pwc 資誠

Guide to Taiwan's health industries

September 2024

Contents

This publication was compiled by Damian Gilhawley, an industry specialist at PwC Taiwan. The content is drawn from publicly available information and is current as of 31 Aug. 2024, unless otherwise stated.

Foreword

Health systems around the world are facing a host of challenges, including ageing populations requiring more care, rising healthcare costs, a shortage of medical workers and the recovery from the Covid-19 pandemic.

At the same time, consumers and patients are expecting new clinical and care delivery capabilities (centred around digital solutions) and better experiences from health systems across their end-to-end care journeys.

In response, health systems are working to transform towards a more sustainable model of care delivery, as can be seen in Taiwan's efforts to build on its successful Covid response and accelerate healthcare innovation.

Taiwan has a high performing healthcare system that is recognised for its universal health coverage and care, but it faces mounting pressure to meet the rising demands of a fast ageing population and chronic diseases.

Digital health is playing a key role in countering those challenges, as seen in the growing number of strategic alliances between local medical institutions and businesses in innovative areas such as AI, Big Data and IoT.

Furthermore, the government is actively fostering the growth of Taiwan's biomedical industry and accelerating the development and commercialisation of emerging medical technologies and treatments for precision health.

These innovation activities are attracting growing interest from international health and biomedical companies in Taiwan's health industries market and the potential opportunities for growth, investment and collaboration.

In view of that, PwC has compiled this comprehensive introductory guide for organisations wanting to know more about Taiwan's healthcare system and its biotechnology, pharmaceutical and medical device sectors.

We hope you will find the guide to be a useful reference resource. If you would like more information or have questions about Taiwan's health industries and how we can be of help, please do not hesitate to contact us.

Lily Wong
Health Industries Advisory Leader
PwC Taiwan

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 provision of high-quality and affordable healthcare and medical services for all.
- The government-run compulsory national health insurance (NHI) programme provides the population with easy access to an extensive 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 since there is no strict gatekeeper or referral system.
- The healthcare system is highly digitalised, making extensive use of health information technology to assist administration, clinical care and public health, and it is built around a credit-card-sized NHI smart card.
- National health expenditure is low by international comparisons, reflecting the monopsony power of the government, as the single buyer and payer of healthcare services through the NHI, to control spending.
- The NHI uses a global budget payment system, which caps reimbursement levels for medical services, to constrain the rapid growth of healthcare expenditure, with shortfalls largely borne by medical institutions.

Main challenges

- A rapidly ageing population and a growing chronic disease burden, together with the rising costs of new medical technologies and advanced treatments, are putting increasing strain on the healthcare system.
- A major structural issue is the 'all-you-can-eat' provisions of the NHI programme and relatively weak constraints on demand and supply, which encourages overuse and wastage of healthcare resources.
- The lack of a primary care gatekeeper allows for patients to seek treatment for minor ailments at hospitals, leading to overcrowding and overworked conditions for health workers and causing retention problems.
- Supply-induced demand for medical care also drives up health resource utilisation, as the prevailing fee-for-service reimbursement mechanism incentivises hospitals to compete for outpatient business with clinics.
- Due to underfunding and fiscal constraints, the NHI's adoption of cost-containment measures has led to challenges in balancing costs and medical care, impacting patient access to new and innovative drugs.
- With the NHI continuing to face mounting financial pressure due to rising healthcare demand and costs, there is a pressing need for additional funding and deeper reforms to ensure the scheme's sustainability.

Executive summary

Taiwan's biomedical industry

Industry overview

- Taiwan's biomedical industry—including biopharmaceuticals, medical devices, health and wellness and other emerging fields—is a priority focus for promotion and development under government initiatives.
- Strong policy support and investment has produced a comprehensive biomedical ecosystem spanning the entire industry value chain, from research, discovery and development to manufacturing and marketing.
- This report primarily focuses on the industry's three core pillars of applied biotechnology, pharmaceuticals and medical devices, which together represented a total domestic market size of US$17.8bn in 2023.
- The current industry focus is on biomedical innovation, centred on the development of precision and digital health solutions, which is creating opportunities to transform patient care and improve healthcare delivery.
- The topics of regenerative medicine, precision medicine and digital health are also discussed throughout this report, given their importance for the future growth and direction of the overall biomedical industry.

Biotechnology sector

- Decades-long government support and commitment has helped drive the expansion of the biotechnology sector since the 2000s, which has quintupled in market size over the past 20 years to US$4.7bn in 2023.
- The sector is highly rated for its investment attractiveness due to its complete biotechnology infrastructure and value chain, as well as ample clinical trial experience and cost-competitive R&D and manufacturing.
- Growth momentum remains strong, supported by the continued promotion of innovative biomedical R&D and investment, a robust biotech IPO market and the maturation of drug pipelines and service offerings.

Pharmaceuticals sector

- Taiwan is a net importer of pharmaceuticals, reflecting a large and growing demand for chronic disease treatments as the population ages rapidly, with the sector having a market size of US$7.8bn in 2023.
- The tight-budgeted hospital market accounts for 80% of total pharmaceutical sales, which limits profits for drugmakers, and this is further compounded by a long reimbursement timeline and annual price reviews.
- As demographic and epidemiological trends will increase future demand for new drugs, the government plans to speed up the approval process and provide more funding for breakthrough drugs and treatments.

Medical devices sector

- A fast-ageing population and related higher demand for healthcare products and services, especially for advanced devices, is driving growth in the medical devices sector, which was worth US$5.3bn in 2023.
- The sector depends on imports for 60% of domestic demand, mostly for high-end devices used in hospitals, while local device makers rely on exports of mid-to-low-end medical equipment for 60% of their revenues.
- Current efforts to move up the value chain seek to increase higher-value device manufacturing and greater uptake of new medical technologies, which is underpinned by government policy support and guidance.


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1. Taiwan's healthcare system


Vol
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cmH2O
TVinsp ml
Ppeak
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Pplat
TVexp ml
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24
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Art 200
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NIBP
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Sys
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Manual
T1+T2
°C
T1
T2
T2-T1
Silence Alarms
Freeze
Take Snapshot
Alarms Setup
Record/ Print
ECG
Help
Reset Case
Trends
Monitor Setup
Patient Data

1.1 Healthcare overview

Taiwan has one of the top healthcare systems in the world, according to several international rankings. A key reason is the National Health Insurance (NHI) programme, which provides universal and affordable health coverage and care to the island's 23 million population of citizens and residents. Enjoying easy access to a comprehensive range of subsidised and high-quality healthcare and medical services, and facing few limits on their choice of provider or doctor, public satisfaction with the NHI remains consistently high at about 80%-90%.

Some of the 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 globe, due in large part to the experience and capabilities of its health sector. In addition to leveraging the lessons learned from the 2003 SARS epidemic, Taiwan's early successful response to the pandemic was made possible through integrating innovative health information technology and a robust healthcare infrastructure.

Such achievements notwithstanding, the NHI, like many other healthcare systems around the world, has encountered numerous challenges over the years, including serious financial deficits. The government has managed these through successive policy adjustments and reforms, in particular the implementation of a second-generation NHI in 2013. But even so, the NHI continues to face several issues, as highlighted by the return of deficits in recent years, which will necessitate further substantive reforms to secure its future viability.

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

A rapidly greying population and a growing chronic disease burden, together with the rising costs of new health technologies and treatments, are putting strain on the healthcare system. With Taiwan projected to become a super-aged society by 2025, NHI expenditure on elderly healthcare will grow sharply in the years ahead. Besides driving medical costs higher, ageing demographics will also entail a shrinking workforce and a reduced premium base, which, in turn, will exacerbate the sustainability issues currently facing the NHI programme.

The health authorities are already taking steps to address many of these issues, including efforts to shift some of the burden of primary care away from large hospitals, and greater use of cloud-based data-sharing platforms to reduce waste and inefficiencies and improve patient outcomes. Additional and deeper reforms will be needed over the mid- to long-term as demographic and epidemiological trends put mounting pressure on NHI finances. But healthcare is a politically contentious issue, so any major policy changes will likely be a protracted process.

After a new government took office in May 2024, the health authorities said they would implement NHI reforms and increase investments in healthcare to realise President Lai's vision of creating a healthier populace. This "Healthy Taiwan" initiative focuses on disease prevention and health maintenance, with goals ranging from decreasing deaths from cancer to ensuring the financial sustainability of the NHI system. The Presidential Office has established a Healthy Taiwan Promotion Committee to help expedite implementation of the plan.

The rest of this chapter looks more closely at the key elements of Taiwan's healthcare system—including its governance framework, delivery infrastructure and workforce, patient demand and resource utilisation trends, and healthcare expenditure and financing—and examines the major sustainability challenges facing the NHI.

