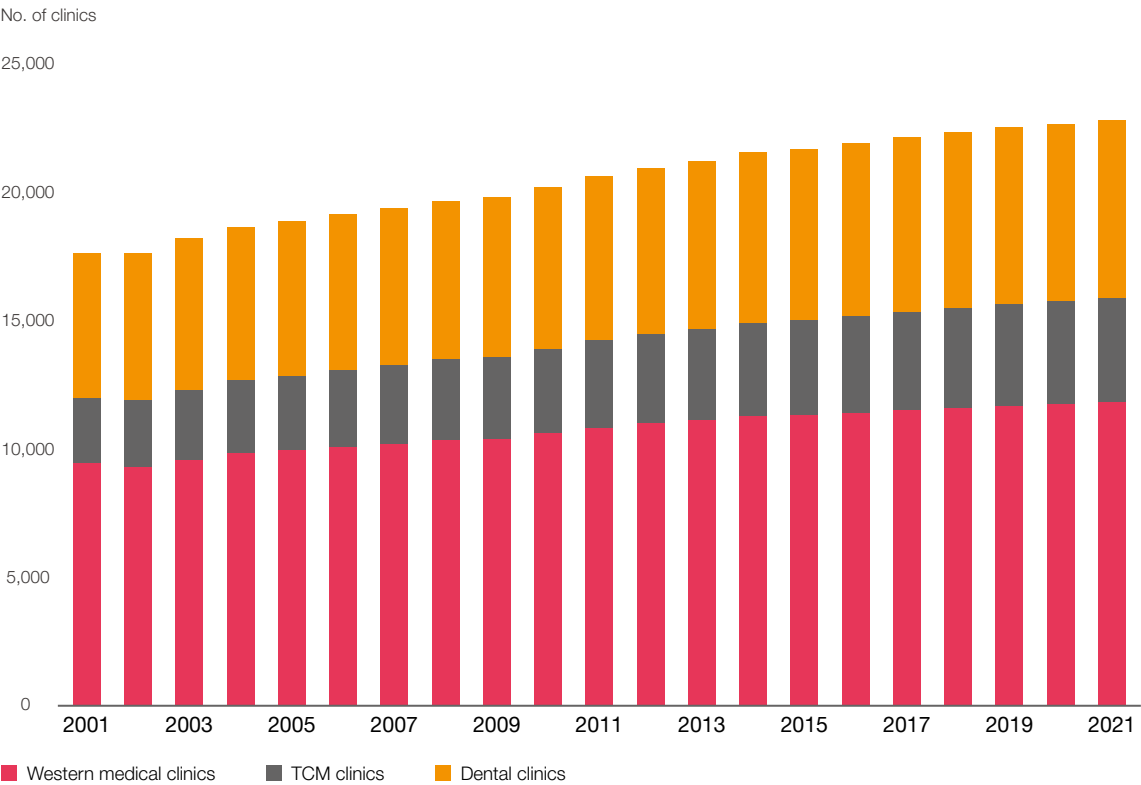


Figure 4: Number of primary care clinics in Taiwan, 2001-2021



Doctors and nurses

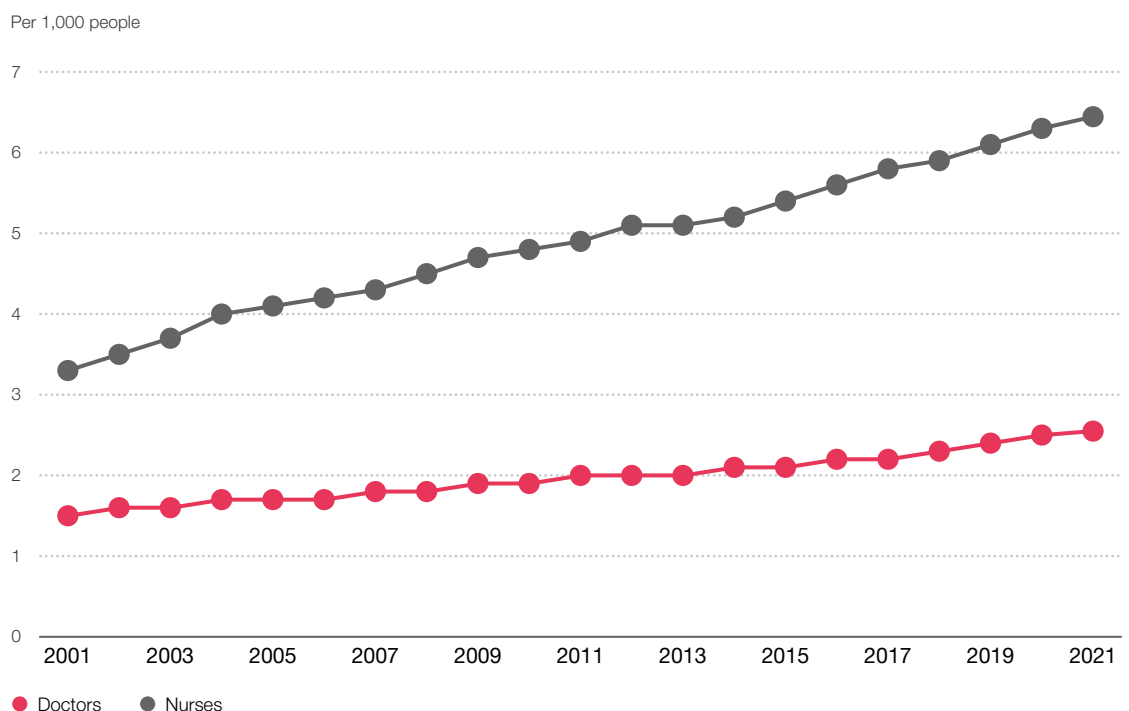
Medical workers, in particular doctors and nurses, are the cornerstone of healthcare systems. In 2021, Taiwan had 59,591 doctors (both Western and TCM) and 150,645 nurses, or 2.5 doctors and 6.4 nurses per 1,000 population, which are both lower than the respective OECD 2019 averages of 3.6 and 8.8. That's partly because the population of medical personnel is controlled by government quotas, with medical school enrolments restricted to 1,300 students a year. Also, medical personnel shortages have become an issue in recent years.

Some 40% of Taiwan's doctors practice in their own primary care clinics and the rest work in hospitals as employees. Hospital-based physicians in all specialties also see patients on an outpatient basis. There is no shortage of registered doctors per se, but rather in certain specialties due to stressful working conditions or where the rewards don't commensurate the workload, for example in emergency care, surgery and geriatrics. To help prevent occupational burnout, resident doctors are now covered by the Labour Standards Act, since 2019, which restricts the hours that they can work.

While the overall number of registered nurses is increasing, it's still not enough to meet the growing healthcare demands of an ageing population, especially in rural and remote regions. Additionally, an increasing number of nurses are leaving the profession due to long hours, low wages and stressful working conditions. In an effort to improve the workplace environment for nurses, the MOHW has in recent years implemented various reforms aimed at facilitating retention and encouraging nurses who left their professional field to return.

Medical personnel shortages in Taiwan have largely been brought about by the design of the NHI scheme—and in particular by the global budget system, which caps reimbursement levels for medical services. To contain costs, some providers have opted to increase the workloads of doctors, nurses and other medical staff. Coupled with relatively low levels of pay, the deterioration in working conditions at hospitals has resulted in shortages of doctors in key specialties as well as nurses. The MOHW continues working to address hospital staffing shortages and improve retention.

Figure 5: Number of doctors and nurses per capita in Taiwan, 2001-2021



Source: Ministry of Health and Welfare.

Health information technology

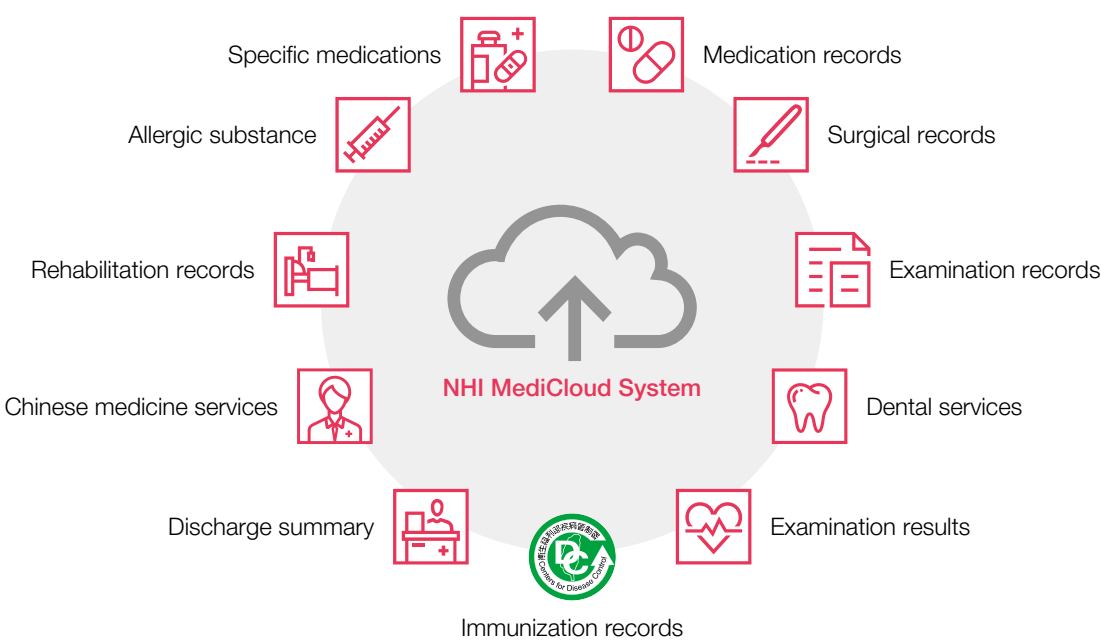
Taiwan’s health information technology system is more extensive than in many other countries and is used to assist administration, clinical care and public health. It is built around a credit-card-sized NHI smart card, which is issued to every insured enrollee to access medical care. The IC-embedded card is used to identify the individual, store a brief medical history and to bill the NHIA. The patient presents the card each time when using medical services, and the care provider will then submit a claim electronically for the case-related charges.

The patient’s health record is entirely electronic at every level of care. Contracted care providers are required to report to the NHIA, on a 24-hour basis, on each patient visit and service delivered, thus enabling the tracking of individual and aggregate service utilisation data in almost real time. This provides the NHIA with a good sense of healthcare expenditure at any point in time, and also helps it to identify and manage heavy users of services. The NHI’s claims data constitutes the largest repository of people’s health information in Taiwan.

This huge database has been put to new and innovative uses in recent years. For example, the NHIA has expanded its use of cloud-based data-sharing systems to reduce waste and improve the quality of medical care services. In particular, the NHI MediCloud system allows doctors to quickly retrieve a patient’s medical records from other hospitals and facilities to prevent any duplication of medications and tests. Also, My Health Bank is an electronic medical records repository that helps patients better manage their own personal health.

The NHIA has also opened up its data to enable the development of AI-based smart medical care. In 2019, it launched a pilot programme to allow researchers (including hospitals, universities or research institutes) to access NHI data to create AI and big data applications that facilitate medical treatments, healthcare management and disease prevention. Many successful AI applications have been adopted by hospitals, which will help improve the accuracy and quality of healthcare, and push forward smart and precision medicine in Taiwan.

Figure 6: NHI MediCloud system



Source: National Health Insurance Administration.

Taiwan's COVID-19 experience

Taiwan fared better than many other countries during the COVID-19 pandemic, notably without imposing any strict lockdown measures, but rather stringent border controls. Despite a major surge in COVID-19 infections after March 2022, the cases recorded in Taiwan are still low by global standards. At end-August 2022, some 5.3 million infections and 9,914 deaths had been reported since COVID began. Vaccinations started slowly but picked up pace, and now 87% of the population are double vaccinated and around 72% have had a booster.

Taiwan experienced several phases of the COVID crisis, with different outcomes for each. During the first 16 months of the pandemic in particular, from January 2020 to mid-May 2021, Taiwan sustained very few cases and deaths. This was largely the result of a set of actions that the government took early on, including the activation of a national contingency response plan that incorporated lessons learned from the 2003 SARS crisis, the imposition of strict border controls, and swift and effective contact tracing and quarantine measures.

The number of COVID-19 cases surged in May 2021 as community spread took hold in Taiwan. The government raised its emergency alert to level 3 (of four levels), which triggered a partial lockdown nationwide from mid-May to end-July 2021. This included the closure of all recreational establishments and schools, a ban on indoor dining, a mask-wearing mandate and social distancing. The situation quickly came under control and the alert was lowered to level 2 at the end of July 2021, though some level-3 measures were kept in place.

Life returned to some semblance of normality in the subsequent period through to early 2022, with few new cases of community transmission. The emergence of the more infectious Omicron variant, however, saw a sustained spike in domestic cases from end-March 2022 on, though the government didn't raise its alert level, citing the mild symptoms seen in cases and the high rate of vaccination. In April 2022, it signalled more comfort with "living with the virus" by dropping its zero-COVID policy and focusing on harm mitigation amid opening-up.

Aside from the widespread Omicron outbreak in 2022, Taiwan has generally been applauded for its management of the pandemic. Key contributory factors included political leadership, early action, a national Covid response plan, innovative health information technology, good resource allocation and a cooperative public. In particular, the breadth and timeliness of information provided by the NHI smart card and electronic health records system were key to Taiwan's technology-based approach to managing and containing the COVID-19 threat.

Examples of the NHIA's integration of resources across various domains and departments include the optimisation of the NHI MediCloud system, the development of an instant warning system, as well as comprehensive collection of TOCC information (travel history, occupation, contact history, cluster) of people seeking medical care to avoid gaps in containment measures. In addition, the NHI card was used to facilitate a mask rationing system, and the My Health Bank app was improved to allow users to access their vaccination and test results.

In addition, to accelerate the detection of telling signs of COVID-19 infection in chest X-rays, the NHIA collaborated with domestic research teams to develop AI-assisted diagnosis models to provide quick assessments to doctors on whether further treatment was needed to prevent the spread of COVID-19. Also, in order to maintain medical capacity, the MOHW expanded the use of telemedicine (medical services via the Internet) during the COVID-19 pandemic to cover people in isolation as part of Taiwan's response measures.

Healthcare demand and utilisation

Coupled with rising incomes and advances in medical care technologies, the NHI has brought substantive healthcare improvements to Taiwan’s population since its introduction in 1995. Health outcome measures compare favourably to most OECD countries with regards to life expectancy (80.9 years in 2021, up from 74.5 years in 1995) and infant mortality rates (3.6 per 1,000 live births in 2020, down from 6.5 in 1995). However, Taiwan has much lower fertility and birth rates, a situation which has persisted for decades and given rise to a higher rate of ageing than the OECD average.

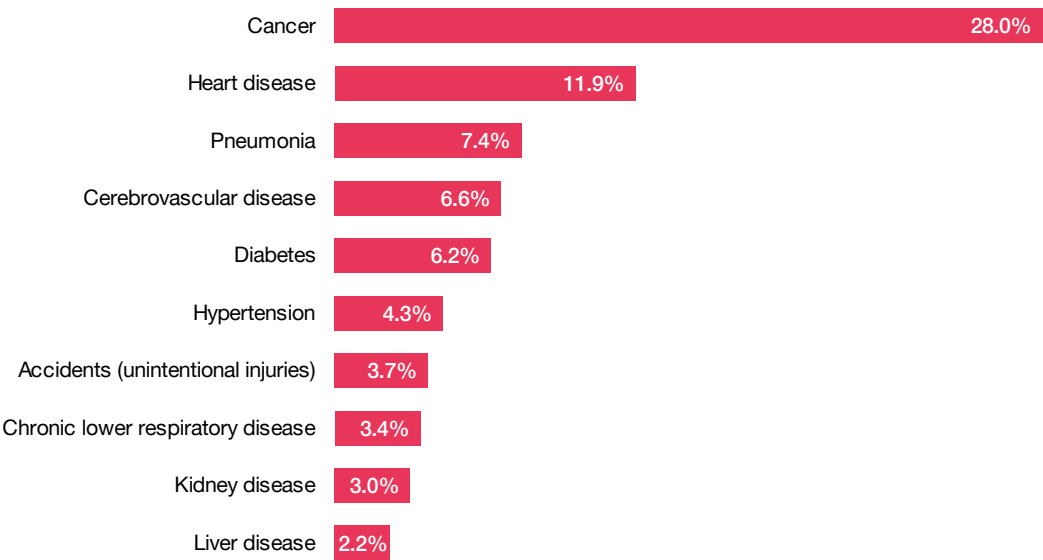
Major disease trends

National immunisation programmes have reduced the toll from infectious diseases, until the COVID outbreak, but non-communicable chronic diseases (NCDs) have become a growing health challenge in Taiwan. According to MOHW statistics, the top ten leading causes of death accounted for 76.6% of all deaths in 2021 and were primarily NCDs. Cancer was the main cause of death for the 40th year, accounting for 28.0% of all deaths, followed by heart disease (11.9%) and pneumonia (7.4%).

The medical journal, *The Lancet*, reported in 2018 that Taiwan had one of the world’s lowest mortality rates from NCDs among 30-70 year olds; just 17.6% of men and 9% of women of this age die from NCDS. All the same, the financial costs of treating chronic conditions are substantial. Acute and chronic kidney disease (affecting 445,000 patients) was Taiwan's most expensive illness in 2020, costing NT\$56.2bn (around US\$2bn) in NHI reimbursements. Taiwan has the highest incidence and prevalence of end-stage renal disease in the world, particularly among the elderly population.