1.2 Governance framework

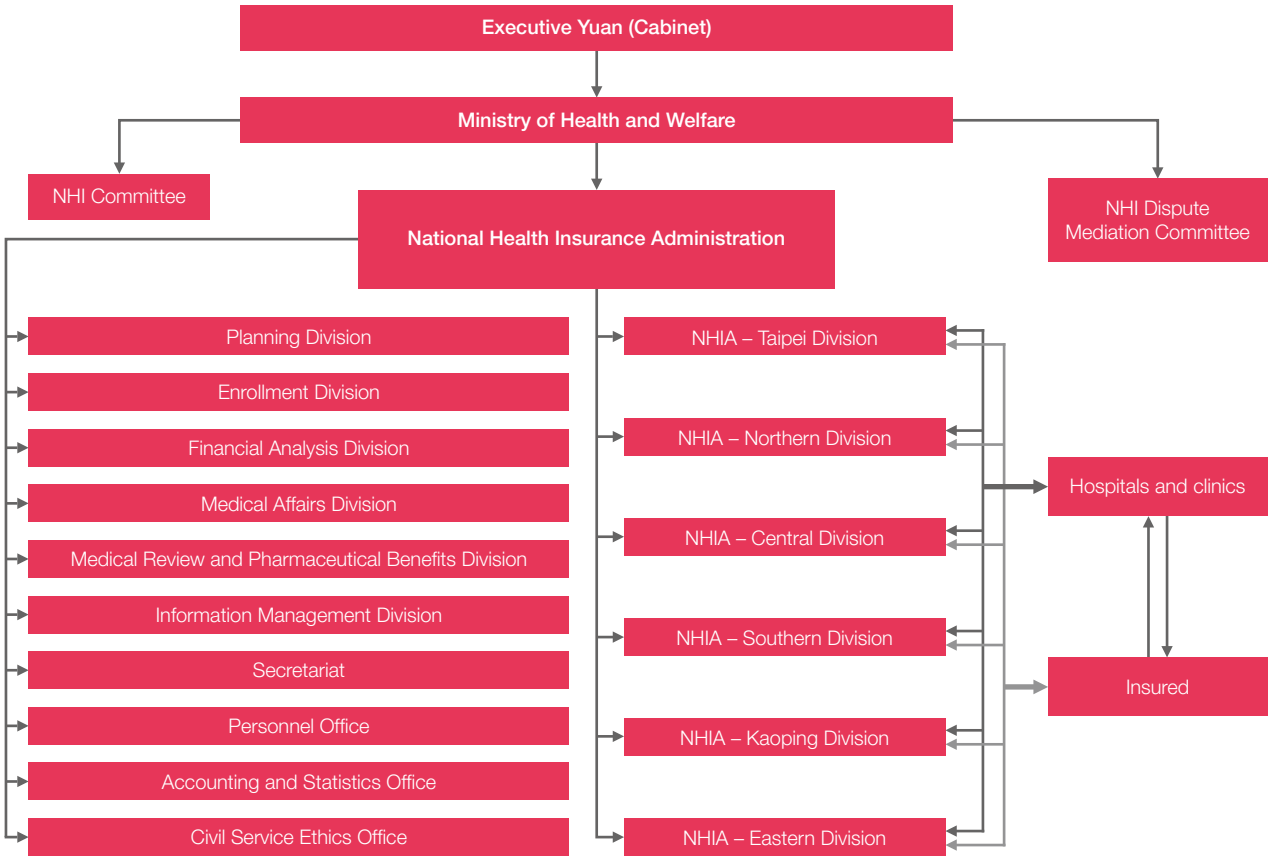
The Ministry of Health and Welfare (MOHW) is the main regulatory body for health and social welfare matters in Taiwan, and its mission is to promote the health and well-being of all citizens. Its responsibilities encompass health promotion, disease prevention and control, medical care, long-term care, food and drug management, social insurance, social welfare, social assistance and protective services. The MOHW also administers the operations of 26 medical institutions (mainly hospitals and psychiatric centres) and 13 social welfare institutions.

Taiwan has a two-level administrative structure of healthcare governance. At the central level, the MOHW is the responsible authority for overall health administration, including policy development and regulations, as well as the guidance, supervision and coordination of regional health bureaus. At the local level, there are 22 public health bureaus under the jurisdiction of city and county governments, which are responsible for managing health and medical care matters within their respective areas, as well as 374 public health centres islandwide.

The MOHW has six subordinate agencies which look after different areas of health and social welfare. These include the Taiwan Centers for Disease Control (CDC); Taiwan Food and Drug Administration (FDA); Health Promotion Administration (HPA); National Health Insurance Administration (NHIA); National Research Institute of Chinese Medicine (NRICM); and the Social and Family Affairs Administration (SFAA). The NHIA oversees and administers Taiwan's national health insurance programme, commonly known as the NHI (see Figure 1).

The MOHW supervises the NHI through its NHI Committee, which helps plan and monitor NHI-related tasks, and its NHI Dispute Mediation Committee deals with health insurance disputes. As the single-payer insurer, the NHIA is responsible for managing health insurance affairs, medical quality, research and development, manpower training and information management. The organisation's operations are supported by six regional offices connected by a health information infrastructure and are funded out of the central government budget.

Figure 1: Organisation of Taiwan's health system



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

1.2.1 NHI programme overview

The NHI was established in 1995 to provide universal health protection by merging and enlarging Taiwan's then-existing social health insurance schemes, which at that time covered only around 60% of the population. Coverage under the NHI is now close to 100% as enrolment is mandatory for all citizens and foreign residents, who have access to healthcare services in case of illness, injury and childbirth. The scheme is primarily funded by a payroll-based insurance premium which is jointly borne by the insured, employers and the government.

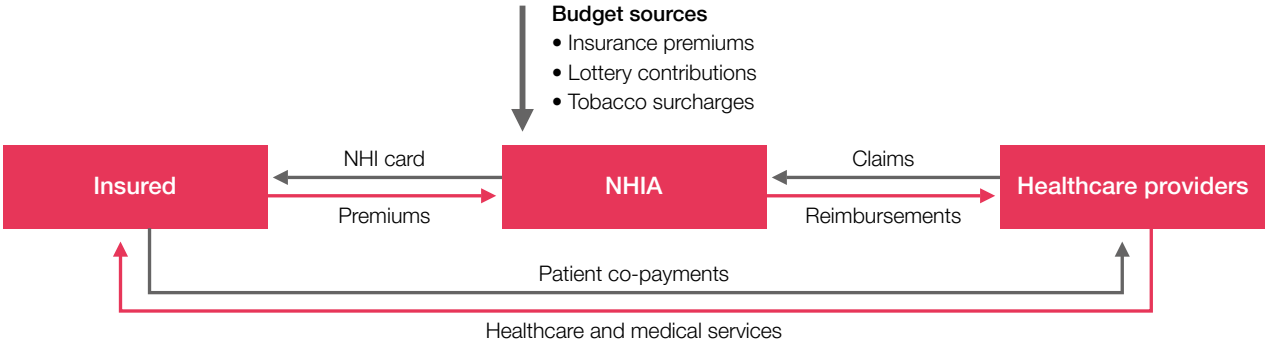
This general NHI premium is based on an insured person's monthly salary at the current rate of 5.17%, and it is also payable for dependents. In addition, the insured are charged a supplementary NHI premium of 2.11% on certain other types of income they receive. Together the premiums account for about 90% of NHI revenues, with the balance coming from government premium subsidies for low-income households and other specific groups, fines on overdue premiums, public welfare lottery contributions and tobacco health and welfare surcharges.

The NHI offers a comprehensive benefits package which covers all medically necessary services. This 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 services are to be covered by the NHI in consultation with a broad range of stakeholders, and such decisions are subject to budgetary considerations.

The bulk of NHI-covered services are provided through a predominantly private healthcare delivery system, though some hospitals are owned and operated by public authorities. While it is voluntary for providers to participate in the NHI programme, around 92% of hospitals and clinics in Taiwan have joined it. Contracted facilities file claims with the NHIA for reimbursement of services provided to insured patients, and they are reimbursed according to plural payment programmes under a global budget payment system (see Figure 2).

Individuals enrolled under the NHI programme enjoy almost free access to healthcare. The premiums collected by the NHIA are used to help pay for the healthcare expenses of the insured, although co-payments are required for outpatient care and prescription drugs and co-insurance for hospital stays, subject to limits and exemptions. To ensure that people who need healthcare are not denied access because of their financial circumstances, individuals meeting certain conditions are exempt from co-pays, such as patients with catastrophic diseases.

Figure 2: Framework of the NHI programme



Source: National Health Insurance Administration.

1.3 Healthcare delivery infrastructure

Providing equal access to healthcare is a foundational pillar of Taiwan's NHI programme, and so the insured have freedom of choice among different providers. They also receive unfettered access to doctors, including hospital-based specialists, since there is no requirement to register with a primary care physician (as in the UK). The NHIA ensures that access by maintaining an extensive network of contracted providers, which is a mixture of public and private hospitals and clinics, dentistries, pharmacies and other facilities (see Figure 3).

In general, provider licensing by local health authorities and hospital accreditation by the Joint Commission of Taiwan (JCT) are trusted to assure an acceptable standard of care, and serve as the basis for contracting with the NHIA. According to the Medical Care Act, there are two types of medical care institutions: hospitals and clinics. Based on accreditation results, hospitals are classified as medical centres, regional hospitals and district hospitals. Also, medical care and treatment is divided into Western medicine and traditional Chinese medicine.

The institutions in each tier are expected to fulfill distinct functions in healthcare service delivery. Clinics and district hospitals are primarily responsible for monitoring and treating stable chronic diseases, whereas regional hospitals and medical centres focus on teaching, research and providing care for emergency cases and challenging diseases. Although Taiwan has a bi-directional referral system in which patients can be referred between higher and lower tiers, patients can directly access any level of healthcare/specialists without a referral.

There is a high level of healthcare-seeking behaviour in Taiwan, as it is part of the local culture to take medicines or to seek medical help frequently, even for minor ailments. With no gatekeeper restrictions under the NHI, people tend to flock to large hospitals regardless of whether they have serious or mild illnesses, which has led to an over-expansion of tertiary medical institutions dominating outpatient primary care delivery. To address this imbalance, the health authorities have sought in recent years to strengthen a tiered medical care system.

Since 2017, the MOHW has been actively promoting a tiered approach to healthcare in an effort to allocate resources more efficiently and engender better healthcare-seeking behaviour. The policy aims to progressively reduce the number of outpatient visits to larger hospitals by setting target goals, while at the same time increasing the public's use of primary care facilities. It encourages two-way referrals for transferring patients between the higher and lower tiers, with co-payment incentives for patients to seek care at the lower tiers first.

Figure 3: Status of medical institutions in Taiwan, 2022-2023

Medical care institutions*	23,896
Hospitals	476
Clinics	23,420
Pharmacies	8,665
Nursing institutions	1,593
General nursing homes	525
Psychiatric nursing homes	46
Home care practices	752
Post-natal nursing institutions	270
Blood donation institutions	18
Blood donation centres	4
Blood donation stations	14
Pathology institutions	11

Other medical institutions	5,611
Midwifery practices	24
Medical examination clinics	355
Medical care radiological clinics	47
Physical therapy practices	411
Occupational therapy practices	133
Mental counselling clinics	202
Psychotherapy clinics	114
Speech therapy centres	103
Dental technology centres	994
Hearing clinics	30
Home respiratory care practices	15
Optometry practices	3,144
Nutrition counselling institutions	39

* The number of hospitals and clinics is for 2023 and the other data is for 2022.
Source: Ministry of Health and Welfare.

1.3.1 Hospitals and clinics

Taiwan had a total of 23,896 medical care institutions in 2023, comprising 476 hospitals and 23,420 clinics, the vast majority of which are contracted with the NHIA (see Table 1). Most of the hospitals (83%) and an even greater proportion of the health clinics (98%) are privately owned, and many are small in size. Western medicine, with its emphasis on diagnosis and treatment, is the predominant form of care, representing 53% of all registered healthcare providers, followed by dental clinics (29%) and Chinese medicine institutions (18%).

The overall number of hospitals has decreased in recent decades due to the closure or mergers of small district hospitals amid increasing competition from larger and better-resourced regional hospitals and medical centres (see Figure 4). The existing facilities have grown in size and opened more beds to boost efficiency and revenues—total hospital beds grew from 114,179 in 2000 to 138,664 in 2023, with two-thirds owned by private entities. Taiwan currently has 5.9 hospital beds per 1,000 population, higher than the OECD average of 4.3.