The rising burden of chronic NCDs has serious implications for Taiwan’s healthcare system, in terms of both the growing utilisation of services and associated healthcare costs, and potentially higher demand for a larger healthcare workforce. Moreover, as demographic ageing is a key driver of the increasing prevalence of NCDs, the rapid expansion of Taiwan’s elderly population in the coming years (as detailed in the following section) will put more resource and cost pressure on an already strained healthcare system, and poses a major risk to the NHI’s longer-term sustainability.

Figure 7: Top ten leading causes of death in Taiwan, 2021



Source: Ministry of Health and Welfare.

Ageing demographics

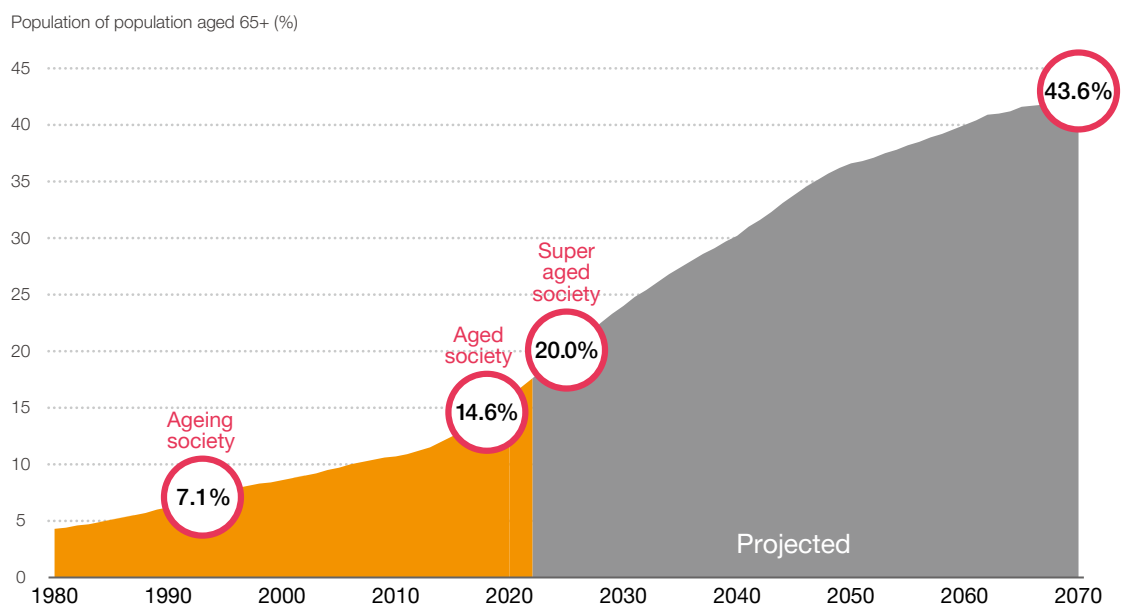
Taiwan's population of around 23 million people is ageing quickly due to a shrinking fertility rate (just 0.98 children per woman in 2021) and longer life expectancy. Government measures to encourage people to have more babies, such as stipends for new parents and more childcare benefits, have so far had little effect on raising the low birth rate. Taiwan's population shrank for the first time on record in 2020, when the demographic growth rate declined by 0.2%, and the population level fell again for a second straight year in 2021 by 0.8%.

Taiwan has one of the fastest-ageing populations in the world. It has gone very quickly through the stages of an ageing society (in 1993) and now an aged society (in 2018). The proportion of people aged 65 or older accounted for 16.9% of Taiwan's population in 2021, which means one out of every six people is a senior citizen, and the old-age dependency ratio was 23.8%. Current government estimates predict Taiwan's population will become a super-aged society in 2025 when the number of elderly people will exceed 20% of the population.

NHIA statistics show that the higher the age, the more spent per person on healthcare. The cost of hospitalisation for 50-64 years old is about twice that of the 35-49 age group, and the cost for those over 65 years of age is three times that of 35-49 years old. Total health spending on patients aged 65 and over currently accounts for about 40% of the NHI's annual expenditures. And with the size of Taiwan's senior population forecast to expand significantly over the coming years, spending on healthcare for the elderly will rise correspondingly.

In addition to pushing medical costs higher, a fast-greying demographic will also entail a smaller workforce and a reduced premium base, which will similarly threaten the long-term sustainability of Taiwan's healthcare system. At the same time, the long-term care of senior citizens has become a highly salient social, personal and political issue for Taiwan, and will continue to be so for future generations. This will necessitate the government having to increase expenditure on long-term care services and assistance for more elderly people.

Figure 8: Ageing population trend in Taiwan, 1980-2070



Source: National Development Council, Population Projections for Taiwan: 2022-2070.

Healthcare resource utilisation

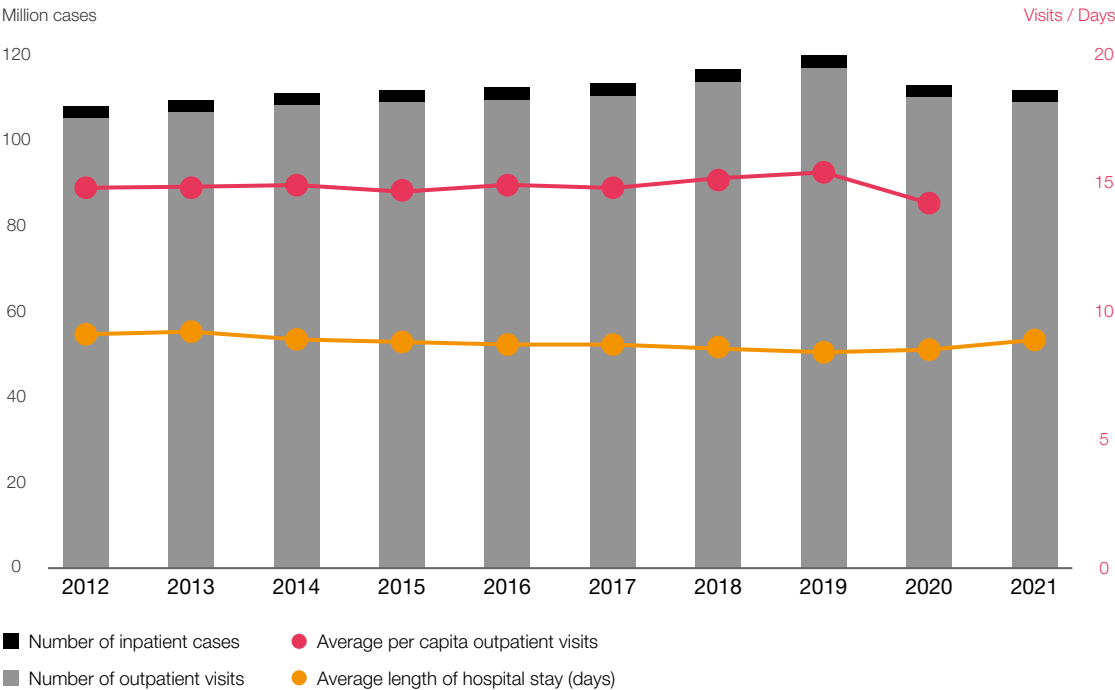
An ageing population and rising chronic disease prevalence are consistent drivers of demand for medical care services in Taiwan. Excessive use of healthcare resources is a problem, however, due to patients having relatively unrestricted access to care and low cost sharing. Hospitals provide both out- and in-patient services, and patients are free to choose specialists on an outpatient basis, with or without a referral. Coupled with the cultural belief by many in Taiwan that more healthcare is better, the demand side drives up utilisation of resources.

The pre-Covid annual number of outpatient visits to hospitals grew by 15.8% in 2010-2019, while the average outpatient visit rate per person per year increased from 14.3 to 15.4 times over the period, more than double the OECD 2019 average of 6.8 doctor consultations per person. The high visit rate can be attributed to easy patient accessibility to affordable care in Taiwan, as well as an ageing demographic profile, as older people typically use more medical care services and suffer from more serious chronic illnesses than other age groups.

As patients can visit any number of doctors without referral restrictions, this encourages doctor- and hospital-shopping, even for minor ailments. Locals generally trust the quality of medical care provided at hospitals more than clinics, and this had led to overcrowding issues in many hospital outpatient departments, particularly at the larger hospitals. While this accessibility is convenient for patients, the high volume of outpatient visit activity inevitably increases the workloads of doctors and limits the time that they consult with each patient.

As for inpatient care, the pre-Covid annual number of hospital cases rose by 14.0% during the 2010-2019 period, while the average length of stay declined from 9.2 to 8.4 days, though still higher than the OECD 2019 average of 7.6 days. The growth in inpatient numbers has been driven by a combination of several factors, including the lack of an effective patient referral mechanism (similar to the gatekeeper system in the UK) for specialist care and hospitalisation, more elderly and chronic cases, and insufficient facilities for long-term care.

Figure 9: Medical service volume of hospitals in Taiwan, 2012-2021



Source: Ministry of Health and Welfare and National Health Insurance Administration.
Note: The number of outpatient visits and inpatient cases both fell in 2020-21 due to COVID-19

Supply-induced demand for medical care is also an influential factor, as hospitals are incentivised to compete for patient and service volume in the outpatient setting, which is more profitable than the provision of inpatient services under the NHI's medical fee reimbursement system. Payments to hospitals accounted for 43.9% of all spending on personal healthcare in 2020, comprising 24.1% for outpatient care and 19.8% for inpatient care. This underlines the dominant role played by hospitals in the provision of outpatient as well as inpatient care.

Efforts to reduce the moral hazard behaviour of both patients and providers have been stepped up in recent years, with a view to shifting some of the burden of primary care away from hospitals to local clinics. These include measures designed to encourage more use of family physicians, partly through the imposition of higher co-pays on non-referrals to hospitals and specialist clinics. But opposition to changes that threaten patient choice is strong, while hospitals are reluctant to relinquish their hold on the lucrative outpatient care business.

The NHI system guarantees healthcare access to patients regardless of their financial means. But to optimise the use of resources and curb rising costs, all enrollees are required to co-pay for most services and medications, though some categories of patients are exempt from such payments. Co-pays include fixed fees for outpatient visits, which range from NT\$50 (about US\$2) at local clinics to NT\$550 (US\$18) at large hospitals, and 5%-30% of hospitalisation costs for inpatients, depending on the type of illness and the length of hospital stay.

Patient co-pay levels have been adjusted several times since the NHI's inception in 1995 in an effort to reduce moral hazard behaviour and improve patients' usage of healthcare resources. In March 2022, the NHIA announced proposed increases in patient co-pays for tests, prescription drugs and emergency treatment. Their implementation was postponed because of a Covid resurgence. The charge ceiling for patients with mild illnesses seeking emergency treatment at medical centre-level hospitals will rise from NT\$550 to NT\$800.

Table 2: NHI co-payments for outpatient visits

Institution class	Basic co-payments (NT\$)					
Type of institution	Western medicine Outpatient care		Emergency care Triage classification		Dental care	Traditional Chinese medicine
	With referral	Without referral	Grades 1 & 2	Grades 3 to 5		
Medical centres	170	420	450	550	50	50
Regional hospitals	100	240	300	300	50	50
District hospitals	50	80	150	150	50	50
Clinics	50	50	150	150	50	50

Source: National Health Insurance Administration.

Note: Proposed adjustments to emergency care co-pays, due to take effect on 15 May 2022, were postponed due to Covid-19.

Medical tourism promotion

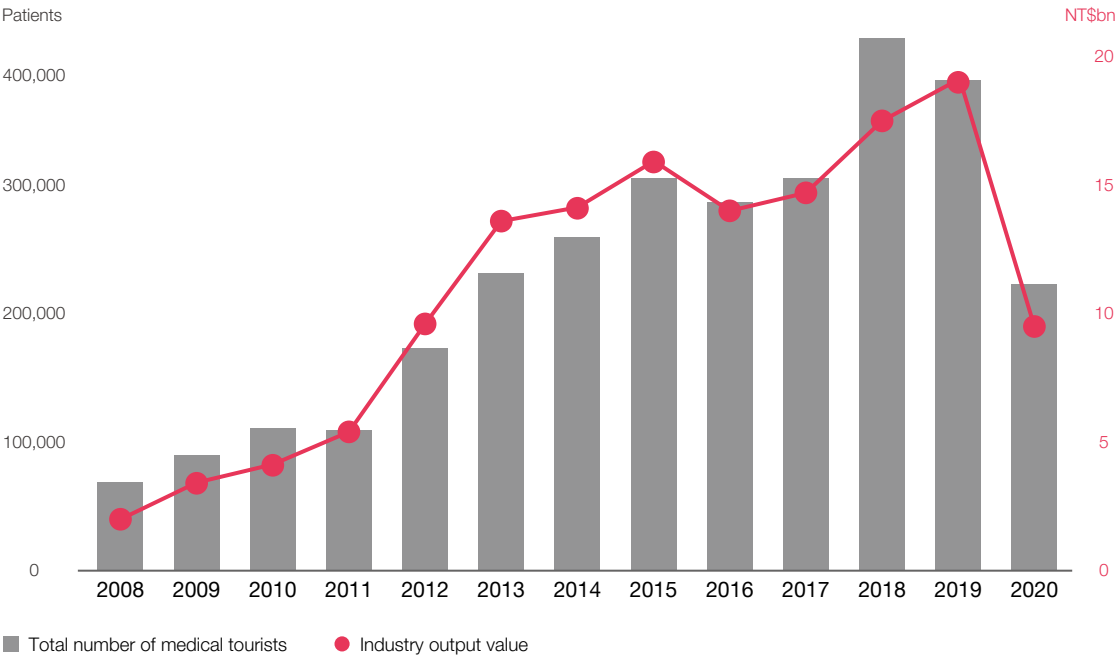
Another driver of demand for healthcare in Taiwan is medical tourism. Since 2007, the government has promoted the internationalisation of medical services as part of broader efforts to attract more tourists to Taiwan. Supported by the MOHW, the Taiwan Task Force on Medical Travel coordinates an alliance of 113 qualified hospitals and clinics to promote medical services to patients from all over the world. The focus is primarily on personalised healthcare services, including health check-ups, cosmetic surgery and serious disease treatment.

Taiwan has emerged as a favourable destination for medical tourism, due in part to its competitive costs. The quality of medical care in Taiwan is on a par with developed countries, but less expensive. For example, the cost of heart bypass surgery or a hip replacement in Taiwan is about one-fifth of similar procedures in the US. Its other advantages include an abundance of high-quality hospitals and doctors and sophisticated medical technology. As of June 2022, there were five facilities in Taiwan accredited by the Joint Commission International.

Taiwan’s medical tourism sector grew steadily in the years before the COVID pandemic. According to MOHW statistics, the number of medical visits to Taiwan jumped from 68,545 in 2008 to 381,496 in 2019, with the majority of the medical tourists coming from Southeast Asia (boosted in part by the government’s New Southbound Policy) and China, followed by visitors from the Americas and East Asia. The total output value of international medical services increased from NT\$2bn (about US\$70m) in 2008 to NT\$19bn (US\$680m) in 2019.

Taiwan closed its borders when COVID-19 started to spread globally in early 2020, bringing a halt to medical tourism. Foreigners were prohibited from entering Taiwan for international medical services, with the exception of special or emergency cases. As the local pandemic situation stabilised, Taiwan opened up in March 2022 to foreigners seeking fertility treatment due to its time-sensitive nature. The government has not yet determined when it will allow unrestricted entry to foreign visitors with non-urgent medical needs, as well as other tourists.

Figure 10: International healthcare promotion results, 2008-2020



Source: Ministry of Health and Welfare, 2021 Taiwan Health and Welfare Report.

Healthcare expenditure and financing

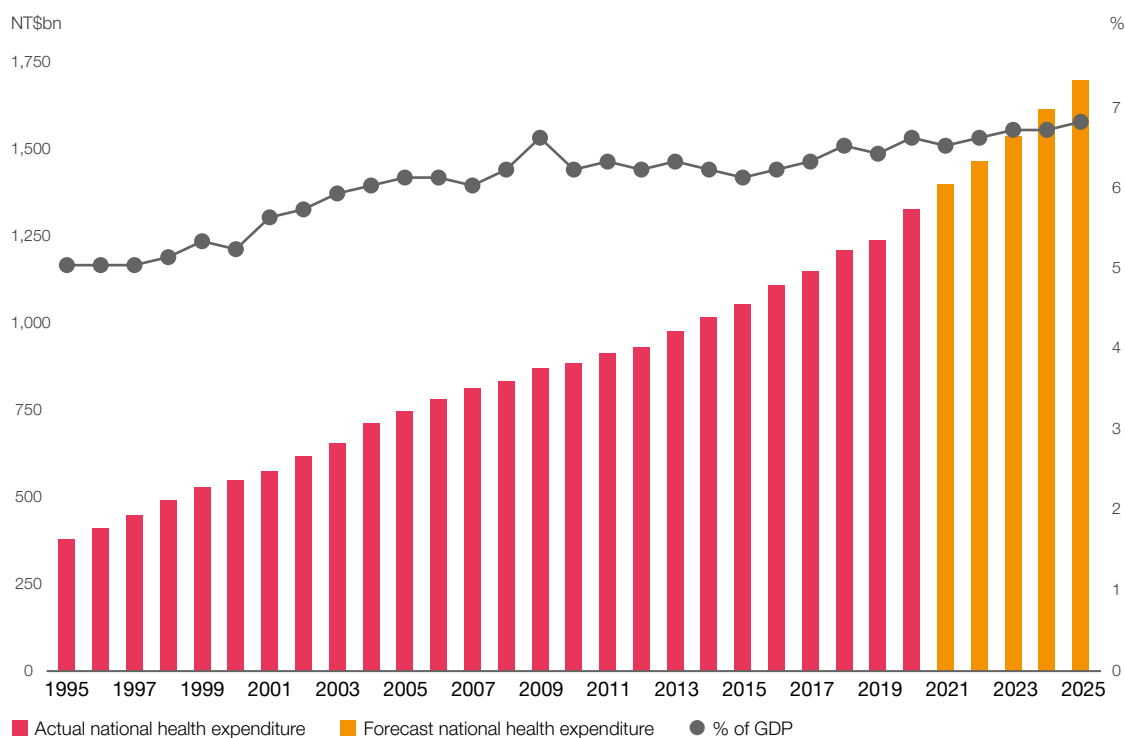
Spending on healthcare in Taiwan has increased steadily in nominal terms over the recent decades following the implementation of the NHI scheme. It expanded from NT\$379bn (US\$14bn) in 1995 to NT\$1,325bn (US\$47bn) in 2020, at a CAGR of 5.4%, and on a per capita basis from NT\$17,805 (US\$672) up to NT\$56,199 (US\$1,900). National health expenditure as a share of GDP rose from 5.1% to 6.7% over the same period, but it was still lower than in other advanced Asian economies such as Japan (11.0%) and South Korea (8.2%), and also below the OECD 2019 average of 8.8%.

A key reason for Taiwan's relatively low level of health spending is the monopsony power of the government, as the single buyer of and payer for healthcare services through the NHI, to set and regulate service fees, and impose a global budget system that caps total NHI expenditure. Another key contributory factor is the high administrative efficiency of the NHI's IT-driven system, which is characterised by administrative simplicity and low overheads. General administrative expenses took up just 2.1% of Taiwan's national health spending in 2020, which is among the lowest levels globally.

Taiwan's rapidly ageing population and a rising prevalence of chronic diseases will continue to push up healthcare spending as well as drive innovative solutions. Some cost-containment is inevitable, though the overall expenditure trend will continue on its upward trajectory. Research firm Fitch Solutions estimates national health expenditure will grow at a five-year CAGR of 5.1% to NT\$1,697bn (US\$61bn) by 2025, and at a ten-year CAGR of 5.3% to NT\$2,210bn (US\$79bn) by 2030. As a proportion of GDP, it will remain at between 6% and 7% over the full forecast period.

The public sector accounted for 60% of Taiwan's national health expenditure in 2020, with the NHI representing the majority at 53%. Enrolment in the NHI is mandatory for all residents in Taiwan, and it is primarily financed by insurance premiums paid by individuals and employers as well as from government subsidies. Despite universal access to subsidised healthcare provision through the NHI, patients have to co-pay for both out- and in-patient care. Cost-shifting to patients has seen out-of-pocket spending as a share of national health expenditure rise from 22% in 1995 to 31% in 2020.

Figure 11: Healthcare expenditure in Taiwan, 1995-2025



Source: Ministry of Health and Welfare (1995 to 2020) and Fitch Solutions forecast (2021 to 2025).

Health spending analysis

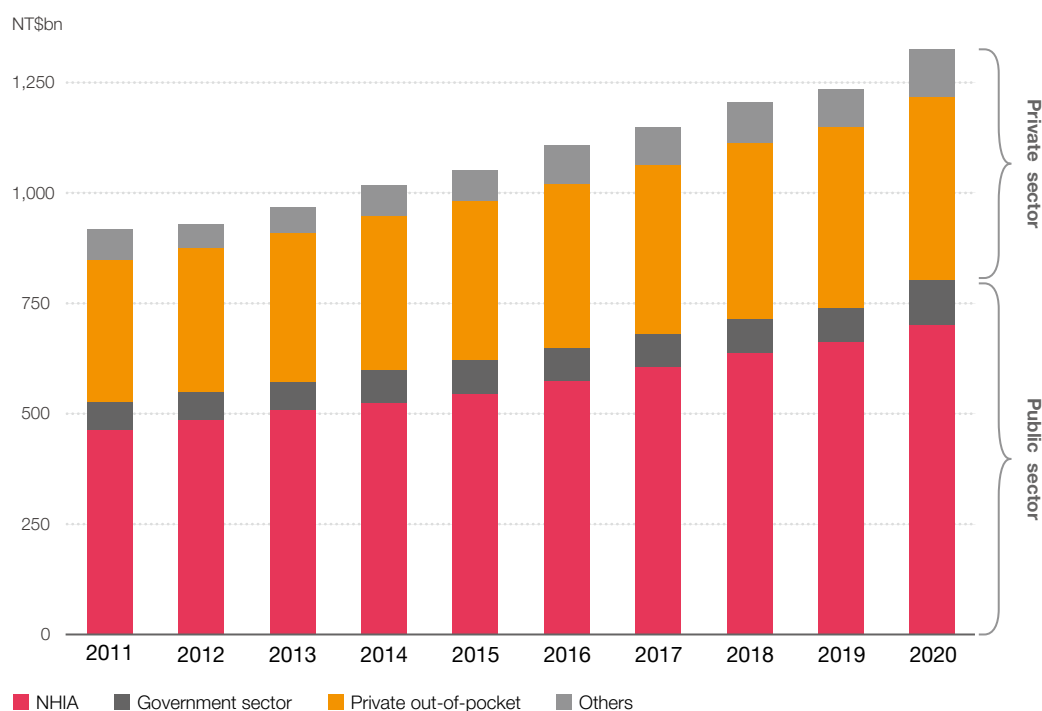
Breaking down national health expenditure data by financial resources, households accounted for 47.5% of total spending in 2020, followed by the government sector (25.0%) and then private sector enterprises and non-profits (21.7%). The majority of private spending on healthcare was accounted for by NHI premium payments and household out-of-pocket expenses—largely patient co-payments, registration fees, or for medical care services and products not covered by the NHI. Around 60% of government spending on healthcare was directed into the NHI programme in the form of subsidies.

Analysing the flow of healthcare spending through financial agents, the public sector accounted for 60.5% of national health expenditure in 2020, compared with 39.5% from private sources. The NHI programme represented the majority of total healthcare spending at 52.9%, followed by out-of-pocket expenses at 31.4%, mostly co-payments for doctor visits, hospitalisations and prescription drugs. With future NHI expenditure on healthcare expected to outpace revenues due to the impact of population ageing, policymakers may well have to consider increasing the patients' share of costs.

According to the financial allocation of national health spending, personal healthcare accounted for the largest share at 86.0% in 2020, followed by capital formation (7.7%), public health (4.2%) and general administration (2.1%). Within personal healthcare spending, hospitals accounted for the largest share at 43.9% (including outpatient care 24.1% and inpatient care 19.8%), followed by clinics at 21.6% (comprising Western medicine 10.4%, dental care 9.2% and TCM 2.0%), specialty care (3.1%) and others related to the purchase of medical supplies, equipment and goods (17.3%).

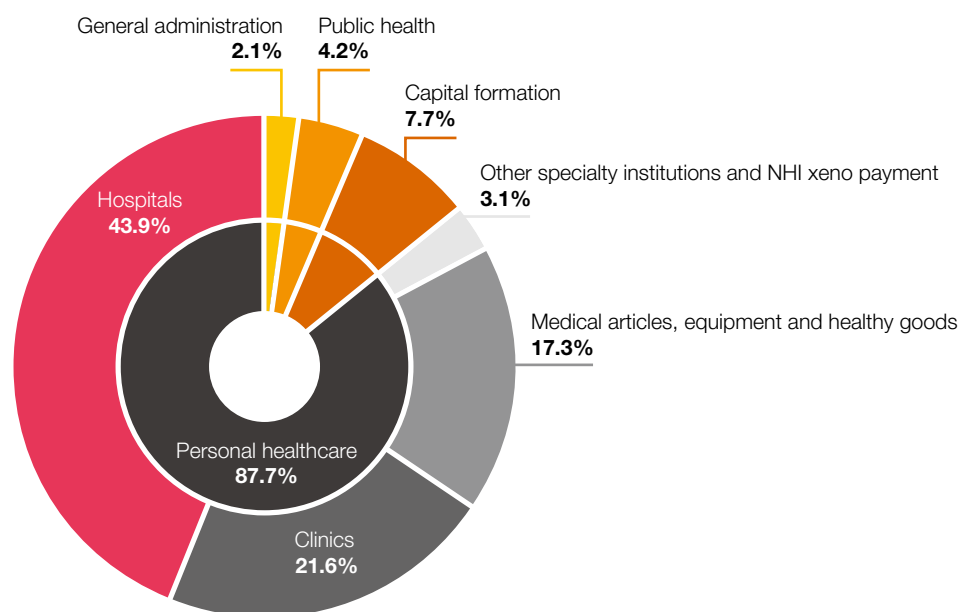
Total spending on pharmaceuticals accounted for 19.9% of Taiwan's national health expenditure in 2020, which was higher than the OECD average of 16.7%, and represented the third largest health-spending component after inpatient and outpatient care. Medication expenses reimbursed by the NHI amounted to NT\$217.5bn (US\$7.8bn) in 2020, or around 28% of its overall spending, having more than doubled in size since 1998. As part of its cost-containment efforts, the NHIA has targeted the escalating drug expenditure and pushed through regular price cuts on medications to reduce costs.

Figure 12: National healthcare expenditure by financial agents, 2011-2020



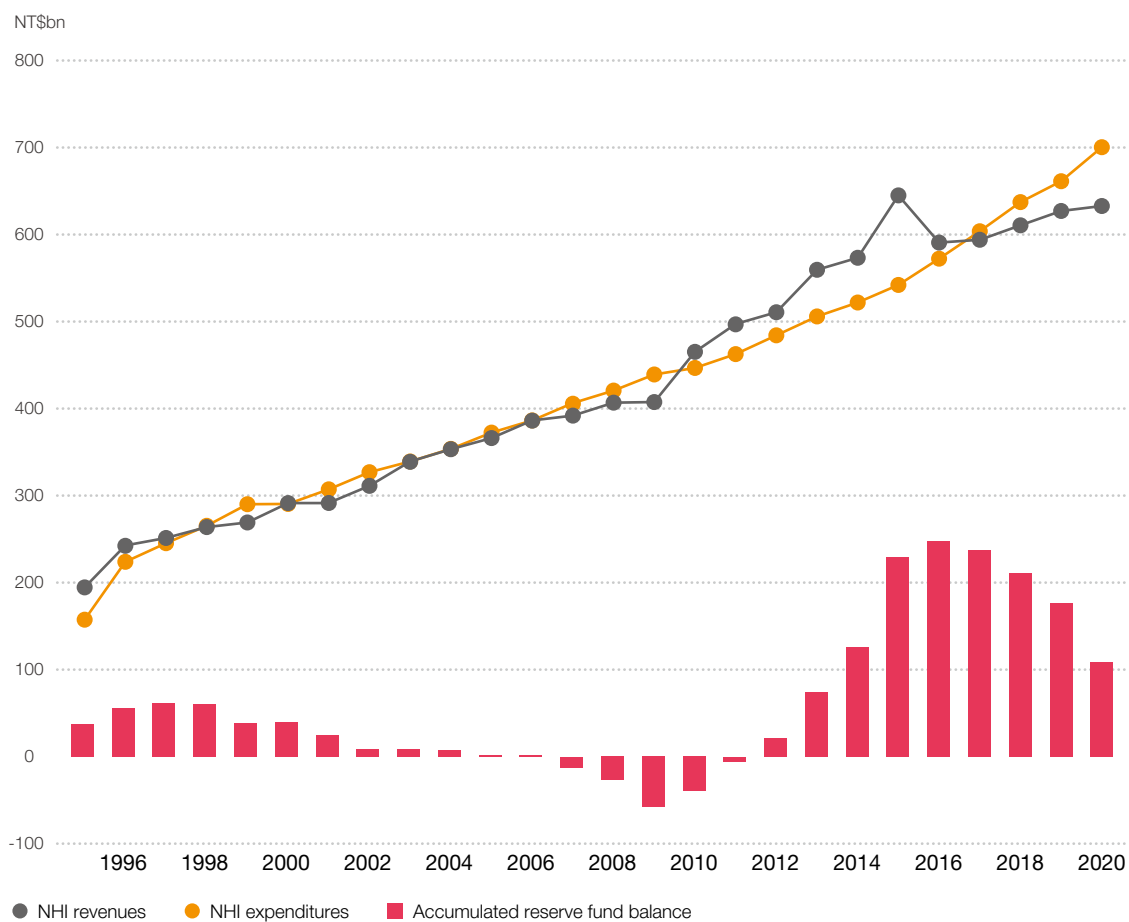
Source: Ministry of Health and Welfare.

Figure 13: National healthcare expenditure by financial allocation, 2020



Source: Ministry of Health and Welfare.

Figure 14: NHI financial revenue and expenditure, 1995-2020



Source: National Health Insurance Administration.

NHI programme overview

The NHI is a compulsory social health insurance programme. It was established in March 1995 by merging and expanding existing health insurance schemes, which at that time only covered around half of Taiwan's population. The mandatory nature of NHI affiliation—with the government subsidising the premiums for vulnerable patient groups—has seen health insurance coverage become universal. By the end of 2020, the total number of insured people in the NHI scheme was 23.9 million, and the NHI coverage rate hovered at around 99.9%.

The NHI offers a comprehensive benefits package which covers all medically necessary services. It encompasses inpatient and outpatient treatment and care (both primary and specialist), prescription drugs, dental care, traditional Chinese medicine, childbirth care, physical rehabilitation, home care, chronic mental healthcare and end-of-life hospice care. The NHIA determines which health services are to be covered by the NHI in consultation with a broad spectrum of stakeholders, and decisions are subject to considerations of budgetary impact.

The NHI is funded primarily through payroll-based premiums jointly paid by the insured, employers and the government, in addition to subsidies for low income and disadvantaged people. Reforms to the NHI in 2013 broadened the premium base to include supplemental sources of income. The rates for the basic and supplementary premiums are currently 5.17% and 2.11%. The NHI's other revenues come from fines on overdue premiums, public welfare lottery contributions, and a health and welfare surcharge levy on tobacco products.

In 2020, the NHI had insurance revenues (on an accrual basis) of NT\$633bn (around US\$23bn), of which the largest share was premium revenues at 97.1%. General NHI premiums totalled NT\$508bn (contributed collectively by beneficiaries, group insurance applicants and the government) and supplementary premiums were NT\$47bn. Its insurance costs totalled NT\$700bn (US\$25bn), of which medical benefits accounted for 99.2%. The resultant deficit of NT\$68bn was offset using the reserve fund, which stood at NT\$109bn (US\$4bn).

Insurance revenues grew by an average of 3.1% per year in the most recent decade, while costs increased by an annual average of 4.6%, driven by higher resource utilisation and medical costs. The NHI began experiencing financial deficits as early as 1998 and this has forced policymakers to pursue both cost-containment measures and occasional hikes in its health insurance premium rates (in 2002, 2010 and 2021) to help ensure that revenues keep pace with rising healthcare costs, and thereby support the NHI's dwindling reserves.

Financial reforms implemented in 2013, including the introduction of new supplementary premiums, helped to stabilise the NHI's finances. However, the reduction of both the basic and supplementary rates at the beginning of 2016 contributed to a drop in insurance revenues and eroded the NHI's budget surplus. Premium rate increases in 2021 have failed to stem deficits, so further rate hikes are likely over the next few years, though more fundamental structural reforms will be required to ensure the NHI system's long-term sustainability.

Cost-containment strategies

Balancing the NHI's budget has been a persistent challenge for the government. Aside from various initiatives to boost the revenue side, efforts to curb spending have also been pursued. These include the implementation of a range of cost-containment measures designed to decrease both demand and supply. While patients incur higher co-payments for overuse or misuse of resources, policymakers have been wary of imposing other additional costs on users of the NHI system. Instead, government efforts to balance the NHI's budget have focused principally on the supply side, as detailed below.

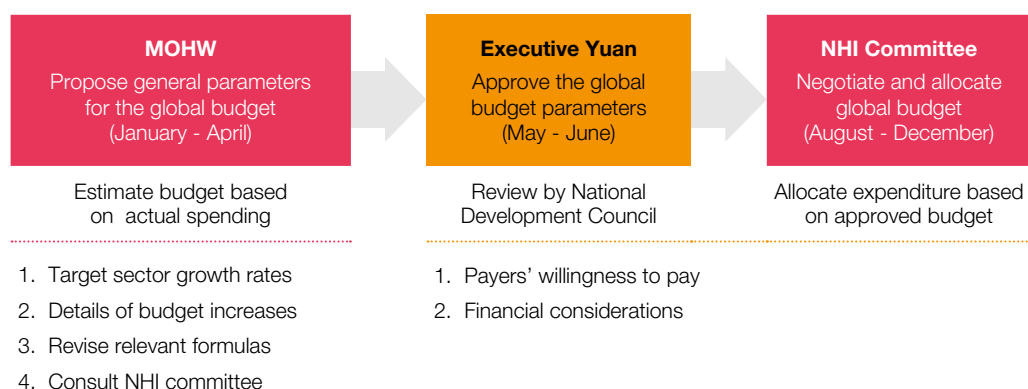
Global budget payment system

The adoption of a global budget payment system is the most significant cost-containment measure that has been implemented to date. It was phased in between 1998 and 2003 to constrain the rapid growth of healthcare expenditure under the NHI's fee-for-service reimbursement mechanism, which tends to encourage quantity of care. Global budget caps are set every year for four sectors: hospitals, primary care clinics, dental care and TCM. This in turn forces NHI-contracted providers to decide for themselves as to how to use their limited funds to satisfy the medical care needs of their patients.