The reason for the high level of private sector involvement in healthcare delivery is that the NHI was designed from the start to attract non-public investment, since the public health infrastructure was not capable of meeting the jump in demand triggered by the scheme's implementation in 1995. Private hospitals currently outnumber their public counterparts by more than five to one. Many are organised as foundations in order to enjoy the tax benefits afforded to not-for-profit medical institutions, although most of them behave as if they were for-profit.

In 2022, 79% of 238 medical institutions that received more than NT$200m (US$7m) in NHI payments reported surpluses on medical-related income. Hospitals are mostly paid fee-for-service and also derive revenues from direct payments for non-NHI-covered services and goods, co-pays for outpatient services and co-insurance for inpatient services and registration fees collected at the time of service. Many also depend on non-medical business income (from food courts, parking lots, etc.) to balance fiscal gaps from shrinking NHI reimbursements.

Competition for revenues under the NHI's global hospital budget system is intense. Hospitals are therefore under pressure to be more efficient, compete for patient volume and provide more services with higher margins; their business strategies include mergers, expanding market share and direct-to-consumer advertising. This heightened competition creates a supply-induced demand for medical care services under the predominantly fee-for-service reimbursement system, which in turn contributes to the high utilisation of healthcare resources.

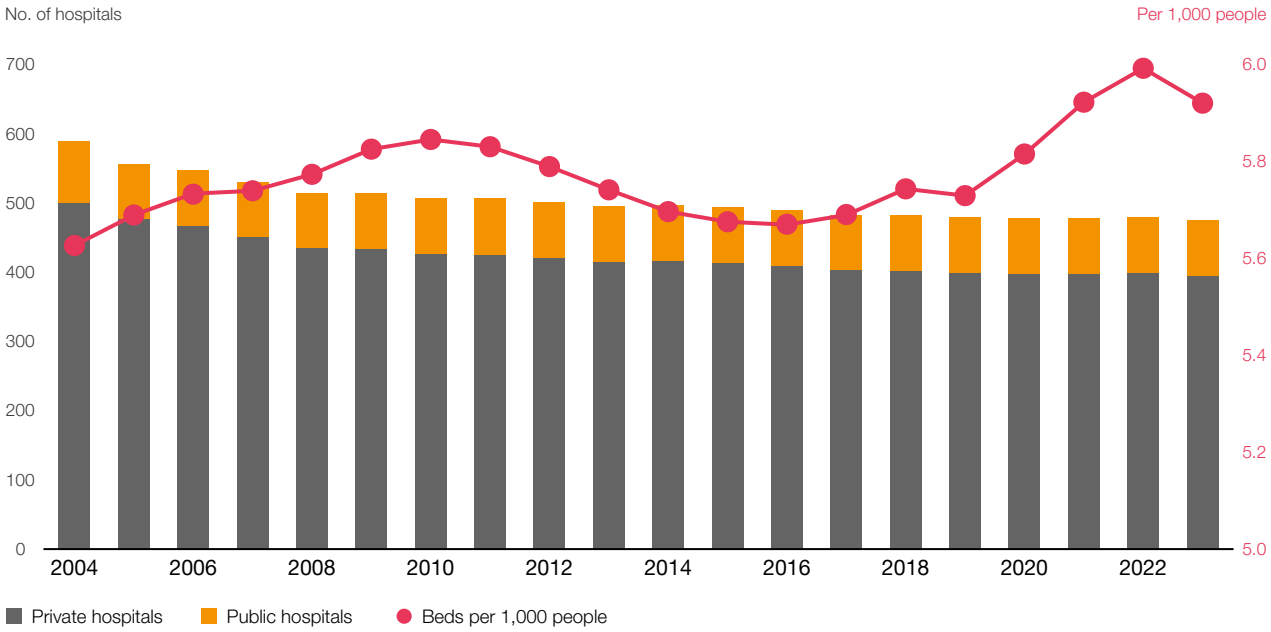
As for primary care clinics, their total number grew from 17,413 in 2000 to 23,420 in 2023, consisting of 12,200 Western medicine clinics, 7,026 dental clinics and 4,194 Chinese medicine clinics (see Figure 5). The increase has been supported by the government's efforts to reduce patient reliance on hospitals for the provision of primary care services, and the growing trend for cosmetic and aesthetic treatment services. Around 40% of Taiwan's doctors work as private practitioners in their own clinics and 80%-90% of clinics are solo practices.

Table 1: Number of NHI-contracted hospitals and clinics, 2023

	Total	Western medicine hospitals	Chinese medicine hospitals	Dental hospitals	Western medicine clinics	Chinese medicine clinics	Dental clinics
Medical care institutions	23,896	471	4	1	12,200	4,194	7,026
Contracted hospitals and clinics	22,085	467	4	1	10,759	3,961	6,893
% of contracted health facilities	92.4	99.2	100	100	88.2	94.4	98.1

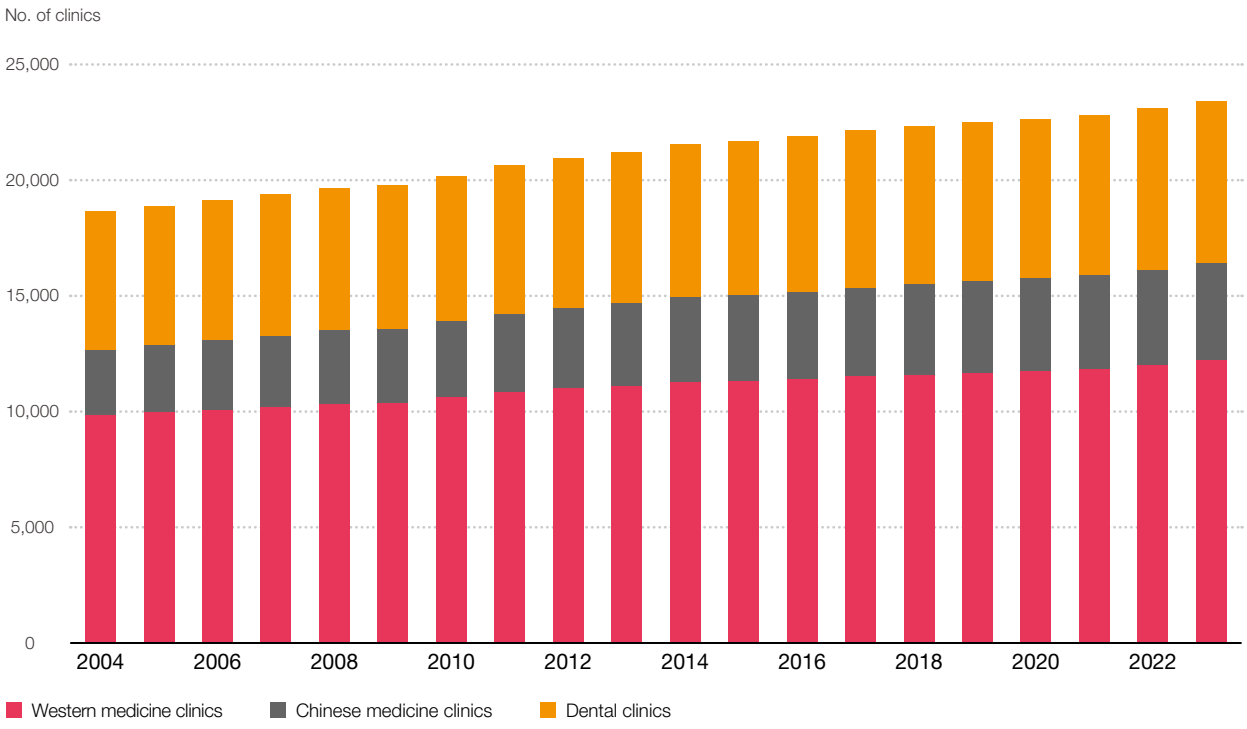
Source: Ministry of Health and Welfare and National Health Insurance Administration.

Figure 4: Number of hospitals and hospital beds in Taiwan, 2004-2023



Source: Ministry of Health and Welfare.

Figure 5: Number of primary care clinics in Taiwan, 2004-2023



Source: Ministry of Health and Welfare.

1.3.2 Doctors and nurses

Taiwan's healthcare system faces workforce challenges, exacerbated by limited NHI funding for hospitals. In 2023, Taiwan had 61,849 doctors (both Western and Chinese medicine) and 154,106 nurses, or 2.6 doctors and 6.6 nurses per 1,000 population (see Figure 6), both lower than the respective OECD averages of 3.7 and 9.2. That is partly because the number of health professionals in Taiwan is controlled by quotas, with medical school recruitment capped at 1,300 a year. Also, staff shortages have become an issue in recent years.

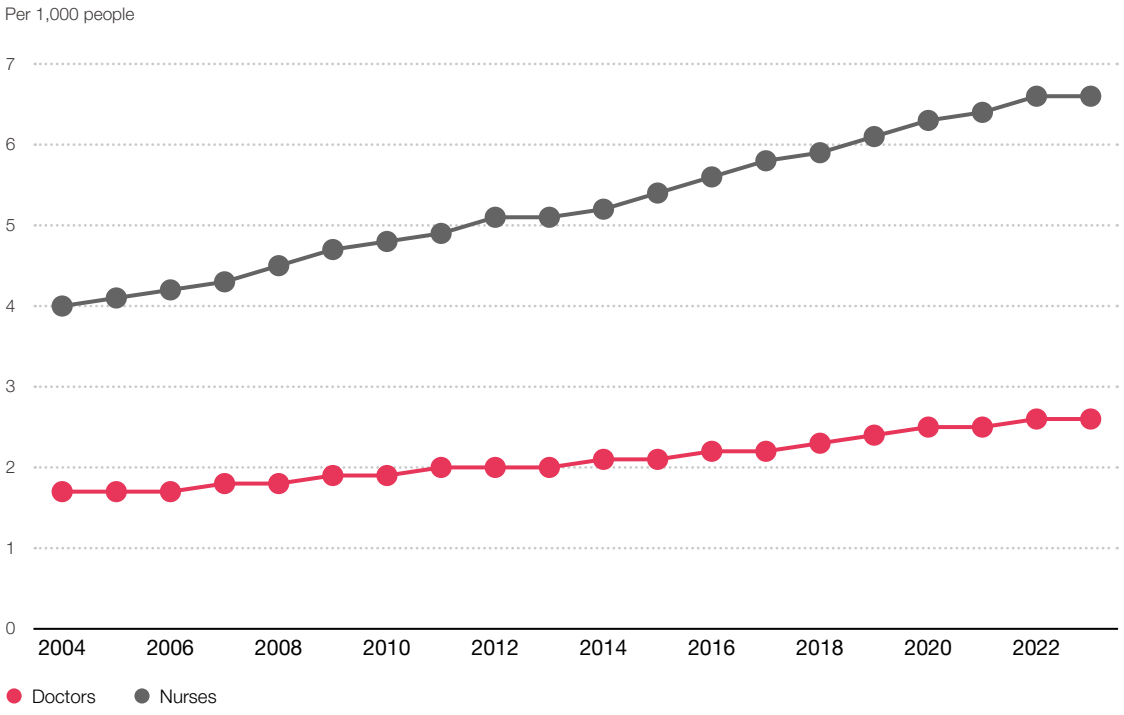
Some 40% of Taiwan's doctors practice in their own clinics and the rest work in hospitals as employees; hospital-based physicians in all specialities also see patients on an outpatient basis. There is no shortage of registered doctors per se, only in certain specialties due to poor working conditions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

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

Most recently, in September 2023, the health ministry announced a broad incentive programme to add at least 67,000 nurses by 2030 to mitigate current shortages and meet future care demand. Key aspects include the implementation of new standards for nurse-to-patient ratios in hospitals for different shifts, providing financial incentives and higher wages for working night shifts, and changing the frequency and structure of the national nursing exam. The plan will cost about NT$18bn (US$560m) annually to implement over the next seven years.