Taiwan's global budgeting system for healthcare involves annual negotiations on discrete budgets for NHI expenditure in the four sectoral areas. Six months before each fiscal year begins, the health authorities propose the global budget parameters to the Executive Yuan (Cabinet). Once approved, the multi-stakeholder NHI Committee meets in the autumn to discuss and set the final global budget and how it will be allocated. Each sector's budget is then split between six geographic regions based on their share of total spending and the number of beneficiaries. The NHIA's regional offices manage their budgets through the national point-based fee schedule and a region-specific conversion factor.

Within the global budgeting system, providers are reimbursed by the NHI through a mixture of fee-for-service and other payment methods using a floating point-value scale. The point values used by the NHIA to reimburse medical care services are reviewed each quarter and reduced if service volumes increase too much. This helps to ensure that total reimbursement payments stay under the cap in each sector. Since its implementation, the system has consistently kept expenditure growth below 5% a year, compared with rates of 8% that prevailed before the rollout of global budgeting.

Figure 15: Decision-making process for NHI's annual global budget



Source: National Health Insurance Administration.

Alternative reimbursement mechanisms

The NHIA has also pursued alternative methods to pay contracted providers to curb rising healthcare costs. Reimbursement is generally on a fee-for-service basis per national uniform fee schedules. However, the financial incentives inherent in this payment method tend to drive up supply-induced demand for care, which partly explains the high utilisation of healthcare resources in Taiwan. For that reason, the NHIA has adopted certain other reimbursement payment methods in recent years, in an effort to encourage more efficient and cost-conscious behaviour by all healthcare providers.

These approaches include the expanding use of diagnosis-related group payments for inpatient care. Known as TW-DRG and first introduced in 2010, this mechanism caps reimbursements for specific services at defined levels. The NHIA had planned in 2016 to extend the application of flat-sum payments from 401 to 1,663 items (or 58% of all inpatient treatments), but the measure was shelved in the face of concerted opposition from doctors and care providers. The NHIA has further introduced pay-for-performance, capitation and bundled payments for certain episodes of care.

The TW-DRG payment model seeks to standardise operating procedures and to enhance the overall quality of care and efficiency. However, doctors have expressed concerns that it forces them to perform under a fixed budget with little flexibility. They claim, for example, that it discourages the treatment of complex patient cases, as hospitals are required to absorb losses related to inefficient treatments. For its part, the NHIA maintains that the TW-DRG system has helped to spur a decline in hospital stay length and readmission rates, as well as in the average use of medical resources.

Annual drug price adjustments

Other measures to reduce healthcare spending include the imposition of tighter controls on the price of certain inputs, notably pharmaceutical drugs which account for approximately one quarter of NHI's total costs. To date, most of these efforts have been dominated by policies designed to limit drug reimbursement prices, and have done little to address overprescribing. Regular price cuts have forced the removal of some medications from NHI's reimbursement schedule, while restrictions on reimbursement of expensive new medicines have delayed the introduction of some innovative drugs.

Taiwan currently uses a drug expenditure target (DET) system to adjust pharmaceutical prices on an annual basis. It was implemented in 2013 and replaced the previous system of biennial reviews using drug price and volume surveys. Under the DET mechanism, the NHIA sets a target for NHI drug spending for a year, and should expenditure exceed the amount allocated, price adjustments will subsequently be made. In the latest review, the prices of 6,645 drug products were cut by an average of 4.1%, from 1 January 2022, which will help generate savings of NT\$7.5bn (US\$270m).

Besides cost savings, the drug price cuts are also aimed at reducing the gap between procurement and reimbursement prices from which hospitals profit. Most hospitals in Taiwan operate in-house pharmacies and are allowed to buy medicines at discounted rates, whilst charging for dispensing them at the NHI reimbursement prices, which are often significantly higher. Recent estimates show that hospitals together make a profit of NT\$25bn (US\$890m) from this so-called 'drug price black-hole' every year, and pharmaceutical companies claim this artificially inflates the NHI's drug costs.

Table 3: Drug price adjustments under DET system, 2013-2020

	2013	2014	2015	2016	2017	2018	2019	2020
Target expenditure (NT\$bn)	138.0	142.6	147.5	154.8	151.1	156.0	162.3	170.2
Overspend amount (NT\$bn)	5.7	8.2	3.2	5.7	7.4	5.8	4.0	7.5
Effective date of price cut	1 May 2014 1 Jul 2014	1 Apr 2015	1 Apr 2016	1 Apr 2017	1 Apr 2018	1 Apr 2019	1 Oct 2020	1 Jan 2022
Average price reduction (%)	3.9	5.3	2.1	3.5	4.6	3.5	2.3	4.1
No. of drugs reduced in price	7,583	6,821	7,392	7,331	7,476	7,470	7,237	6,645

Source: National Health Insurance Administration.

Note: Implementation of annual drug price adjustments scheduled for 2019 and 2020 were postponed due to COVID-19.

Tackling waste and fraud

The NHIA has also targeted the wastage of medical resources, especially prescription drugs. Reports indicate patients in Taiwan dump some 70 tonnes of drugs each year, mostly medications for chronic diseases. To reduce such waste, the NHIA has expanded use of its medical information sharing system, NHI MediCloud, to more closely monitor the drug usage of patients and the prescribing practices of doctors. It also plans to soon increase the co-pay ceiling for outpatient prescription drugs from NT\$200 to NT\$300 (US\$10). Switching more drugs to OTC status is also under consideration.

Claims monitoring has also been stepped up in a bid to tackle waste and fraud. The NHIA's audits and inspections have been used to monitor the veracity of NHI claims, and to pinpoint providers and patients guilty of over-treatment, overuse or abuse of the system. Providers' charges are also subject to closer scrutiny, with hospitals claiming more than NT\$200m (US\$7m) in reimbursements required to submit detailed accounts to the NHIA, the reporting requirement threshold having been lowered from NT\$400m starting from fiscal 2018.

Private health insurance

Taiwan's private health insurance market is small, and consists mostly of policies offered by private for-profit insurers that supplement NHI coverage. Generally, these are disease-specific indemnity policies, or riders to non-medical policies, such as life or car insurance. They mostly offer one-time, event-trigger insurance payments for certain health occurrences, such as cancer or hospitalisation for surgery. Private health insurance policies do not cover medical services that are covered by the NHI, nor do they buy faster access to any type of care, or more choice of medical specialists or hospitals.

Even so, private health insurance is expanding in Taiwan, having grown at a CAGR of 5.5% in the 2011-2020 period, and accounting for NT\$402bn (US\$14bn), or 12%, of total insurance industry premiums in 2020. Individual health insurance products with a fixed payment scheme dominate the Taiwan market. Property and casualty insurers have marketed yearly renewable insurance plans since 2008, and these have posted strong growth. Reimbursement-based health insurance products have only started to be rolled out in recent years.

Notwithstanding universal access to subsidised provision through the NHI, households currently foot 31% of overall healthcare expenditure on an out-of-pocket basis, up from 22% in 1995. This increasing share of rising healthcare costs amid cost-shifting to patients, as an ageing population puts the NHI under strain, will impose a growing financial burden on households. This, together with higher insurance awareness resulting from the COVID-19 crisis, could lead to more demand for private insurance to protect patients against downside risks and to drive better care decisions.



Biomedical industry

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Taiwan's biomedical industry

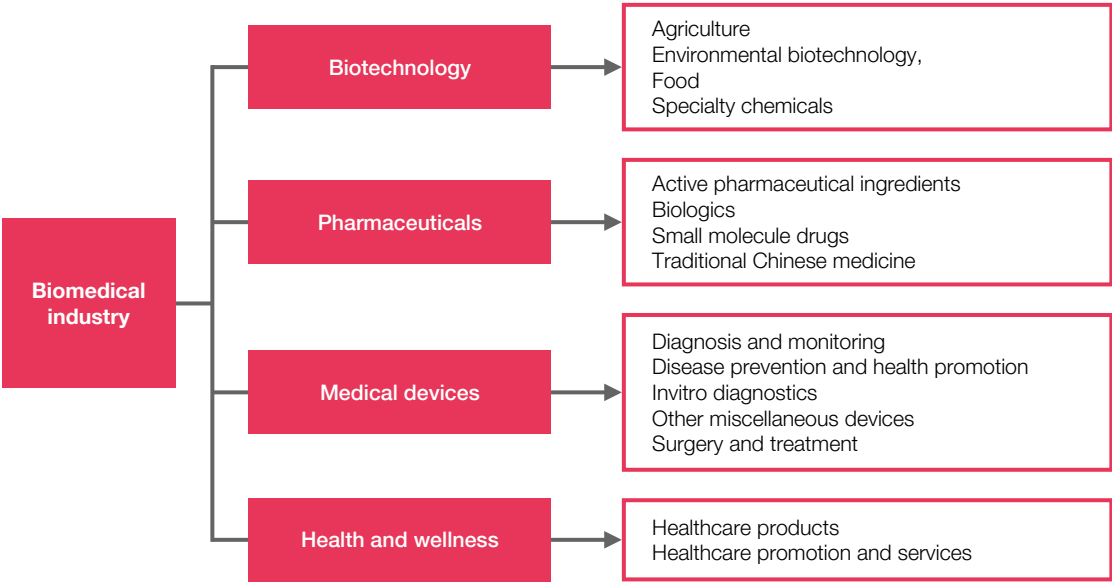
The biomedical industry in Taiwan comprises the applied biotechnology, pharmaceutical, medical device, and health and wellness sectors. A long period of investment has produced a solid foundation, with an ecosystem that spans the entire value chain of the biomedical industry, from pre-clinical and clinical research in drug discovery and development to manufacturing and marketing. It is a priority policy focus for promotion under the government's current six core strategic industries initiative to transform Taiwan's industrial structure.

The Biomedical Industry Innovation Programme (BIIP), which launched in 2016, is the national plan for developing the industry, with the aim of raising its output value and competitive capabilities, and positioning Taiwan as a regional hub for biomedical R&D. Its targets for 2025 call for an output value of over NT\$1 trillion (US\$33bn), development and international marketing of twenty new drugs, introduction of eighty high-value medical devices to global markets, and fostering of at least ten biotechnology and health-related flagship brands.

The BIIP has laid the foundation for the next-phase promotion of precision health, which is the current strategic focus for the biomedical industry. In 2020, the government launched a Precision Health Strategy Development Programme, which seeks to establish Taiwan as a global leader in precision health and the development of high-tech solutions to epidemics. The objective is to leverage Taiwan's digital infrastructure to accelerate the integration of technology and medical data in order to drive development of new biomedical products.

These government initiatives have helped support growth momentum in Taiwan's biomedical industry, which offers potential investment and collaboration opportunities. Total industry revenues (excluding the health and wellness sector) grew at a 5-year CAGR of 6.2% to NT\$557bn (US\$20bn) in 2021. The pharmaceutical sector accounted for the largest share of market revenue at NT\$240bn, or 43%, followed by medical devices (NT\$187bn, 34%) and biotechnology (NT\$130bn, 23%). These three sectors will each be analysed in more detail.

Figure 16: Scope of Taiwan's biomedical industry



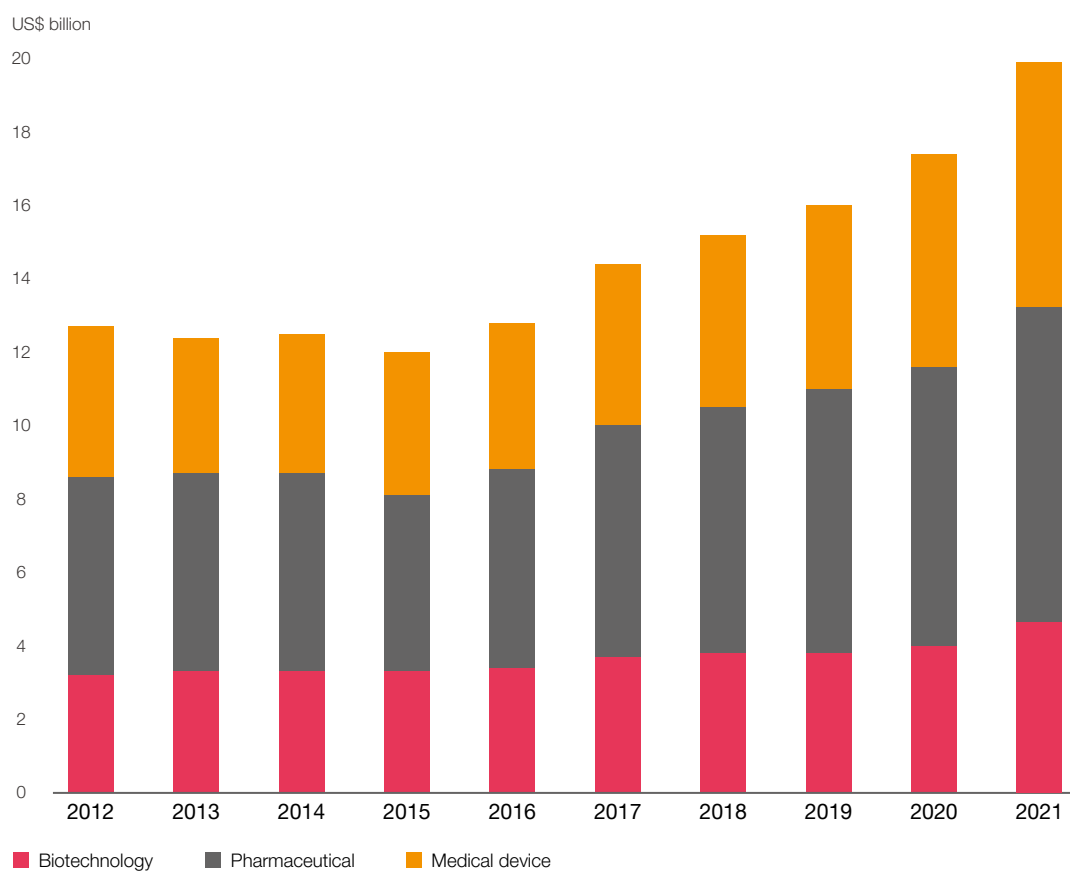
Source: Biotechnology and Pharmaceutical Industries Promotion Office.
Note: The health and wellness sector was included in the official scope of Taiwan's biomedical industry from 2018.

Table 4: Status of Taiwan's biomedical industry, 2012-2021

Unit: US\$ billion	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Revenue	8.9	9.3	9.5	9.4	9.7	10.7	11.4	11.8	13.4	16.2
No. of companies	1,505	1,601	1,631	1,871	1,918	2,004	2,082	2,143	2,245	2,290
Personnel	69,470	71,580	73,769	76,159	78,019	80,732	85,623	89,907	92,435	94,163
Export value	3.2	4.0	4.1	4.4	4.8	5.2	5.7	6.0	6.8	8.2
Import value	6.9	7.1	7.1	7.1	7.9	8.9	9.5	10.2	10.8	11.9
Import:Export	65:35	64:36	65:35	65:35	61:39	59:41	52:48	N/A	N/A	N/A
Domestic market size	12.6	12.4	12.5	12.0	12.8	14.4	15.2	16.0	17.4	19.9

Source: Industrial Development Bureau (MOEA), 2013-2022 Biotechnology Industry White Papers.

Note: The health and wellness sector is excluded from the overall biomedical industry for analysis purposes.

Figure 17: Market size of Taiwan's biomedical industry, 2012-2021

Source: Industrial Development Bureau (MOEA), 2013-2022 Biotechnology Industry White Papers.

Note: The health and wellness sector is excluded from the overall biomedical industry for analysis purposes.