The shortage of medical professionals has largely been brought about by the design of the NHI scheme—and in particular by its global budget system, which caps reimbursement levels for medical services. To contain costs, some hospital providers have sought to increase the workloads of doctors, nurses and other medical staff. The resultant deterioration in working conditions, coupled with low levels of pay, has led to shortages of doctors in some specialities as well as nurses, and poses a sustainability challenge for the healthcare system.

Figure 6: Number of doctors and nurses per capita in Taiwan, 2004-2023



Source: Ministry of Health and Welfare.

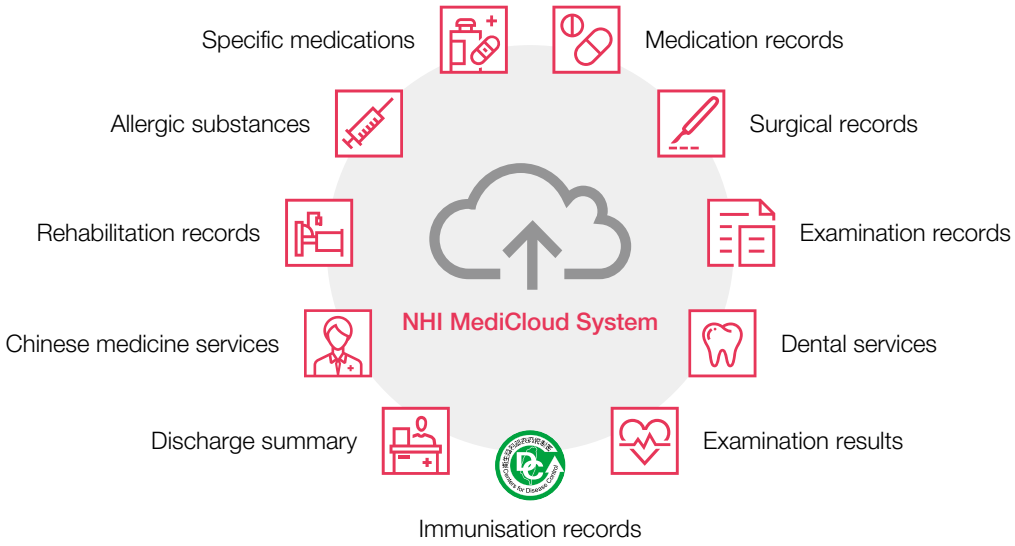
1.3.3 Digital healthcare

Taiwan's healthcare system is highly digitalised, making extensive use of health information technology 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 person to access medical care. The IC-embedded card is used to identify the individual, store a brief medical history and bill the NHIA. The patient presents it each time when using medical services, and the provider will then electronically submit a claim for reimbursement for the case-related charges.

The patient's health record is entirely electronic at every level of care. Contracted 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 enables it to identify and manage heavy users of services. The NHI claims data set constitutes the largest repository of people's health information in Taiwan.

In recent years, cloud computing technology has been increasingly applied to give the NHI card additional and more powerful functions, with the aim of reducing inefficiencies and improving the quality of medical care. For example, the NHI MediCloud system (see Figure 7) allows doctors to quickly retrieve a patient's medical records from different hospitals and other health facilities to prevent any duplication of medications and tests, while a personalised cloud-based service, My Health Bank, enables patients to check their own health records.

Figure 7: NHI MediCloud system



Source: National Health Insurance Administration.

Following the Covid-19 pandemic, the health authorities have strengthened their focus on digital solutions to expand healthcare access and improve patient outcomes. This includes the smarter integration of information, integrating clinical decision support information, real-time analysis and early risk prediction, and automated monitoring and remote support. Taiwan's strong ICT industry is contributing to this healthcare transformation effort, with solutions ranging from wearable devices and mobile health applications to telehealth platforms, etc.

As telemedicine (i.e., medical services via the Internet) became more widely used during the pandemic and is becoming a new normal for healthcare, the MOHW has progressively relaxed its rules on the provision of such services and expanded eligibility through a pilot programme, which started in 2021 and initially was only available to people living in remote areas. Telemedicine coverage is being broadened to include more geographical areas and medical conditions so as to better meet the needs of an increasingly ageing population.

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

1.4 Demand and utilisation trends

Coupled with rising incomes and advances in medical care technologies, the NHI has brought substantive improvements in public health since its inception almost 30 years ago. For instance, life expectancy rose from 74.5 years in 1995 to 80.2 in 2023, and infant mortality fell from 6.5 per 1,000 live births to 4.3 over the same period. Yet, Taiwan still lags behind several OECD countries on these and other key health outcome indicators, such as cancer mortality and survival rates, which has been partly attributed to insufficient health investment.

1.4.1 Chronic disease burden

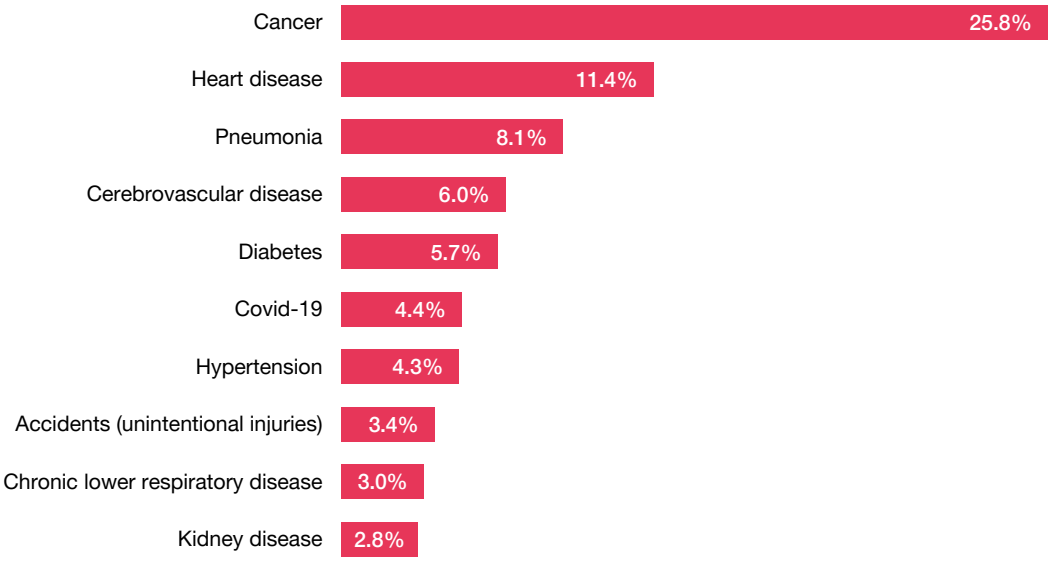
Taiwan's immunisation efforts have effectively controlled the spread of infectious diseases (including Covid), but the rising prevalence of non-communicable chronic diseases (NCDs) among the population has become a major health challenge. In 2023, the ten leading causes of death in Taiwan represented 75% of all deaths and were mostly NCDs (see Figure 8). Cancer (primarily lung cancer) was the main cause of death for the 42nd consecutive year, accounting for 25.8% of deaths, followed by heart disease (11.4%) and pneumonia (6.1%).

The chronic disease burden has serious implications for Taiwan's healthcare system, in terms of both the growing utilisation of medical resources and associated costs as well as the potentially higher demand for a larger health workforce. Furthermore, since demographic ageing is a key driver for the majority of chronic diseases, the projected rapid expansion of Taiwan's elderly population in the coming years will place additional resource and cost pressures on the already strained NHI, and poses a major risk to its long-term sustainability.

The financial costs of treating chronic conditions like cancer are substantial. With the local incidence of cancer increasing year after year, NHI expenditure on cancer treatment jumped from NT$78bn (US$2.6bn) in 2014 to NT$140bn (US$4.5bn) in 2023, accounting for over 40% of all major illness insurance claims. The growing use of expensive targeted therapies is a major driver of cancer costs and increases in pharmaceutical expenditures, with spending on cancer drugs surging from NT$18bn to NT$39bn over the 2014-2023 period.

Even so, the government is committed to improving the prevention and treatment of cancers, with an ambitious goal of reducing cancer deaths by one-third by 2030, using the 2022 baseline of 222.7 deaths per 100,000 population. Policy measures to support this goal centre around extending NHI coverage of early-stage cancer screening services (including next-generation sequencing [NGS] genetic testing) and cancer medications, and establishing a dedicated NT$10bn (US$320m) fund to enhance patient access to innovative cancer treatments.

Figure 8: Top ten leading causes of death in Taiwan, 2023



Source: Ministry of Health and Welfare.

1.4.2 Ageing demographics

Taiwan's population of 23 million is steadily shrinking due to a falling fertility rate (just 0.9 children per woman in 2023 versus a global average of 2.3) and longer life expectancy. Measures to encourage people to have more babies, such as stipends for new parents and more childcare and leave benefits, have had a negligible effect on lifting the birth rate. The number of newborns fell to a historic low of 135,571 in 2023, down by 25% from the 181,601 babies born in 2018, continuing a trend which is shaking up Taiwan's demographic profile.

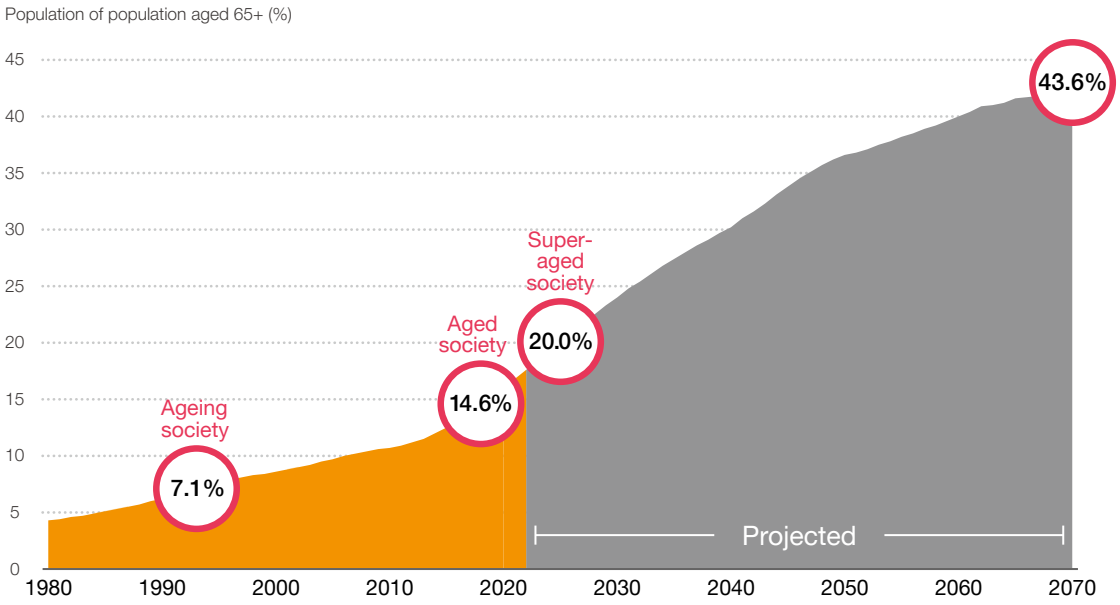
Taiwan has one of the fastest-ageing populations in the world after Japan and South Korea. It has gone very quickly through the stages of an ageing society (in 1993) and an aged society (in 2018). The proportion of people aged 65 or older accounted for 18.3% of Taiwan's population in 2023, which means nearly one out of every five people is a senior citizen. The latest official estimates project that Taiwan will become a super-aged society in 2025, when the number of elderly people will exceed 20% of the total population (see Figure 9).

NHIA statistics show that the higher an individual's 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 the 35-49 category. Total health spending on patients aged 65 and over currently accounts for about 40% of annual NHI expenditure and this share can be expected to grow further in the coming years ahead, based on the projected significant increase in the size of Taiwan's elderly population.

In addition to driving medical costs higher, the ageing demographics will also lead to 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 the elderly population has become a highly salient social, personal and political issue in Taiwan, and will continue to be so for future generations. This will therefore necessitate the government having to increase expenditure on long-term care services and assistance for more elderly people.

The MOHW plays an important role in long-term care through a set of programmes which are largely separate from the NHI. Its ten-year Long-term Care Plan 2.0, which launched in 2017, promotes ageing in place and provides various subsidies for elderly care facilities and services. The plan relies on public budget allocations and supplementary tax revenues, but the rapid growth of long-term care needs is placing heavy demands on funding—its annual budget surged from around NT$5bn (US$160m) in 2017 to NT$83bn (US$2.6bn) in 2023.

Figure 9: Ageing population trend in Taiwan, 1980-2070



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

1.4.3 Healthcare resource utilisation

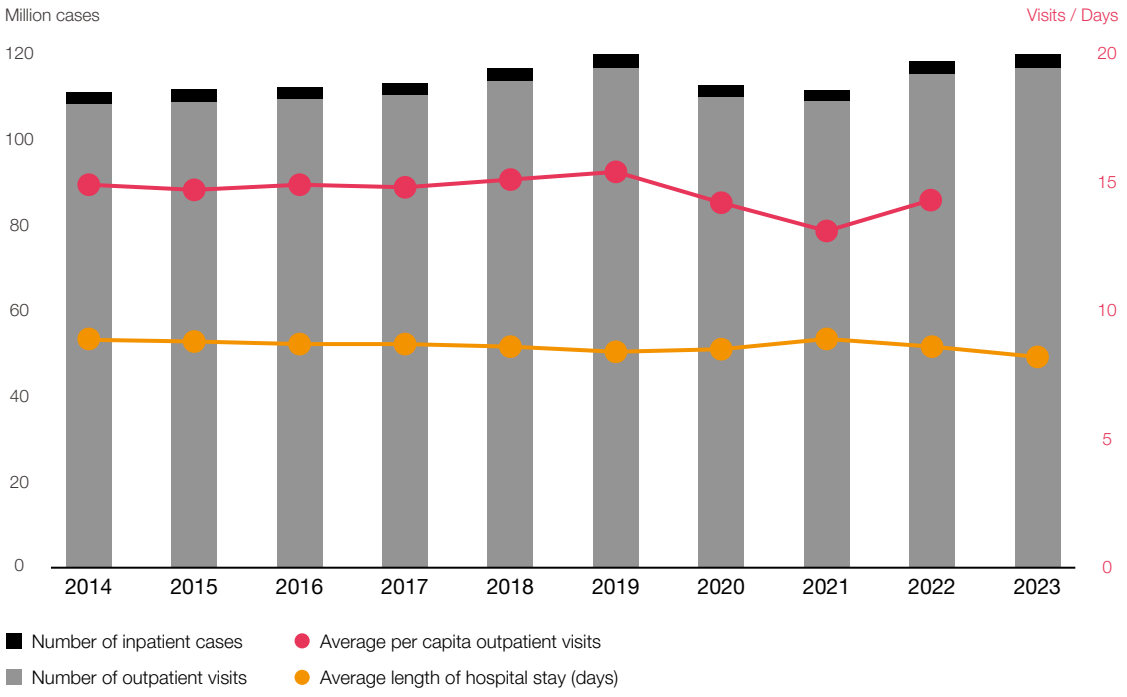
An ageing population and a growing chronic disease burden are the key drivers of demand for medical care in Taiwan. Excessive use of health resources is a problem, however, due to patients having relatively unrestricted access to providers and low cost-sharing. Hospitals provide both in- and out-patient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

Prior to the Covid disruption in 2020-2022, the annual total number of hospital outpatient visits increased from 108.1m in 2014 to 116.7m in 2019, and the average visit rate per person per year from 14.9 to 15.4 times over the same period (see Figure 10), more than double the OECD average of six doctor consultations per person. The high rate reflects the ease of access to providers and doctors as well as ageing demographics, as older people typically use more medical services and suffer from more serious chronic illnesses than other age groups.

Since patients can visit any number of doctors without referral restrictions, this encourages doctor- and hospital-shopping, even for minor ailments. Taiwanese generally trust the quality of medical care provided at hospitals more than clinics, and this has 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 can consult with each patient.

As for inpatient care, the pre-Covid annual number of hospital cases increased from 2.8m in 2014 to 3.1m in 2019, while the average length of stay declined from 8.9 to 8.4 days (see Figure 10), though still higher than the OECD average of 7.7 days. The growth in inpatient numbers has been driven by a combination of factors, including the lack of an effective patient referral mechanism (such as a primary care gatekeeper system) for specialist care and hospitalisation, more elderly and chronic cases and insufficient facilities for long-term care.

Figure 10: Medical service volume of hospitals in Taiwan, 2014-2023



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

Supply-induced demand for medical care is another significant driver of resource utilisation, as hospitals are incentivised to compete for patient and service volume in the outpatient setting, which is more profitable than providing inpatient services under the NHI reimbursement system. Payments to hospitals represented 36.9% of all personal healthcare spending in 2022, consisting of outpatient (22.9%) and inpatient (14.0%) expenditure (see Figure 14). which underlines the dominant role played by hospitals in both outpatient and inpatient care.

Efforts to reduce the moral hazard behaviour of both providers and patients have been stepped up in recent years, with a view to shifting some of the burden of primary care away from large hospitals to clinics. These include measures designed to encourage more use of family doctors, 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 scheme guarantees healthcare access to patients regardless of their financial means. But to optimise the use of resources and curb rising costs, all patients are required to co-pay for most services and medications, though some categories of patients are exempt. Co-payments include fixed fees for outpatient visits, which range from NT$50 (about US$1.50) at local clinics to NT$750 (US$25) at large hospitals (see Table 2), and 5%-30% of hospitalisation costs for inpatients, depending on the type of illness and the length of hospital stay.

Co-payment levels have been adjusted several times since the NHI's inception in a bid to reduce moral hazard behaviour and improve patient usage of resources, but the amounts remain modest by international standards. The latest adjustments, in July 2023, increased co-pays for outpatient prescription drugs (from NT$200 to NT$300) and emergency care (from NT$550 to NT$750) at regional hospitals and medical centres. The hikes aim to encourage patients with stable, chronic conditions to use local clinics and free up emergency resources.

Table 2: NHI co-payments for outpatient services

Institution class	Basic co-payments (NT$)				
Type of institution	Western medicine Outpatient care		Dentistry	Traditional Chinese medicine	Emergency care
	With referral	Without referral			
Medical centres	170	420	50	50	750
Regional hospitals	100	240	50	50	400
District hospitals	50	80	50	50	150
Clinics	50	50	50	50	150

Source: National Health Insurance Administration.