Biomedical industry clusters

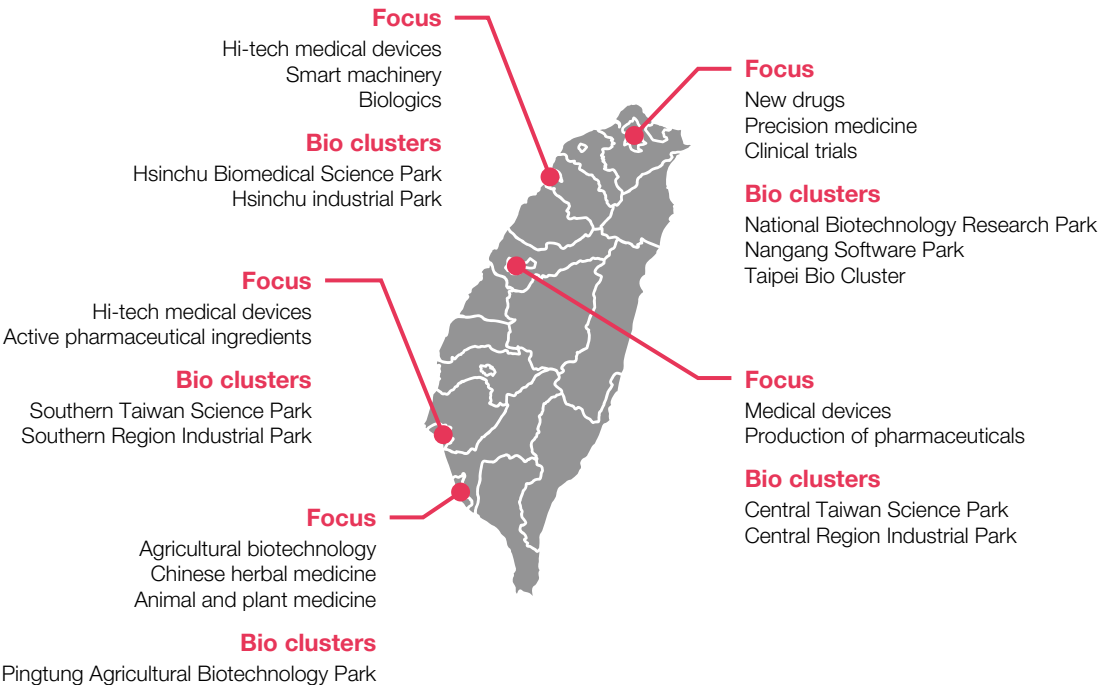
Taiwan has well-developed clusters which support value creation and export growth across the biomedical industry. New drugs, medical devices and biological preparations are the focus in the north of Taiwan, while pharmaceuticals and medical devices are the main areas in central Taiwan, and pharmaceuticals, medical implants and minimally invasive surgical instruments are the focal point in the south. A biomedical industry corridor is effectively connected from the north to the south of Taiwan, as shown in the figure below.

In the north, the best known clusters include the National Biotechnology Research Park (Nangang), Neihu Technology Park (Taipei) and the Hsinchu Biomedical Science Park. The cluster sites in Nangang and Neihu, in particular, specialise in innovative biotechnology and pharmaceuticals and new medical devices because of their strong R&D capabilities. The Hsinchu Biomedical Science Park, which is adjacent to the technology-focused Hsinchu Science Park, focuses on medical equipment, in-vitro testing and biological preparations.

The central region is home to Taiwan’s precision machinery and tooling hub, which in recent years has benefited from the rise of robotics, smart applications and value-added data services. Bio-medical businesses at the Central Taiwan Science Park in Taichung have linked up with engineering companies to develop precision machining for medical devices and instruments, such as minimally invasive medical materials and smart assistive devices. The manufacturing of medicinal products is another focus area in central Taiwan.

In the south, besides the production of active pharmaceutical ingredients, biomedical firms have taken advantage of the strong metal processing capabilities in Kaohsiung to develop minimally invasive surgical instruments for dentistry and orthopaedics in the Southern Taiwan Science Park. In addition, with the advantage that Taiwan possesses in the agricultural field, the Pingtung Agricultural Biotechnology Park focuses on the development of functional foods, modern Chinese medicines, animal vaccines and animal breeding.

Figure 18: Biomedical industry clusters in Taiwan



Source: Biotechnology and Pharmaceutical Industries Promotion Office.

Biotechnology sector

Biotechnology, or biotech for short, encompasses a broad variety of techniques that involve the use and manipulation of living organisms to develop or make commercial products and services, mainly for use in agriculture, food science and medicine. In Taiwan, the applied biotechnology sector covers agriculture, food and environment biotechnology, as well as new biopharmaceuticals and contract services. The first national plan for biotechnology development in 2009 helped kick-start the sector, which has since doubled in size to reach NT\$119bn (US\$4bn) in 2020. The primary focus is on the development of new drugs and biologics.

Strong government commitment has helped drive the expansion of Taiwan's biotechnology sector since the late 2000s. A significant milestone was the passage of the Act for the Development of Biotech and New Pharmaceuticals Industry in 2007, which laid the foundation for future growth of the biomedical industry. Two years later, in 2009, the government launched its Diamond Action Plan for Biotech Take-off to strengthen the basic industrial structure. In 2013, the second phase of the policy initiative, renamed as the Biotech Industrialisation Take-off Action Plan, focused on growing the capabilities of the biotech value chain.

A change of government in 2016 saw continued support for the burgeoning sector. For example, biomedicine was designated a key innovative area for development, and the Biomedical Industry Innovation Programme was launched with the goal of making Taiwan an international hub for biomedical R&D. The current focus is on precision health, which in 2020 was marked as one of six core strategic industries. Under its Precision Health Strategy Development Programme, the government is pursuing various strategies to build up Taiwan as a global leader in precision health and the development of new biomedical products.

Taiwan has indeed many of the critical elements to become an important hub for biomedical R&D. Its clinical research capacity has grown rapidly in the past decade, supported by a large talent pool of well-trained practitioners, good quality research and medical infrastructures, international clinical trial experience, and high quality, cost-competitive drug R&D and manufacturing. Although the scale of Taiwan's biotechnology sector is still relatively small, its upward growth momentum is strong and is expected to continue. Key drivers will be further policy and investment support, and the maturation of companies' drug pipelines and service offerings.

Table 5: Status of Taiwan's biotechnology sector, 2012-2021

Unit: US\$ billion	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Revenue	2.5	2.6	2.7	2.8	2.9	3.2	3.5	3.6	3.9	4.5
No. of companies	450	490	500	510	525	557	596	626	651	671
Personnel	16,770	17,540	18,340	19,259	20,219	21,432	22,718	23,854	24,570	24,447
Export value	1.0	1.0	1.0	1.1	1.2	1.4	1.5	1.6	1.7	1.8
Import value	1.6	1.7	1.6	1.6	1.7	1.8	1.9	1.9	1.9	2.0
Import:Export	60:40	62:38	62:38	62:38	61:39	60:40	58:42	57:43	55:45	55:45
Domestic market size	3.2	3.3	3.3	3.3	3.4	3.7	3.8	3.8	4.0	4.6

Source: Industrial Development Bureau (MOEA), 2013-2022 Biotechnology Industry White Papers.

Regulatory environment

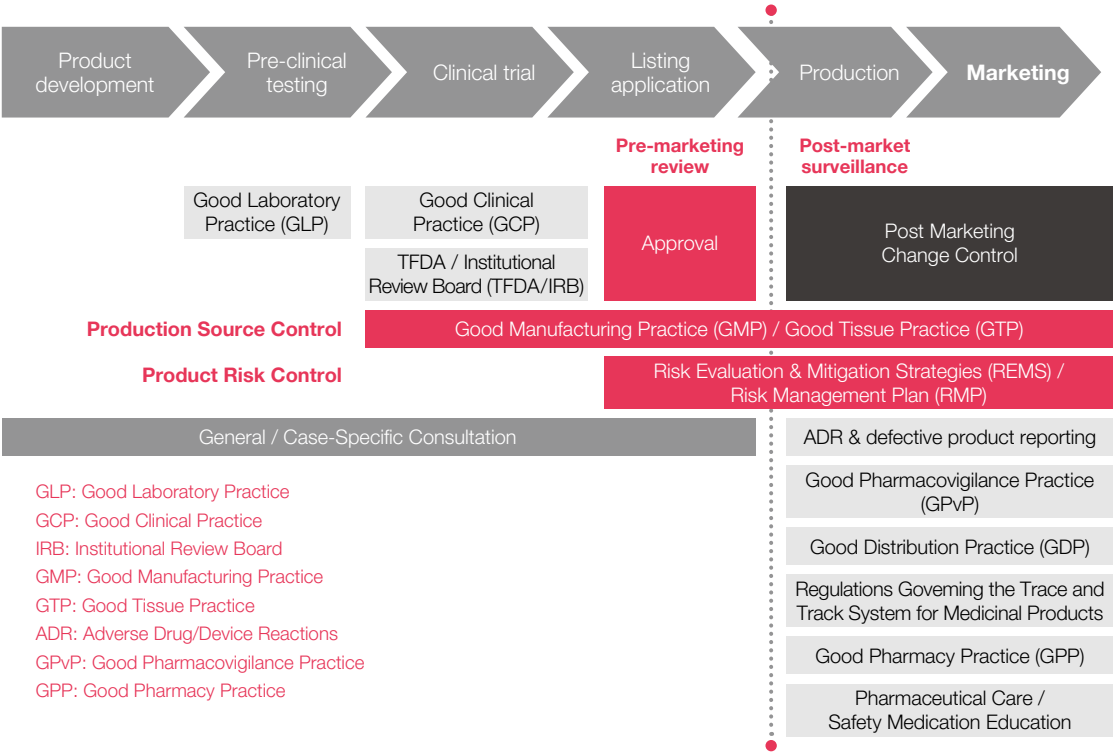
The Taiwan Food and Drug Administration (TFDA), an agency of the MOHW, is the body responsible for the enforcement of laws and regulations related to food, cosmetics, medicine and medical devices, as well as the issuance of all licences, permits and authorisations. It has established a comprehensive life cycle management system, which is in line with international standards, to effectively control the safety, efficacy and quality of medicinal products. TFDA conducts reviews, audits and inspections at the various stages of the drug life cycle to monitor and ensure compliance with operating practices.

The Center for Drug Evaluation (CDE) assists the TFDA to conduct technical reviews of applications for clinical trials, new drugs and medical devices. The main role of this MOHW-backed organisation is to improve the quality and speed of clinical trials as well as drug and device approval processes. It also sets regulations for new therapy treatments and ensures the transparency of review processes. A new bill, which is still awaiting approval, aims to upgrade the CDE to take over responsibility for all evaluation reviews of drugs and medical devices.

The principal governing law is the 2007 Act for the Development of Biotech and New Pharmaceuticals Industry, which provides for tax incentives, special rules that encourage investment in start-ups and state-sponsored funding. The law was amended in 2017 to expand the R&D tax breaks available to qualified companies for investments in new and emerging biomedical technologies, such as cell-gene therapies and precision medicine. In addition, the Fundamental Science and Technology Act was revised in 2017 to facilitate biotechnology talent flows between the academic and private sectors.

More recently, the biotech statute was amended in December 2021 to extend existing tax breaks for investment in biomedical R&D until the end of 2031, while also providing new tax benefits as part of efforts to further promote the development of the biomedical industry in Taiwan. The law was also expanded to cover emerging fields such as regenerative medicine, digital health and precision health, which are considered key areas for growth. It will also include contract development and manufacturing organisations (CDMOs) from 2022.

Figure 19: Life cycle management structure of drugs



Source: Taiwan Food and Drug Administration.

Conducting clinical trials

Drug development is a long and costly sequential process, from discovery to pre-clinical and clinical development, approval and marketing. In Taiwan, for studies involving human subjects, clinical trials of investigational new drugs (INDs) conducted for marketing approval, and post-marketing studies on approved drug products, are primarily regulated by the Pharmaceutical Affairs Act and Good Clinical Practice (GCP) Guidelines for Medicinal Products, which closely mirror the global GCP standards set by the International Conference of Harmonization.

Taiwan first implemented a clinical trial system in 1993, and the quality of trials has steadily improved over the years, boosted by a number of initiatives to improve biopharmaceutical R&D capabilities and simplify clinical trial processes. For instance, the Taiwan Clinical Trial Consortium (TCTC) was formed in 2011 to work with clinical trial sponsors to advance patient care and provide on-site clinical trial coordination services. The TCTC now brings together 14 disease-specific clinical trial consortia, all of which are Asian prevalent, involving almost 300 clinical trial doctors and principal investigators.

Outsourcing clinical trials is a rapidly growing trend and Taiwan is regarded as a favourable global site for conducting clinical trials of new drugs. The 2019 Biotechnology Competitiveness and Investment Survey by research firm PwC ranked Taiwan second among 17 fast-growing emerging markets, just behind Singapore, for its biomedical investment attractiveness. However, some gaps still need to be closed for Taiwan to compete with mature markets, including resolving drug approval delays, and introducing greater predictability and holistic approaches with regard to market access.

Research and clinical trials infrastructure

Research institutes have played an important role in the development of Taiwan's economy down the years, and nine currently focus on the biomedical industry. The main one is the Development Center for Biotechnology (DCB), which has successfully fostered the development of a complete biotech infrastructure and value chain, as well as a diverse array of applications for use by the private sector. It specialises in the development of biologics and small molecule drugs, botanical drugs, as well as the technologies required for pre-clinical testing.

The official opening of the National Biotechnology Research Park (NBRP) in Taipei City's Nangang District in 2018 marked an important milestone for the biomedical industry, as it integrated Taiwan's R&D and start-up incubation capabilities, focusing all pre-clinical trial activity in a single location. The park houses the TFDA, DCB, National Laboratory Animal Center, Academia Sinica research centres, BioHub Taiwan incubation base and private firms. The NBRP will help increase the scale and scope of local biomedical R&D, and attract multinational pharma companies to conduct research in Taiwan.

This institutional support infrastructure for clinical research is integral to Taiwan's attractiveness as a site for clinical trials. Another positive factor is the availability of high quality, GCP-compliant clinical trial centres. At present, 23 medical centres and 143 hospitals are qualified to conduct clinical trials in Taiwan. Centres of excellence for clinical trials have been set up at leading research hospitals to enhance Taiwan's capacity to conduct early-stage clinical trials. Additionally, the MOHW has funded new clinical trial centres at some hospitals under its Promote the Clinical Trial Development Project.

Clinical trial review and approval process

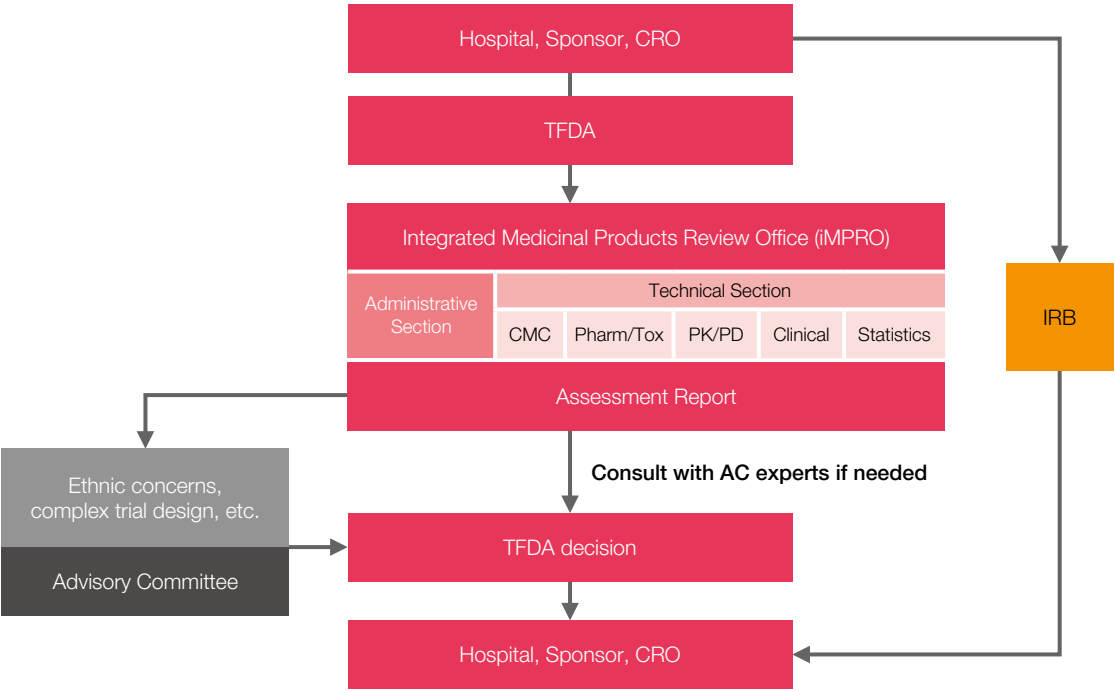
Clinical trials of biomedical interventions typically proceed through four phases, and all require prior approvals from both the TFDA and the relevant IRB (Institutional Review Board). Taiwan has a central IRB system consisting of seven main IRBs and 35 collaborative IRBs, which are formally designated to review and monitor clinical trials involving human subjects. In practice, a clinical trial application for TFDA approval is usually made by the sponsor or contract research organisation (CRO), and the IRB one is filed in the name of the principal investigator.

After a sponsor submits a clinical trial application to the TFDA, the supporting dossier is assessed. If required, a review meeting will be held and also the TFDA may request supplementary documents. The standard review time for an IND application is 45 calendar days, while a fast track pathway for global and regional trials delivers approvals in 15 days. Provided a multinational protocol has been approved by at least one of 10 reference markets, the TFDA will only conduct an administrative review without requiring a technical evaluation from CDE.

The TFDA in 2017 introduced new enhancements to its review processes for clinical trial protocols, which are intended to help accelerate development of new drugs and facilitate earlier patient access to innovative treatments. The measures included the introduction of a new 30-day fast-track review mechanism for clinical trials involving cell and gene therapies, the streamlining of the regulatory review process for first-in-human clinical trials, as well as refining the review process for clinical trial protocol amendments based on the degree of changes.

The number of clinical trials conducted in Taiwan has increased steadily in recent years. The TFDA handles around 300-400 new IND applications every year, mostly for multi-regional, multi-centre Phase II and III trials. Because of the high quality, speed and relatively low cost of conducting clinical trials in Taiwan, almost all the major international pharma companies have set up local clinical trial offices, which have primarily focused on Phase III global multi-centre studies. Even so, Taiwan faces stiff challenges from several regional competitors.

Figure 20: Standard review process for clinical trial (IND) applications



Source: Taiwan Drug and Food Administration.