1.4.4 Medical tourism sector

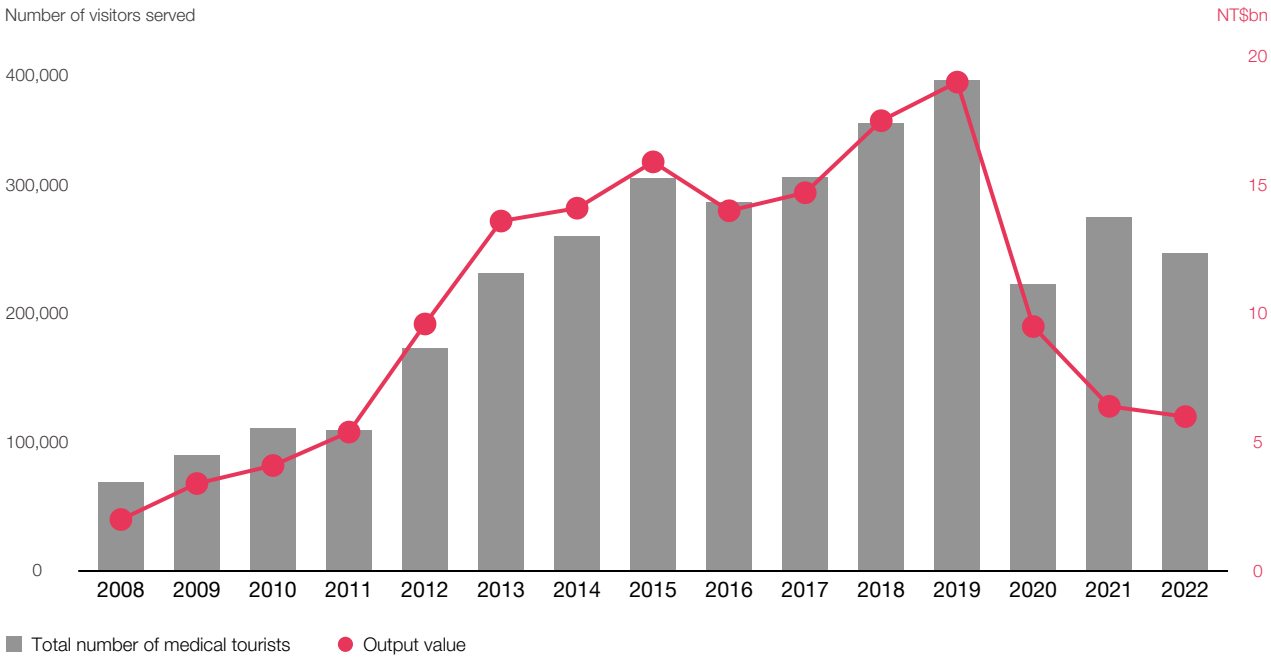
Medical tourism is an additional driver of healthcare demand. Since 2007, the government has promoted the internationalisation of medical services as part of broader efforts to attract more tourists to Taiwan. Supported by the MOHW, the Taiwan Task Force on Medical Travel coordinates an alliance of 113 qualified hospitals and clinics to promote medical tourism to attract 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 large part to its competitive costs. Its quality of medical care is on a par with developed countries, but less expensive. For example, the local cost of heart bypass surgery or a hip replacement is about one-fifth of similar procedures in the US. Its other advantages include an abundance of high-quality hospitals and doctors and advanced medical technology; Taiwan currently has five healthcare institutions that have been accredited by Joint Commission International.

Taiwan's medical tourism sector grew steadily in the years before Covid disrupted international travel. The number of medical tourist visits to Taiwan jumped from 68,545 in 2008 to 381,496 in 2019 (see Figure 11), with the majority coming from Southeast Asia countries (boosted by medical cooperation initiatives under the Taiwan government's New Southbound Policy) and China. The total output value of international medical services expanded tenfold from NT$2bn (US$66m) in 2008 to NT$19bn (US$615m) in 2019, mostly for outpatient care.

Taiwan closed its borders when the pandemic started to spread globally in early 2020, effectively bringing a halt to medical tourism. Non-resident foreigners were prohibited from entering Taiwan for international medical services, except for special or emergency cases. All Covid entry restrictions were lifted in late 2022, allowing foreign and medical tourists unfettered access to the island after nearly three years of strict border and quarantine controls. Medical tourism to Taiwan has since rebounded, though it is still short of pre-Covid levels.

Figure 11: Medical tourism in Taiwan, 2008-2022



Source: Ministry of Health and Welfare, 2023 Taiwan Health and Welfare Report.

1.5 National health expenditure

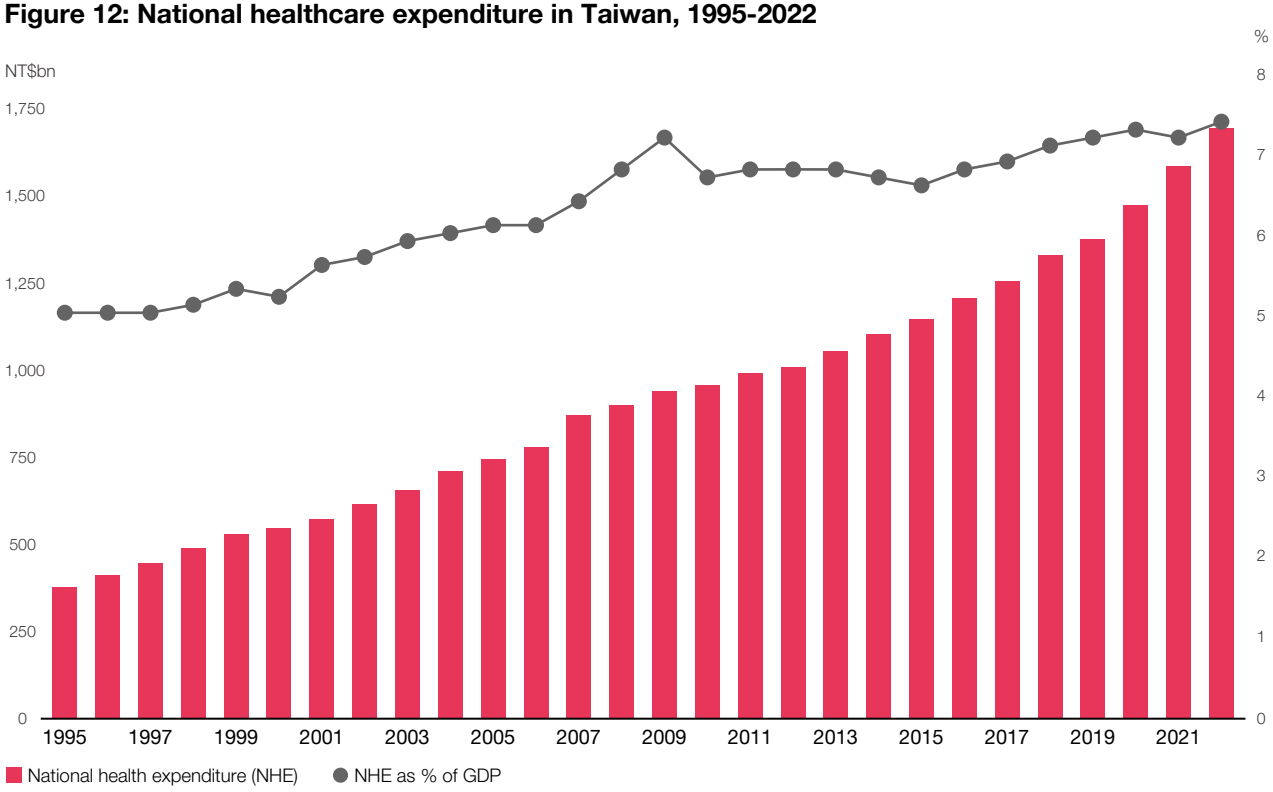
Taiwan's national health expenditure (NHE) has grown at an average annual rate of 5.9% since 1995 (versus 4.5% for GDP), increasing sharply during Covid (see Figure 12). It expanded from NT$379bn (US$14bn) in 1995 to NT$1,695bn (US$57bn) in 2022, and per capita from NT$17,805 (US$672) to NT$72,687 (US$2,438). NHE as a share of GDP rose from 5.1% to 7.5% over the same period, though still lower than in other advanced Asian economies such as Japan (11.5%) and South Korea (9.7%), and also below the OECD average of 9.2%.

A key reason for Taiwan's relatively lower 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 expenditure. Another factor is the high efficiency of NHI's IT-driven system, which is characterised by administrative simplicity and low overhead costs. General administration expenses currently account for around 2% of total health spending, which is among the lowest levels globally.

On the other hand, some experts contend that Taiwan's below-average health spending (as a percentage of GDP) in international comparisons is an indication of lagging investment in healthcare, and a key area where that can be seen is the insufficient funding for breakthrough drugs and treatments. A recent study by PwC for the Taipei-based International Research-Based Pharmaceutical Manufacturers Association, titled Invest in Healthcare: A Review of Healthcare Outcomes and Expenditures in Taiwan, examined this viewpoint in detail.

The government has acknowledged the need to increase overall health spending in view of Taiwan's rapidly ageing society and growing chronic disease burden, though it still remains concerned about containing costs. As part of efforts to improve health financing, in 2023, the government allocated additional funding of NT$44bn (including NT$20bn of excess tax revenues from a post-pandemic special budget) to replenish the NHI reserve fund, which is designed to keep the national health insurance system solvent when facing unanticipated deficits.

Figure 12: National healthcare expenditure in Taiwan, 1995-2022



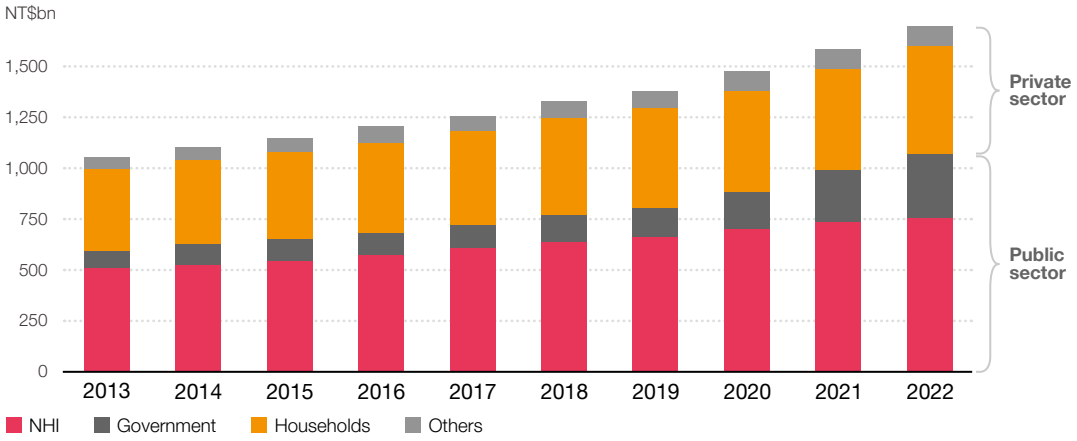
Source: Ministry of Health and Welfare.

1.5.1 Health spending flows

The public sector accounted for 63% of national health expenditure in 2022, which was boosted by higher government spending to tackle the Covid crisis, compared with 37% from private sources (see Figure 13). The NHI represented the majority of total health spending at 44.5%, which comprised reimbursements to contracted healthcare service providers for the cost of care they provide. Households accounted for the next largest share at 31.4%, mostly out-of-pocket payments for doctor visits, hospitalisations and prescription drugs.

NHI enrolment is mandatory for all citizens and foreign residents, and the programme is primarily financed by insurance premiums shared by the insured, employers and the government (see page 9 for more information). The National Health Insurance Act specifies that the annual funds to be allocated by the government to the NHI must be at least 36% of total premium revenues, otherwise it must use other budgets to make up any shortfall. Around 60% of government spending on healthcare is directed into the NHI programme in the form of subsidies.