Figure 21: IND applications in Taiwan by clinical trial type, 2012-2021

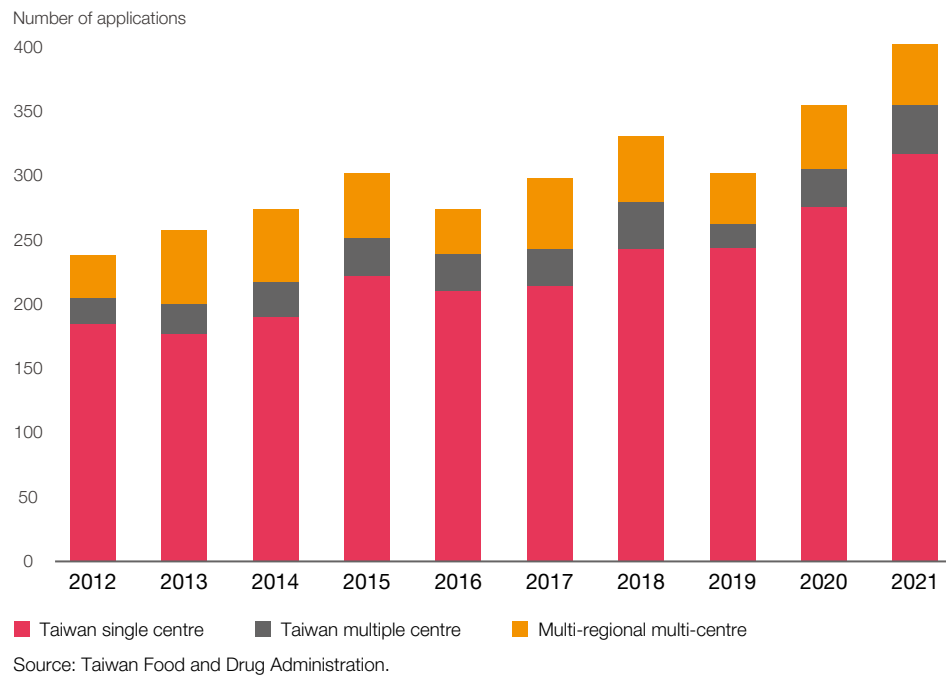
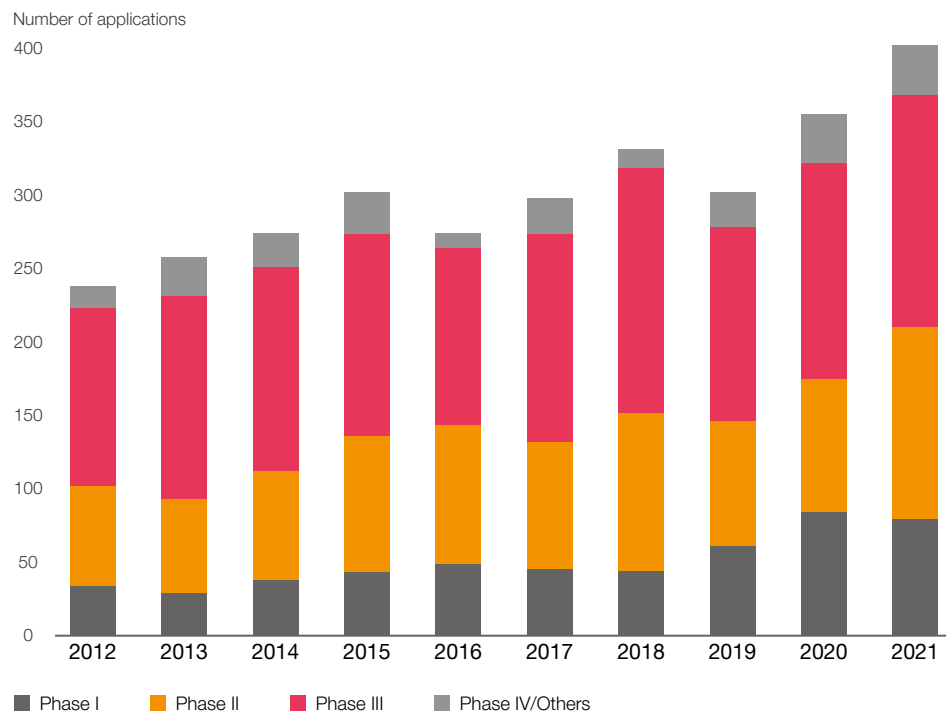


Figure 22: IND applications in Taiwan by study phases, 2012-2021



Business environment

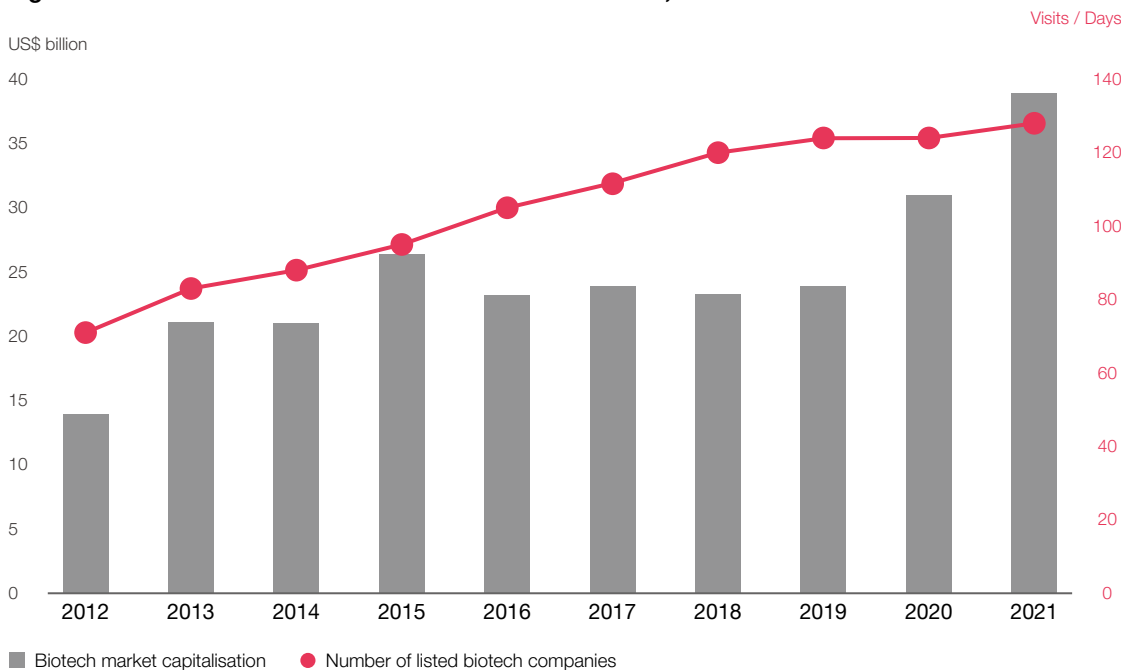
Taiwan's applied biotechnology sector is small in scale and has a fragmented structure. Around 670 enterprises, mostly small and medium sized, are classified as biotechnology companies, and their combined revenues were NT\$126bn (US\$4.5bn) in 2021. Because of Taiwan's small market size, local drug developers often work with CROs and pharma multinationals to develop high-end drugs and expand overseas. Their traditional business model has been to acquire or in-license an early-stage drug candidate, perform R&D to add value and out-license the compound to a larger company.

A number of domestic biotechnology firms are at the forefront of breakthrough drugs, delivery systems and diagnostics. In particular, Taiwan has established a niche in the area of oncology, with several companies developing new cancer drugs. Also, against the backdrop of Taiwan's difficulty in procuring COVID-19 vaccines from abroad, local research institutes and companies are developing vaccines of their own. This could prove beneficial to the wider sector, as the government will likely allocate it more resources in recognition of health-care vulnerabilities and supply chain weaknesses.

As funding is a primary challenge for both biotech start-ups and development-stage companies, the government has encouraged the creation of small and medium biotechnology venture capital funds. Furthermore, the state-run National Development Fund also provides significant funding support to the sector, having to date invested an aggregate total of over NT\$15bn (US\$490m) in biotechnology companies and biotech-related venture capital firms. Also, initial public offering (IPO) rules have been relaxed to make it easier for biotech firms to raise funds through local stock exchange listings.

As a result, the number of biotech companies going public on Taiwan's stock market has risen steadily in recent years, from 71 in 2012 to 128 by the end of 2021. In addition, a further 65 biotech start-ups were listed on the Emerging Stock Board, and 18 on the Go Incubation Board. With Taiwan's biotech sector in the late incubation stage, the maturation of companies' drug pipelines is attracting investor attention and given a boost to biotech stocks. The sector's stock market capitalisation has increased considerably over the past decade, from US\$14bn in 2012 to around US\$39bn as of the end of 2021.

Figure 23: Market value of listed biotech stocks in Taiwan, 2012-2021



Source: Industrial Development Bureau (MOEA), 2013-2022 Biotechnology Industry White Papers.

Pharmaceutical sector

Taiwan's pharmaceutical sector encompasses a broad range of related products, including small molecule drugs, biologics, active pharmaceutical ingredients (APIs) and Chinese herbal medicine. The total domestic market for pharmaceuticals (including imports) was worth NT\$240bn (US\$9bn) in 2021, having grown at a CAGR of 6.6% since 2016. Sales of chemical drugs and APIs account for the majority of the market, with 30% of demand fulfilled by local drugmakers, mostly for APIs and finished drug formulations, and the rest supplied by large and growing imports of innovative drugs.

Market growth has been, and will continue to be, supported by the accelerated ageing of Taiwan's population and high demand for chronic disease treatments and new innovative drugs. A key factor weighing on this growth is cost containment, since Taiwan's drug reimbursement system uses price controls to strictly regulate public spending on patented medicines. Research company Fitch Solutions forecasts total drug sales in Taiwan will grow at a five-year CAGR of 6.3% to NT\$254bn (US\$9.6bn) by 2025, and at a ten-year compound rate of 6.3% to NT\$344bn (US\$13.1bn) by 2030.

Taiwan's advanced healthcare infrastructure also supports the sale of pharmaceuticals, with a large network of hospitals and medical clinics serving as the primary access points for medicines. The lack of proper drug prescribing and dispensing, which allows hospitals to operate their own pharmacies for profit and encourages over-prescribing, is also beneficial to pharma suppliers. Prescription drugs dominate the Taiwan market, accounting for 93% of total pharmaceutical sales in 2020—of which patented drugs represented the bulk at 70%, and the rest by domestically-produced generic drugs.

The over-the-counter (OTC) medicine segment is small and under-developed, representing around 7% of the overall pharmaceutical market. This is largely due to the comprehensive nature of the NHI's prescription drug reimbursement schedule, which lists more than 17,000 items. Nevertheless, as reimbursed price cuts are stifling growth in the prescription drugs sector, pharma companies may look to the OTC sector for opportunities. As part of cost containment efforts, the authorities are taking a more proactive approach to Rx-to-OTC switching and promoting self-medication for minor ailments.

Table 6: Status of Taiwan's pharmaceutical sector, 2012-2021

Unit: US\$ billion	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Revenue	2.7	2.8	2.7	2.4	2.5	2.6	2.7	2.8	3.0	3.3
No. of companies	350	350	350	320	320	357	358	360	375	378
Personnel	18,500	19,000	19,000	18,500	18,500	19,000	19,055	19,100	19,500	19,800
Export value	0.7	0.7	0.6	0.8	1.0	1.0	1.0	1.0	1.1	1.2
Import value	3.3	3.3	3.3	3.2	3.9	4.7	5.0	5.4	5.7	6.5
Import:Export	78:22	76:24	76:24	76:24	66:34	61:39	64:36	63:37	63:37	64:36
Domestic market size	5.4	5.4	5.4	4.8	5.4	6.3	6.7	7.2	7.6	8.6

Source: Industrial Development Bureau (MOEA), 2013-2022 Biotechnology Industry White Papers.

Regulatory environment

The TFDA is the responsible authority for ensuring the quality and safety of pharmaceutical drugs for use in Taiwan. Its Division of Medicinal Products handles the registration, approval and monitoring of drug products. The CDE assists the TFDA with technical dossier reviews of new drugs and APIs. A bill is currently pending approval by parliament to upgrade CDE into an independent, national-level drug testing centre, which will be fully responsible for all evaluation reviews of drugs. If passed, it will help to streamline the review approval processes for licences to market pharmaceuticals in Taiwan.

The Pharmaceutical Affairs Act (PAA) provides the basic structure for the regulation of medicines, and the MOHW has issued more than 100 subordinate regulations, guidelines and standards to clarify the implementation of the PAA. A new Medical Devices Act was promulgated in 2020 in order to separate the market regulation of medical devices from that of pharmaceutical drugs (see page 46 for further details). The PAA divides pharmaceuticals into raw materials (APIs) and finished formulation products, with the latter category further split into new drugs, biological agents, generic drugs and orphan drugs.

Taiwan's regulatory framework for pharmaceutical drug products has been internationally accredited by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) since 2013. This guarantees that Taiwan's Good Manufacturing Practice (GMP) standards are in alignment with international norms, and enables mutual recognition of pharmaceutical certification. In 2018, the TFDA joined the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which aims to unify the process for drug registration globally.

Pharmaceutical IP protections

The protection of intellectual property rights (IPR) in Taiwan's pharmaceutical sector has improved significantly in recent years. In 2018, the PAA was amended to strengthen IPR protection for drug products, as part of Taiwan's ongoing efforts to join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP, a regional trade deal). The revised PAA established a new pharmaceutical patent linkage system, which was officially implemented in 2019. The mechanism is a positive step forward for Taiwan in its efforts to develop a more innovative pharmaceutical sector.

The patent linkage system aims to ensure that new generics are not launched in Taiwan while the original patent is still valid, as it makes potential patent infringement a mandatory consideration and an examination basis during the review process for generic drug applications. The TFDA must check such an application against a list of patented drugs with therapeutic equivalence, like the US Orange Book. Yet, the PhRMA trade body has expressed concern that the TFDA is narrowly interpreting the new system by excluding patents that protect new doses, new dosage forms or new unit strengths.

The PAA also provides data exclusivity protection to promote a balance between new drug innovation and generic drug competition. It was amended in 2017 to introduce data exclusivity periods for new chemical entities (NCEs) as well as new/changed indications of previously approved drugs. The data exclusivity for NCEs and biologics products lasts five years, with absolute exclusivity granted for the first three years. The protection period for a new or changed indication with international data is three years, and it may be extended to five years where the reference holder conducts clinical trials locally.

Registration and approval

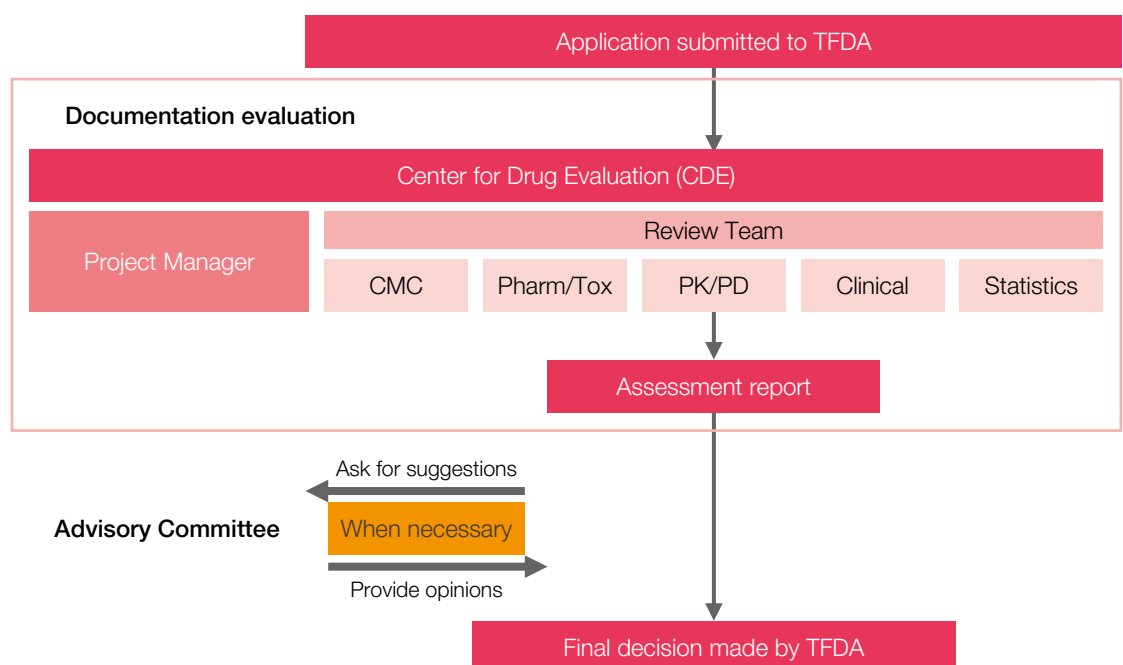
All locally-produced and imported pharmaceutical drug products must be reviewed and approved for sale and marketing by the TFDA. Applications for approval include a new drug application (NDA), an abbreviated new drug application (ANDA) and an OTC application. For pre-clearance, applicants of NCE drugs must submit relevant information and data relating to, among other items, clinical trials, formulation basis, testing specifications, methods and certificates of analysis for drug raw materials and finished products, and manufacturing records.

The TFDA and CDE review teams examine all of the submitted data related to an application and make a decision to approve it or not. The approval timeline for a NDA differs according to each pathway (Figure 25), ranging from six months (ANDA) to one year (standard NDA). In recent years, the TFDA has developed several expedited pathways to accelerate the approval process for drugs that treat rare or serious conditions. In 2017, the TFDA introduced a refuse-to-file mechanism to reduce unnecessary reviews and incomplete applications.

Notwithstanding recent improvements to expedite the drug review and approval process in Taiwan, the actual review timeline is still relatively lengthy. According to the latest TFDA statistics, the median review time for NCE and biologics applications was 352 days in 2021 (Figure 26), with 50%-60% of the cases meeting the review-time target of 360 days. The revamp of the CDE is expected to help speed up the drug review process, with the percentage of reviews completed for NCE applications within 360 days projected to rise from 50% currently to 90%.

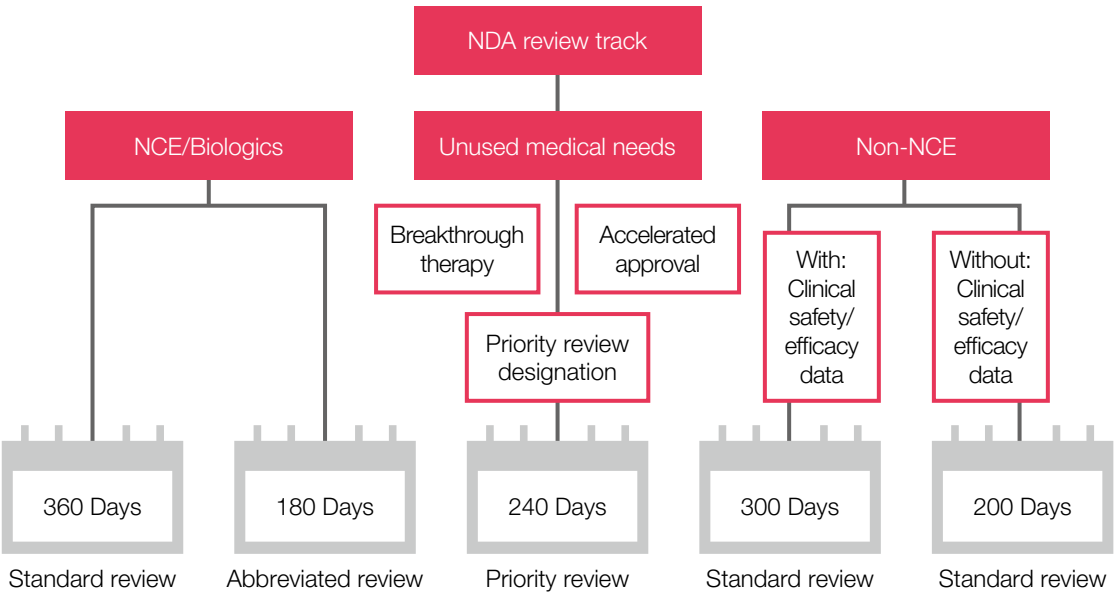
Continued improvements to the current approval process will reduce the time required to launch a pharmaceutical drug product in Taiwan, and help support the expansion of the local patented drug market. In 2021, the TFDA approved a total of 134 new drugs, including 61 NCEs, 31 biologics and 42 non-NCEs. Of the approved applications, 9 were for new drugs developed domestically and 125 for imported drugs. The top therapeutic areas of the new approved drugs were cancer, immune and nervous systems and cardiovascular diseases.

Figure 24: Review process for new drug applications



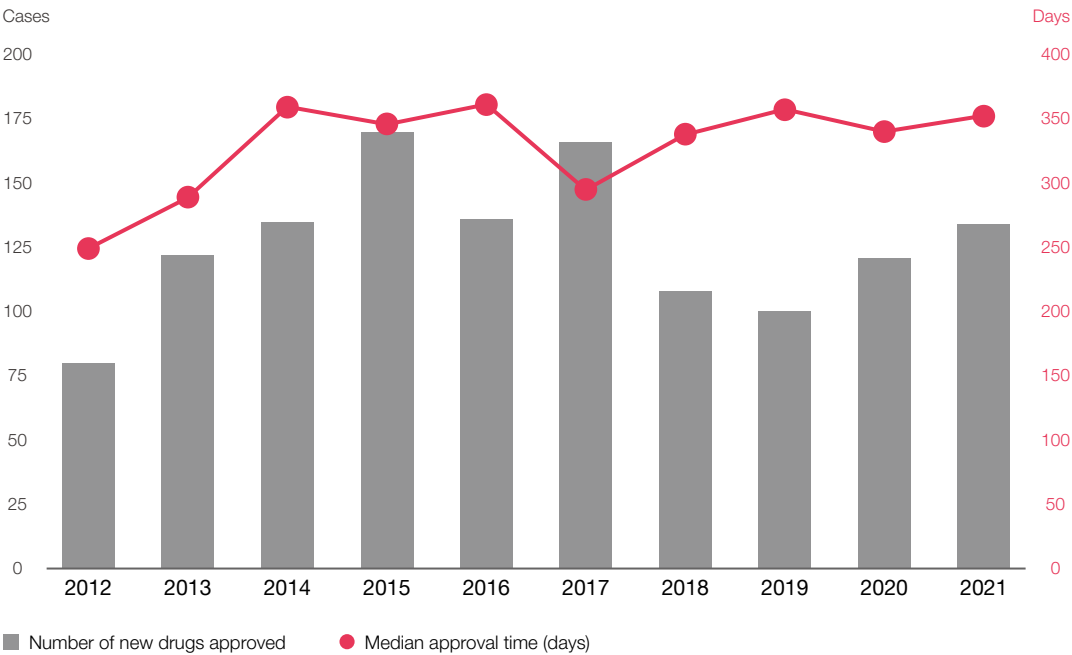
Source: Taiwan Food and Drug Administration.

Figure 25: Review pathways for new drug applications



Source: Taiwan Food and Drug Administration.

Figure 26: New drugs approved in Taiwan, 2012-2021



Source: Taiwan Food and Drug Administration.

Reimbursement and pricing

As the overall majority of pharmaceutical drugs in Taiwan are required to be covered under the NHI programme, the single public payer NHIA plays a leading role in the drug reimbursement and pricing decision-making process. After marketing approval has been granted by the TFDA for a new drug, the manufacturer must submit a separate application to the NHIA for inclusion in the NHI reimbursement schedule for prescription pharmaceuticals—which lists more than 17,000 items. Obtaining a positive reimbursement decision is seen as a prerequisite for the commercial success of new drugs in Taiwan.

A listing on the NHI schedule is just part of a more lengthy process to obtain widespread access to the Taiwan market. Once approved for reimbursement, pharmaceutical companies still need to negotiate separate drug supply agreements with healthcare providers. As prescribing and dispensing of drugs is not separated in most of Taiwan's hospitals and clinics, this means that access to their formularies is vital for pharma suppliers. However, competition for space on providers' formularies—which seldom contain more than 1,000 drug products—is intense. Price is usually the key to securing formulary space.

Reimbursement listing approval

The pharmaceutical listing process involves initial scrutiny by expert groups, recommendations on a drug's benefit status by the NHI Joint Committee for the Pharmaceutical Benefits & Reimbursement Scheme (PBRs) and a final endorsement decision by the NHIA. The PBRs committee is composed of different stakeholders and is tasked with reaching a resolution on a drug's listing and pricing, which is supported by a Health Technology Assessment (HTA) report on the drug. HTAs are conducted by the CDE and involve a comprehensive evaluation of the therapeutic and economic value of new drugs.

According to the NHIA, the time from submission to listing for a new drug was 13.6 months on average in 2020, and 11.1 months in the 2013-2020 period. International pharmaceutical companies have long advocated the need for greater transparency and efficiency in the reimbursement approval process. They point to the lack of set time limits between key review milestones, and also that the scientific data a pharmaceutical company submits to the TFDA and NHIA for their registration and reimbursement processes is reviewed sequentially, creating delays.

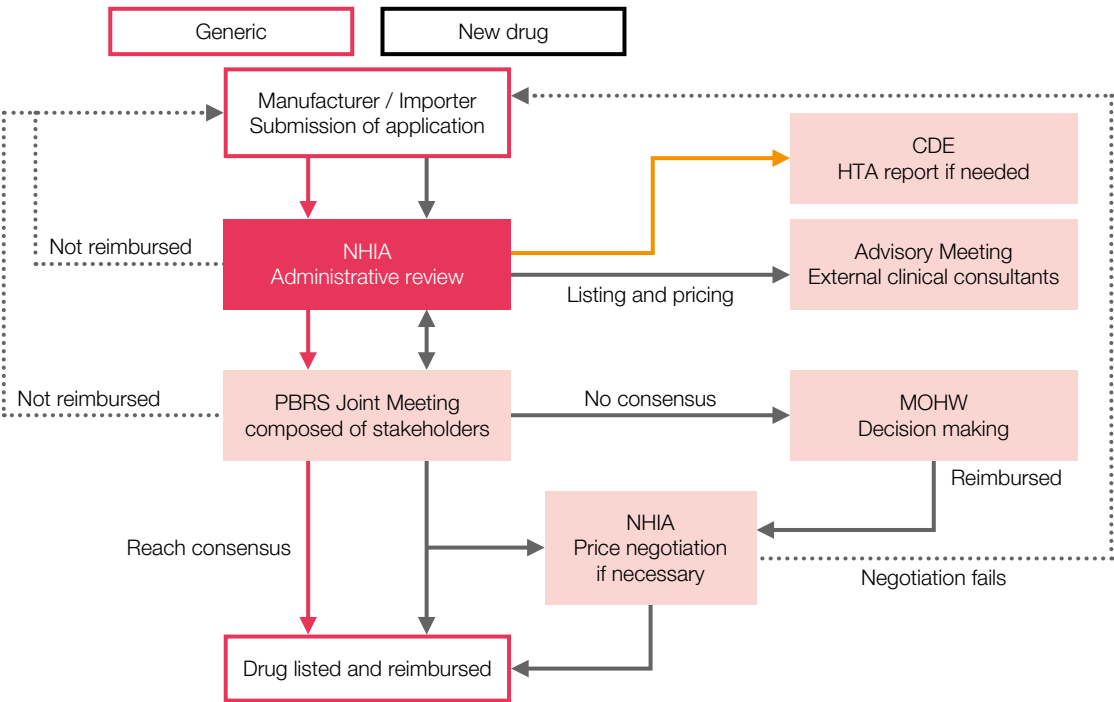
Reimbursement price setting

The NHIA typically acts to reduce the price that it's willing to reimburse for new drugs made available under the NHI scheme, as part of ongoing efforts to control healthcare and pharmaceutical spending. In general, the reimbursement price of brand-name drugs is determined with reference to the prices of these products in ten advanced countries (A10). It is usually set at the lower end of the comparative scale, with the result that NHI prices for new drugs are much lower than A10 median prices. Also, the reimbursement price of generics are typically set at 80%-90% of the price of the original brand drug.

To further control pharmaceutical expenditure, the cost of most new drugs is reviewed on an annual basis under the Drug Expenditure Target system introduced in 2013. Under this scheme, the NHIA sets a target for NHI drug spending for a year, and should actual expenditure exceed this figure, price adjustments will subsequently be made. This has resulted in several price reductions in recent years (see page 24). Low drug reimbursement prices and annual price cuts are a contentious issue for drug multinationals and may affect their willingness to bring new and innovative medicines into Taiwan.

Although NHIA has used price-volume agreements with drug manufacturers to a limited extent as part of its reimbursement model, it is only beginning to adopt risk-sharing agreements—also known as managed entry agreements (MEAs)—which are a way of accommodating innovative but often costly new medications without causing budgets to soar out of control. In 2018, the NHIA set out guidelines for entering into MEA schemes, which may take a variety of forms, some based on assessing the outcome of the drug treatment and some geared to the financial impact. However, international drug companies have increasingly expressed concerns about the implementation and execution of MEAs.

Figure 27: Pharmaceutical listing and pricing flowchart



Source: National Health Insurance Administration.

Figure 28: Reimbursement pricing of new drugs

Category		Pricing	Mark-ups
1	Breakthrough	Median price of A-10 countries	<ul style="list-style-type: none">Domestic clinical trials (10%)Domestic pharmacoeconomic study (up to 10%)Better therapeutic effects (up to 15%)Greater safety (up to 15%)More convenient (up to 15%)Pediatric preparations with clinical implications (up to 15%)
2A	Me-better	Capped at A-10 median price <ul style="list-style-type: none">Lowest price in A10Price in original countryInternational price ratio	
2B	Me-too	Treatment-course dosage ratio <ul style="list-style-type: none">A combination drug is priced at 70% of the sum of each ingredient's price, or at the price of the single active ingredient.	

Source: National Health Insurance Administration.

Note: A-10 reference countries include Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, US and UK.

Business environment

Taiwan is one of the more developed markets in the Asia-Pacific region and it is a net importer of pharmaceuticals. Drugmakers are attracted by its high level of per capita drug spending (US\$265 for 2020), which reflects a large and growing demand for chronic disease treatment as the population ages rapidly. A well-developed healthcare system also serves to support the sale of patented drugs. Posing downside risks to companies looking to launch innovative medicines in the market is the increasing policy focus on cost containment and use of price controls to curb healthcare spending.

The patented drug market is still dominated by pharma multinationals, but Taiwanese firms have started to invest more heavily in researching and developing new drugs. Most of the leading foreign drugmakers are active in Taiwan, mainly focusing on sales and marketing, and they generally use a local pharmaceutical products distributor. Some 378 domestic companies are currently engaged in pharmaceutical manufacturing, largely production of APIs, finished generics or both. Recent phased-in compliance with global PIC/S GMP standards has helped sharpen their export competitiveness.

Research and development

R&D is a critical component of the pharmaceutical sector. Multinational research-based drugmakers continue to lead the way in pharma R&D innovation globally. Most Taiwanese drug manufacturers still focus on the development of generic versions of existing compounds, though some have begun to pursue the creation of more added-value products through the development and application of new formulation or delivery techniques. Interest in the research and development of novel medicines has also risen, and involves both academic institutions and a growing number of local biotech companies.

In recent years, the government has implemented several initiatives and policies to make Taiwan an attractive destination for R&D investment in the biotechnology and pharmaceutical sectors. In 2016, the government launched the Biomedical Industry Innovation Programme, which seeks to establish Taiwan as a R&D hub for the biomedical industry in the Asia-Pacific region. To help achieve that goal, the BIIPP actively promotes academic-industry research collaboration with international pharmaceutical firms, and also encourages foreign drugmakers to set up research centres in Taiwan.

Pharmaceutical retail sector

The principal sales channels for pharmaceuticals in Taiwan are hospitals, clinics and pharmacies. Taiwan has some 35,300 registered pharmacists, of which 45% work in pharmacies located within hospitals and clinics. The remainder work at 8,100 community pharmacies, of which around 6,700 are contracted with the NHIA and allowed to dispense reimbursed prescription drugs. However, only 10% of all prescriptions are dispensed in community pharmacies, reflecting the reluctance of hospitals and clinics to forfeit profits made on the purchase and sale of medicines by their in-house pharmacies.

As a result, community pharmacies must rely on the sale of OTC medicines, which may be sold in licensed premises without a doctor's prescription, and consumer health products. The market share of OTC drugs in Taiwan is low at 7%, yet pharma companies see potential growth opportunities, as the NHIA continues to cut the prices of prescription drugs and is more proactive toward the transfer of prescription drugs (Rx) to OTC status. Changing consumer behaviours, such as higher awareness of personal health issues and a greater willingness to self-medicate, will be another influential factor.



Medical device sector

Taiwan's medical device sector encompasses a wide range of equipment and products used for diagnosis or therapy in patients—everything from simple tapes and adhesives to apparatus used in surgical procedures to sophisticated testing and diagnostic equipment. These are broadly classified into five groups: diagnosis and monitoring; surgery and treatment; in vitro diagnosis; assistance and compensatory; and other medical devices. Taiwan is a world leader in a number of products, including contact lenses, blood glucose and pressure meters, electronic thermometers and electric wheelchairs.

The total domestic market for medical devices (including imports) was worth NT\$187bn (US\$7bn) in 2021, having grown at a CAGR of 7.7% since 2016. Due to the market's limited size, Taiwanese medical-device makers rely on exports for around 60% of their revenues, mostly for mid-to-low-end medical equipment and contracted manufacturing for multinationals. Nonetheless, Taiwan is highly dependent on imports for some 60% of domestic demand, mostly for high-end surgical, therapeutic, and medical imaging devices used in hospitals and supplied from the United States, Europe and Japan.

Further steady growth in the sector is expected in the coming years on account of Taiwan's growing elderly population and related higher demand for assistive devices and bone implants, as well as the government's policy support for more higher-value medical device manufacturing. Research company Fitch Solutions forecasts the market will increase at a CAGR of 4.7% in the 2020-2025 period. The major constraint on growth will be the authorities' continued reliance on cost containment to control public healthcare expenditure, which will increase pricing pressures for medical device companies.

Future growth will be underpinned by government support for biomedical innovation. The Biomedical Industry Innovation Programme, launched in 2016, aims to establish Taiwan as a regional hub for biomedical R&D, and offers incentives to push domestic companies towards the manufacture of higher-end medical devices. Also, the recent implementation of the new Medical Devices Act, which separates the regulation of medical devices from pharmaceutical products for the first time, will bring improvements in regulatory efficiency as well as stimulate innovation in the medical device sector.