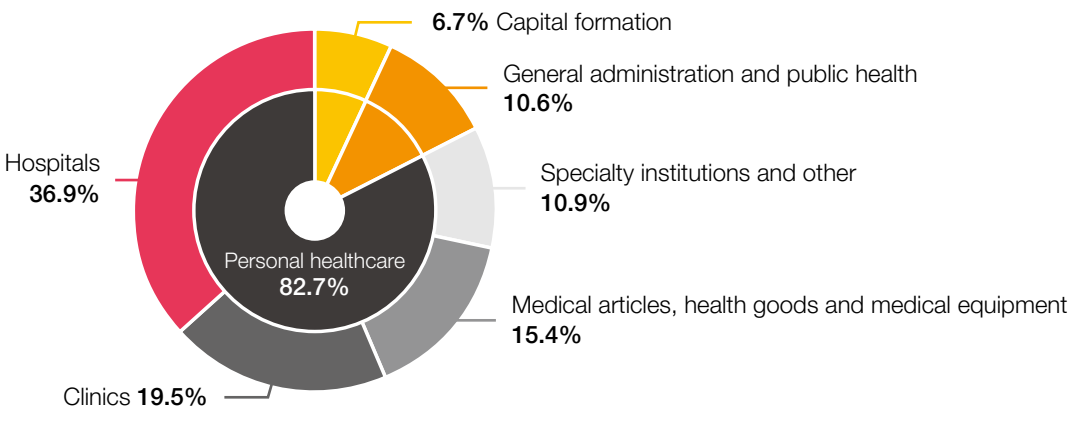
Figure 13: National healthcare expenditure by financial agents, 2013-2022



Source: Ministry of Health and Welfare.

By end-use, personal healthcare represented the largest share of NHE at 82.7% in 2022, followed by general administration and public health (10.6%) and capital formation (6.7%) (see Figure 14). Hospitals accounted for the majority of personal healthcare spending at 36.9%, comprising outpatient (22.9%) and inpatient (14.0%) care. The rest came from clinics (19.5%, including Western medicine 9.4%, dental 8.2% and Chinese medicine 1.9%), expenditure on medical articles, health goods and medical equipment (15.4%) and specialty care (10.9%).

Figure 14: National healthcare expenditure by financial allocation, 2022



Source: Ministry of Health and Welfare.

1.5.2 NHI financial status

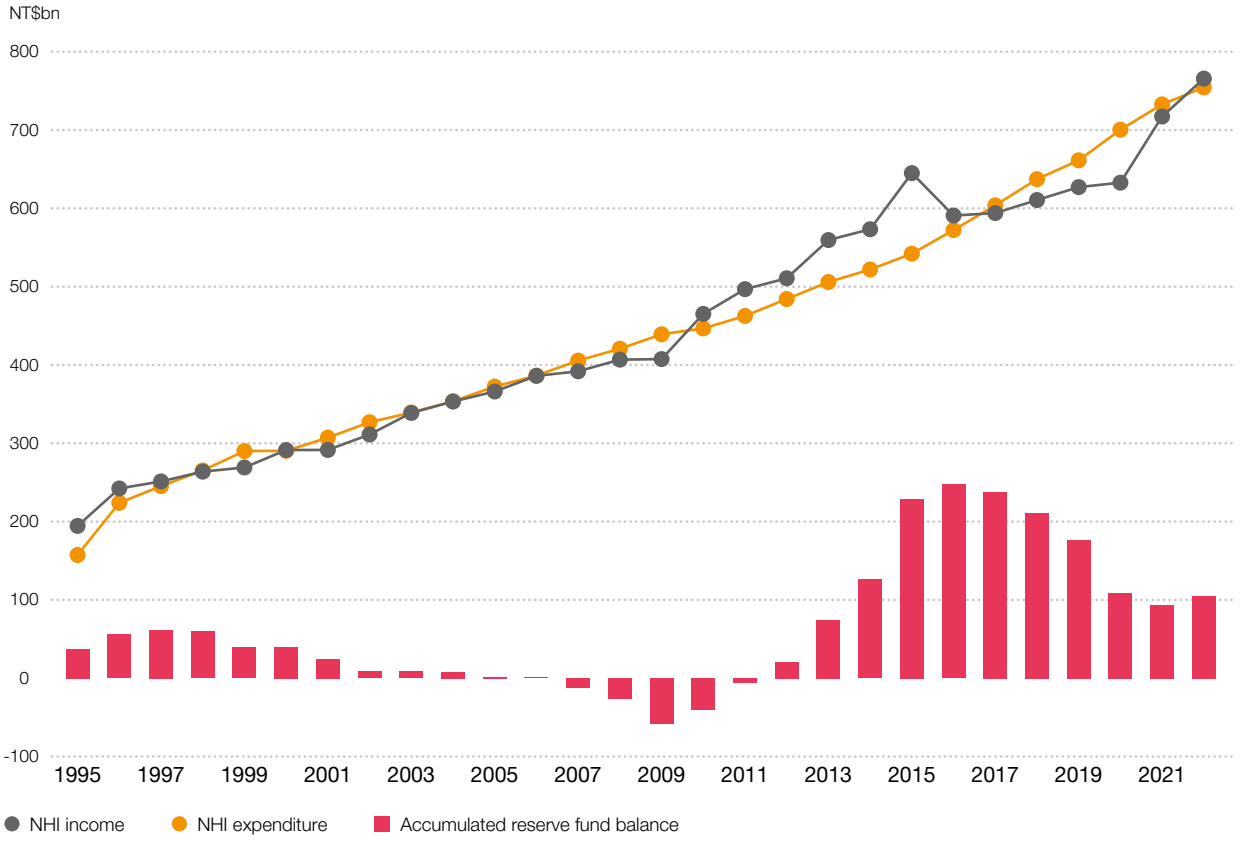
In 2022, the NHI had total income (on an accrual basis) of NT$766bn (about US$25.7bn), with the largest share accounted for by premium revenues at 97.7%. General premiums totalled NT$586bn (contributed collectively by beneficiaries, group insurance applicants and the government) and supplementary premiums were NT$73bn. Total NHI expenditure was NT$754bn (US$25.3bn), of which medical benefits accounted for 99.2%. The surplus of NT$11bn was deposited into the NHI reserve fund, which had a balance of NT$105bn (US$4bn).

Throughout most of the NHI's history, growth in expenditure has outpaced its revenues—at an average increase of 6.2% per year in the most recent decade versus 4.1%, respectively—driven by higher resource utilisation and medical costs (see Figure 15). The NHI began to experience financial deficits as early as 1998 and this has forced policymakers to pursue both cost-containment measures and occasional hikes in NHI premium rates (in 2002, 2010 and 2021) to help ensure that insurance revenues keep pace with rising healthcare costs.

Healthcare system reforms in 2013, in particular the introduction of a new supplementary insurance premium, helped to financially stabilise the NHI. Despite this, premium rates were lowered in 2016, which led to a shortfall in insurance revenues and contributed to annual deficits over the following four years. To balance the NHI budget, premium rates were raised in 2021, which, along with a NT$44bn (US$1.4bn) injection from special public budgets in 2023, bolstered income and supported a return to annual surpluses over the past two years.

Nevertheless, the NHI will continue to face financial pressure going forward due to rising healthcare demand and costs, leading to expectations of further premium rate increases in the near future. By law, the government can raise NHI rates when the safety reserve fund has less than one-month coverage of NHI expenditure. But this is a politically sensitive issue in Taiwan and so the government has been wary to take such action. All the same, more fundamental structural reforms will be required to ensure the long-term sustainability of the NHI.

Figure 15: NHI financial revenue and expenditure, 1995-2022



Source: Ministry of Health and Welfare.

1.5.3 Cost-containment policies

Balancing the NHI budget is a persistent challenge for the government. Besides various initiatives to boost the revenue side, efforts to curb expenditure have also been pursued. These include a range of cost-containment measures designed to decrease both demand and supply. While patients incur co-payments to mitigate overuse or misuse of resources, policymakers are wary of imposing other additional costs on NHI users. Therefore, government efforts to bolster the NHI scheme have mainly focused on the cost (supply) side, as detailed below.

Global budget payment system

The NHIA phased in a global budget payment system 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. Pre-determined, fixed annual budgets are set every year for five major categories: hospitals, primary care clinics, dental care, Chinese medicine and dialysis. This in turn forces NHI-contracted providers to decide for themselves on to how to use their limited funds to satisfy the medical care needs of their patients.

The budgeting process involves annual negotiations on NHI expenditure for each of the five sectoral areas (see Figure 16). Six months before the start of each fiscal year, the MOHW proposes general parameters for the global budget 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 sectoral budget is then split between six geographic regions based on their share of total spending and number of beneficiaries.

Healthcare providers are reimbursed by the NHIA through a mixture of fee-for-service and other payment methods using a floating point-value scale. This unit is convertible to New Taiwan dollars (NT$) and the rate changes quarterly to align overall expenditure with pre-determined budgets. For example, if medical institutions only focus on increasing the volume of medical services delivered or drugs prescribed, this will entail a lower point value and lower payments to providers. Consequently, many are not fully reimbursed for their services.

Since the implementation of the global budget payment system, the gap between medical demand and the budgetary shortfall has long been borne by medical institutions. Recently, this has led to calls from healthcare provider associations for the NHI to shift to an expenditure target system with a service volume target and fixed point value to payment ratio. In May 2024, preliminary discussions were held about a proposed draft bill that would require any over-budget expenditure to be covered by the public purse—not medical institutions.

Figure 16: Decision-making process for annual NHI global budget

Source: National Health Insurance Administration.

Alternative reimbursement payment models

The NHIA has also adopted different approaches to paying providers in an effort to contain healthcare costs. Reimbursement is generally on a fee-for-service basis, which accounts for around three-quarters of hospital payments, but the financial incentives inherent in this method tend to drive up supply-induced healthcare demand. Therefore, the NHIA has adopted some other payment mechanisms, based on the characteristics of different types of medical care, to encourage more efficient and cost-conscious behaviour by all providers.

The diversified payment methods include pay-for-performance, capitation and bundled payments for certain episodes of care, as well as a Taiwanese version of diagnosis-related groups (TW-DRGs) which caps hospital reimbursements for specific services at defined levels. The NHIA phased in the TW-DRG payment model in 2010 and 2014, but uptake has been slow owing to resistance from providers. Around 400 DRGs have been implemented to date and the related costs account for about about 20% of overall inpatient medical expenses.