Table 7: Taiwan's medical device sector, 2012-2021

Unit: US\$ billion	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Revenue	3.7	3.9	4.1	4.2	4.4	4.8	5.3	5.5	6.5	8.4
No. of companies	705	761	781	1,041	1,073	1,090	1,128	1,157	1,219	1,241
Personnel	34,200	35,040	36,429	38,400	39,300	40,300	43,850	46,953	48,365	49,916
Export value	1.6	2.3	2.4	2.5	2.7	2.9	3.2	3.4	4.0	5.2
Import value	1.9	2.1	2.2	2.3	2.3	2.5	2.6	2.9	3.2	3.5
Import:Export	59:41	58:42	41:59	40:60	39:61	39:61	40:60	40:60	40:60	39:61
Domestic market size	4.1	3.7	3.8	3.9	4.0	4.4	4.7	5.0	5.8	6.7

Source: Industrial Development Bureau (MOEA), 2013-2022 Biotechnology Industry White Papers.

Regulatory environment

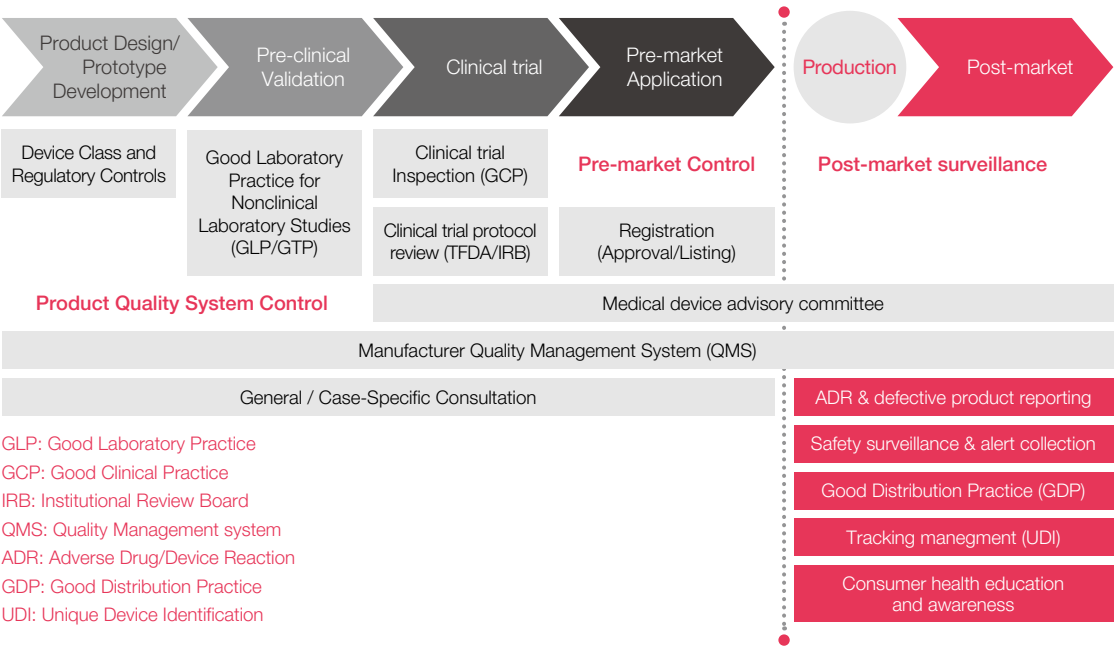
The TFDA is the regulatory authority for medical devices. It manages the medical device life cycle by auditing manufacturers' quality control systems, performing pre-market evaluations and conducting post-market monitoring and surveillance to protect consumers. TFDA's Division of Medical Devices and Cosmetics is responsible for supervision and administration, including product registration and approval, while its Division of Quality Compliance and Management enforces GMP regulations. The CDE assists the TFDA with conducting technical reviews of applications for medical device products.

The regulations for medical device management in Taiwan were originally set in the Pharmaceutical Affairs Act. Owing to the different characteristics of pharmaceutical drugs and medical devices, the new Medical Devices Act was enacted in 2020 to establish a separate legal framework for medical devices. The law took effect in May 2021, and the TFDA has established 22 sub-regulations to build a complete lifecycle management system for medical devices. It has also introduced various measures to give medical device makers time to transition and minimise the impact on the sector.

The separate medical devices legislation provides a more robust regulatory framework concerning the life-cycle management and risk classification of medical devices, from pre-market management (e.g. clinical trials, registration, manufacture and sales) to post-market control and surveillance (e.g. advertising, safety monitoring, adverse incident reporting and safety assessment) and post-market investigations. Most importantly, the new law will help rationalise the regulatory process and resolve many of the difficulties medical device companies faced before in meeting local legal requirements.

The Act establishes a standardised registration process for medical devices, as well as fast-track approvals for innovative products. Certain kinds of low-risk medical devices will be changed to an electronic listing with applicants required to report their devices through an annual declaration system. The statute also strengthens the management of medical device companies. In addition to defining such manufacturers according to manufacturing phases, legal entities that design and place devices on the market under their own name will also be incorporated into the category of manufacturers.

Figure 29: Medical device management framework



Source: Taiwan Food and Drug Administration.

Registration and approval

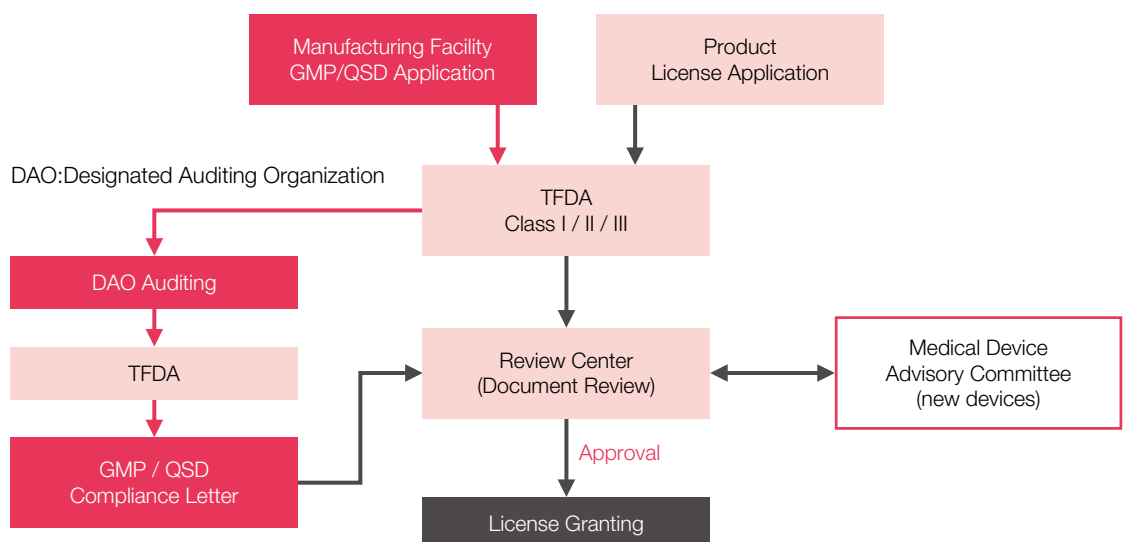
The local manufacturing or importation of medical devices is only allowed after a permit license—that grants registration and market approval—is issued by the TFDA. Medical devices are classified into low- (Class I), moderate- (Class II) and high-risk (Class III) groups. Devices that include materials or technologies novel to the Taiwan market will be classified as new medical devices and require pre-market approval, even if already approved for use by other internationally recognised regulators. These devices require extended review, including local testing, so lengthening the approval process.

Registration of Class I devices just involves a simple paper review, but that of Classes II and III devices, as well as new medical devices, requires the submission of detailed documents. In addition, most medical device manufacturers must submit quality system documentation (QSD) that meets Taiwan's GMP requirements for medical devices. From 2022, the TFDA accepts Medical Device Single Audit Program (MDSAP) reports in lieu of Establishment Inspection Reports (EIRs) as being sufficient to qualify an applicant for the expedited pathway for local licensing of a new medical device.

Under the TFDA's current two-step review process, medical device registration applicants first need to submit all administrative documents for review of their completeness. In the second stage, the TFDA will perform a technical review of the required pre-clinical testing documents pertaining to the product safety and performance of Class II and Class III devices; clinical reports may be needed for certain new medical devices. The TFDA's indicative times for the review and registration of Class I, II and III medical devices are 80 days, 140 days and 200 days, respectively, and 220 days for new devices.

In response to industry calls to reduce pre-market registration times, the TFDA has sought to simplify documentation requirements as well as shorten the registration process for medical devices. In 2017, it introduced a priority review programme for medical devices, which seeks to expedite the approval process for innovative medical devices and devices in urgent demand. Also, in January 2022, the TFDA launched a new online pre-market application platform, which aims to provide manufacturers an alternative way to submit pre-market application documents for medical devices.

Figure 30: Medical device registration process



Source: Taiwan Food and Drug Administration.

Reimbursement and pricing

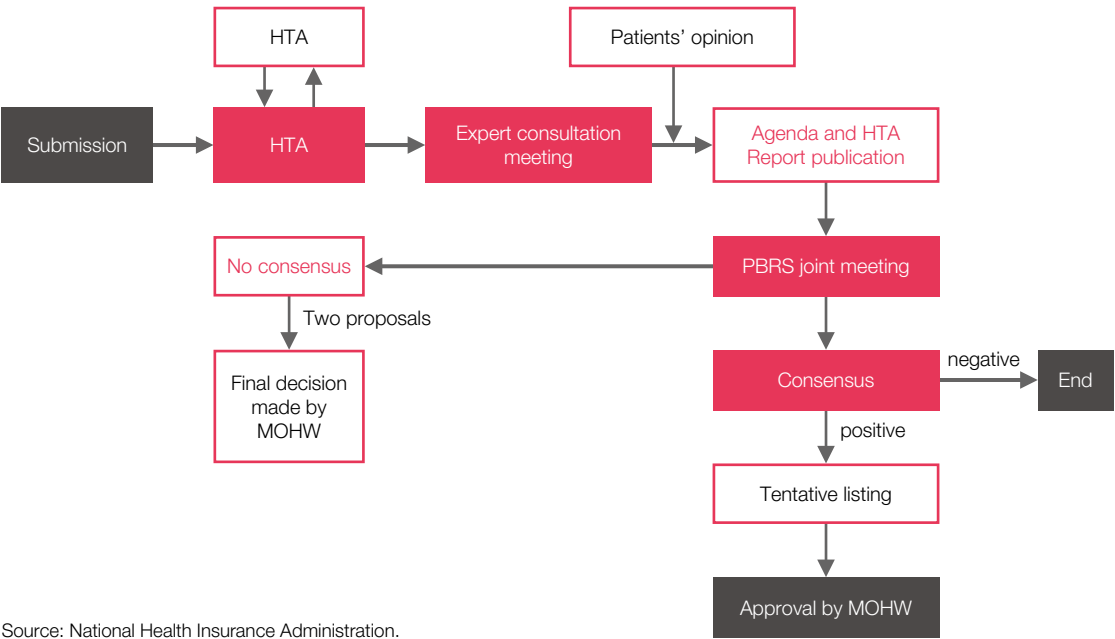
All medical devices must apply for reimbursement review, even if a self-paid product is desired, with the listing and pricing of new devices decided by the NHIA. Once marketing approval is granted by the TFDA, medical device manufacturers have to then submit a new product application to the NHIA. Following its evaluation by the PBRS committee of various stakeholders, the NHIA decides whether or not to list a new medical device for reimbursement, and any restrictions on coverage. If listed, its price will be set by the NHIA and the medical device can then be used at any healthcare facility in Taiwan.

Medical devices are paid for either under a fee-for-service or a diagnosis related group-based scheme, Reimbursement is based mainly on the product’s functionality, with all medical devices performing the same function reimbursed at the same price. Industry players argue this does not differentiate between lower-cost devices and more advanced, higher quality products, and may thus discourage the introduction of innovative devices into Taiwan. Also, the NHIA typically sets reimbursement prices low for new medical devices, compared with similar products currently on the market, as with drugs.

Because of the expenditure caps imposed by the NHI’s global budget and DRG systems, hospitals bargain to obtain transaction prices lower than the reimbursement prices for medical devices in order to make up for shrinking payments for patient care. To ensure reimbursement rates reflect the actual prices that hospitals are paying vendors, the NHIA makes periodic price adjustments to reimbursable medical devices using price-volume surveys. As products may undergo several rounds of surveys and price cuts, this could cause newly marketed devices to lose price competitiveness over time.

A balance billing system allows partial patient self-pay for certain higher-end medical devices, which are often more expensive than similar items in the NHI fee schedule—nine categories are currently listed as balance billing items. Whenever a patient wishes to use such a special device, the NHIA will reimburse the basic payment of a similar existing item and the patient pays the rest. Furthermore, patients have the option to self-pay, out of pocket for devices not approved for reimbursement. But in order for the device to qualify for this option, it must first be assigned a self-pay code by the NHIA.

Figure 31: Reimbursement listing process for new medical devices



Source: National Health Insurance Administration.

Business environment

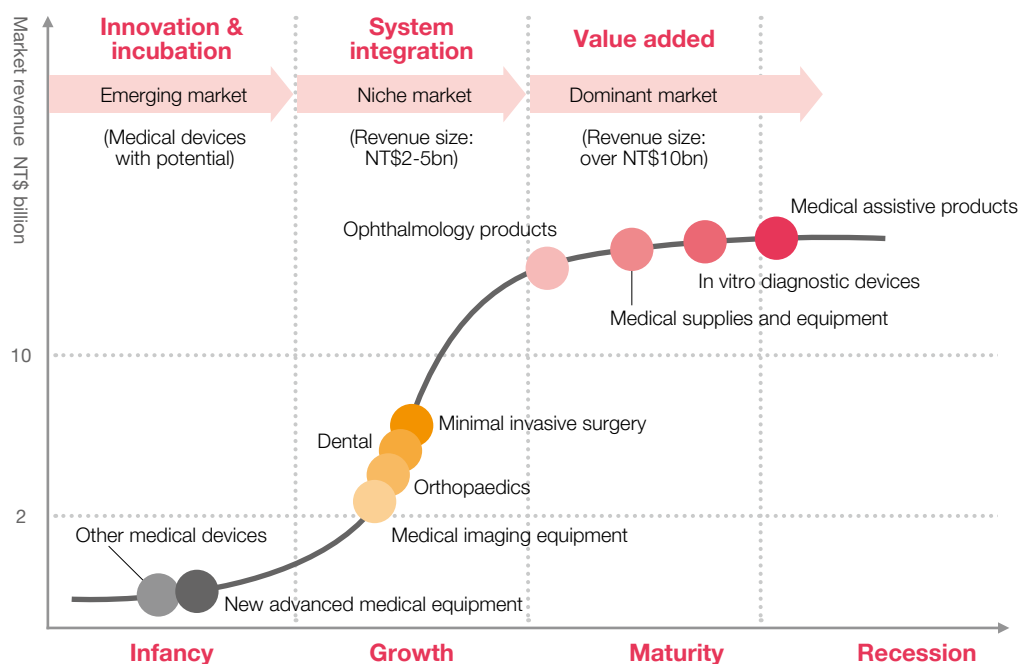
Taiwan's medical device manufacturing sector is dominated by small to medium enterprises, which mostly produce and export mid-to-low-end medical equipment, and conduct contract manufacturing for multinationals. Even so, the sector is growing in sophistication and expanding into new and high-value product areas, backed by strong government support. For example, it has actively promoted the development of 3D printed medical devices, which have a growing presence in a number of product areas, and it has established a medical 3D printing cluster within the Southern Taiwan Science Park.

In recent years, the government has endeavoured to move the medical device sector up the value-added chain, as part of its wider policy goal to build Taiwan into a regional biomedical R&D hub, while addressing the growing needs of Taiwan's rapidly ageing population. Special medical device clusters across Taiwan support new product development efforts. Also, the authorities facilitate upstream and downstream integration in the medical device value chain, such as technology transfers from research institutes to manufacturers, and firms partnering with hospitals to develop new medical equipment.

The global digital transformation trend also offers a significant market opportunity for the medical device sector to help take healthcare to the next level. The trend is attracting a growing number of Taiwanese technology companies to diversify into the biomedical industry to develop innovative smart medical devices that leverage new technologies. These include the use of AI, Big Data and IoT to develop affordable and comprehensive healthcare solutions (focused on digital health, medical imaging, decision support and precision medicine) to improve overall healthcare sector performance.

The sector received an impetus in May 2021 when the TFDA established a smart medical device office, which aims to better coordinate regulations for advanced healthcare equipment while promoting the development of AI- and machine learning-based medical devices. It provides consultation, assistance, training and a matchmaking facility. To encourage the R&D of domestic products, the TFDA has also set several digital health-related guidelines, including for AI and machine learning, software as a medical device, cybersecurity and computer-aided detection and diagnosis devices.

Figure 32: Development status of Taiwan's medical device sector



Source: Industrial Development Bureau (MOEA), 2019 Biotechnology Industry White Paper.



How PwC can help

PwC helps organisations across the health continuum from strategic vision to tangible results.

Our health industries practice in Taiwan focuses on the healthcare, pharmaceutical and life science areas, and our people bring industry experience as it pertains to assurance, tax and advisory services.

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Advisory services

We help health industries clients determine the right strategic priorities to grow profitably and maximise value, and offer support and practical solutions to achieve these objectives. Our service areas include deals, strategy, operations, technology, finance, people and change, risk and forensics. We can assist you with strategic planning and market analysis, as well as with all aspects of the M&A deals process.

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