The TW-DRG system seeks to standardise operating procedures and to enhance the quality of care and efficiency, but doctors are concerned that it forces them to perform under a fixed budget with little flexibility. For example, they claim it discourages the treatment of complex patient cases, since hospitals are required to absorb losses related to inefficient treatments. On the other hand, the NHIA maintains the 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

Total spending on pharmaceuticals accounted for 18.2% of current health expenditure in 2022, higher than the OECD average of 15.2%, and represented the third largest health-spending component after outpatient and inpatient care. Medication costs reimbursed by the NHI amounted to NT$232bn (US$7.8bn) in 2022, or 28.6% of its annual budget, having more than doubled in size since 1995. As part of its cost-containment efforts, the NHIA seeks to control this escalating drug expenditure by imposing direct controls on reimbursement prices.

It has been using a drug expenditure target (DET) mechanism since 2013 to adjust pharmaceutical prices. Under the DET, the NHIA sets an annual target for NHI drug spending based on prior year expenditure and a negotiated growth rate. If actual expenditure exceeds the amount allocated, the excess will be adjusted in the following year through a drug price cut. There have been drug price cuts nearly every year due to overspending (see Table 3), which has led some global pharma companies to withdraw certain drugs from the Taiwan market.

Besides the primary objective of generating cost savings, the DET price cuts are also aimed at narrowing the gap between drug procurement and reimbursement prices from which hospitals profit. Most hospitals in Taiwan operate in-house pharmacies and these are allowed to buy medicines at discounted rates while charging for dispensing them at NHI reimbursement prices, which are often significantly higher. Accordingly, pharmaceutical companies have claimed that this so-called ‘drug price black-hole’ serves to artificially inflate NHI drug costs.

Table 3: NHI drug price reductions under DET mechanism, 2013-2023

	2013	2014	2015	2016	2017	2018	2019	2020	2021-22	2023
Target expenditure (NT$bn)	138.0	142.6	147.5	154.8	151.1	156.0	162.3	170.2	N/A	N/A
Overspend amount (NT$bn)	5.7	8.2	3.2	5.7	7.4	5.8	4.0	7.5	8.2	5.5
No. of drugs reduced in price	7,583	6,821	7,392	7,331	7,476	7,470	7,237	6,645	5,475	4,551
Average price reduction (%)	3.9	5.3	2.1	3.5	4.6	3.5	2.3	4.1	2.1	2.8
Effective date of price cut	May 2014 Jul 2014	Apr. 2015	Apr. 2016	Apr. 2017	Apr. 2018	Apr. 2019	Oct. 2020	Jan. 2022	Apr. 2023	Apr. 2024

Source: National Health Insurance Administration.

1.5.4 Private health insurance

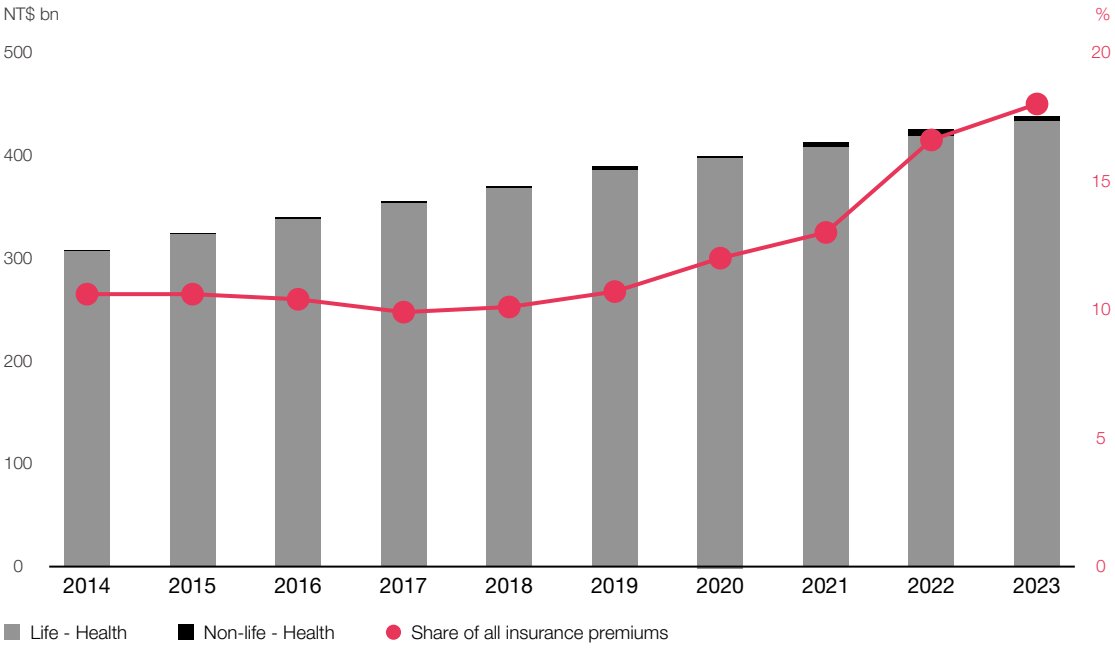
Private health insurance in Taiwan consists mostly of policies that supplement NHI coverage. Generally, these are disease-specific cash indemnity policies, or riders to non-medical policies like life or car insurance. They mostly offer one-time, event-trigger insurance payments for certain health occurrences, 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.

Taiwan's health insurance sector is small but expanding. Premium income from both life and non-life health insurance grew at a ten-year CAGR of 4.0% to reach NT$438bn (US$14.1bn) in 2023, accounting for 18% of total insurance industry premiums (see Figure 17). Individual and group health insurance products with fixed payment terms dominate the line of business, representing 99% of all health insurance premium income. The rest mostly comes from yearly renewable health insurance plans marketed by property and casualty insurers.

Despite universal access to healthcare and medical services through the NHI, private households currently foot 31.4% of total health spending on an out-of-pocket basis, up from 22.3% in 1995. The increase in cost-shifting to patients, due to the mounting strain on the NHI budget, will impose a growing financial burden on households. This, together with higher insurance awareness resulting from the Covid pandemic, may lead to more demand for private insurance to protect patients against downside risks and to drive better care decisions.

Indeed, the NHIA is actively considering to leverage commercial health insurance in order to expand its long-term funding sources and offer an additional layer of medical protection to NHI insured persons. In January 2024, it initiated a comprehensive study through the National Health Research Institutes to create a model for supplemental health insurance. The aim is to investigate the potential role of private health insurance within the NHI framework, with a specific focus on exploring partnerships between the NHI and private health insurers.

Figure 17: Premium income from health insurance in Taiwan, 2014-2023



Source: Taiwan Insurance Institute.


Dice Roll Probability Lab

Taiwan's biomedical industry

2. Biomedical industry

The term biomedical refers to the field of biology and medicine, particularly when it comes to scientific research and development, which seeks to understand and treat health-related issues. The biomedical industry, in turn, consists of businesses that provide various healthcare and medical products and services. It has a focus on innovation to create high additive value by integrating technologies from different fields, as reflected in the growing trend towards more personalised healthcare solutions such as precision health and smart healthcare.

2.1 Industry scope and size

Taiwan's biomedical industry currently comprises six sectors: applied biotechnology, pharmaceuticals, medical devices, health and wellness, digital health and regenerative medicine (see Figure 18). The latter three were included in the official industry scope in 2018, 2022 and 2023, respectively, and have been designated as emerging key sectors. Also, the coverage of the medical devices sector was adjusted in 2023, with medical equipment and supplies for disease prevention and health promotion now included under health and wellness.

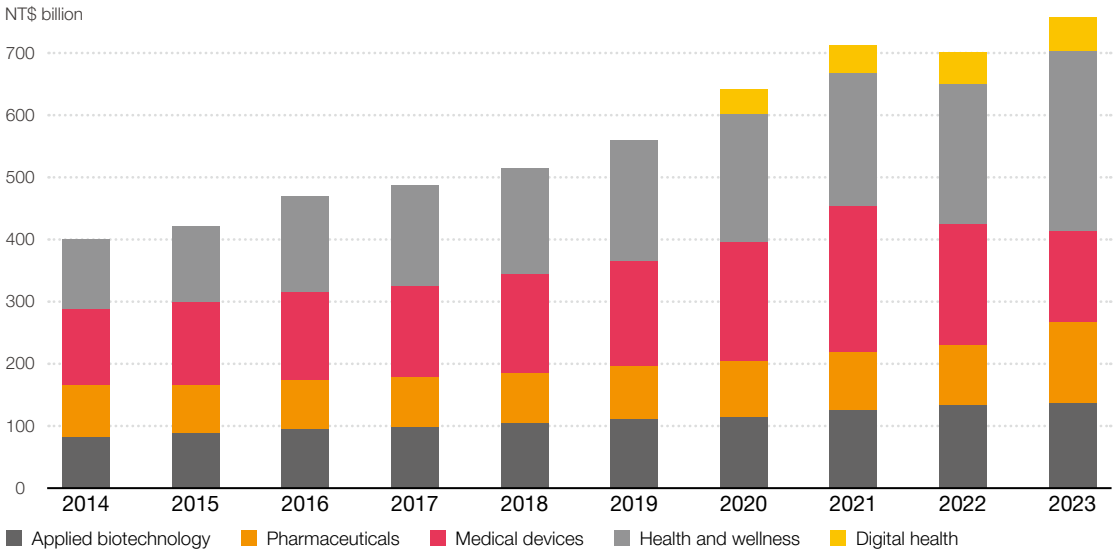
Figure 18: Scope of Taiwan's biomedical industry

Biotechnology	Pharmaceuticals	Medical devices	Health and wellness	Digital health	Regenerative medicine
Agricultural biotechnology products Environmental biotechnology products Food biotechnology products (including health nutrition) Biotech cosmetics and specialty chemicals Related technical services (including precision medicine)	Western medicine preparations Biologics Active pharmaceutical ingredients Chinese medicine preparations	Western medicine preparations Biologics Active pharmaceutical ingredients Chinese medicine preparations	Health promotion products Well-being products and services	Digital prevention, diagnostic and treatment products Hospital information system products Telemedicine products	Regenerative medical preparations Regenerative medical technology services

Source: Industrial Development Administration, 2024 Biotechnology Industry in Taiwan White Paper.

In 2023, the biotechnology industry generated total revenues of NT$758bn (US$24bn), an increase of 8.1% on the year before, according to the latest annual industry report by the Industrial Development Administration of the Ministry of Economic Affairs (see Figure 19). Health and wellness was the largest sector with a revenue share of 38.2% (boosted by the inclusion of reclassified revenues from certain medical devices), followed by medical devices (19.4%), applied biotechnology (18.1%), pharmaceuticals (17.0%) and digital health (7.3%).

Figure 19: Taiwan's biomedical industry by revenue, 2014-2023



Source: Industrial Development Administration, 2024 Biotechnology Industry in Taiwan White Paper.

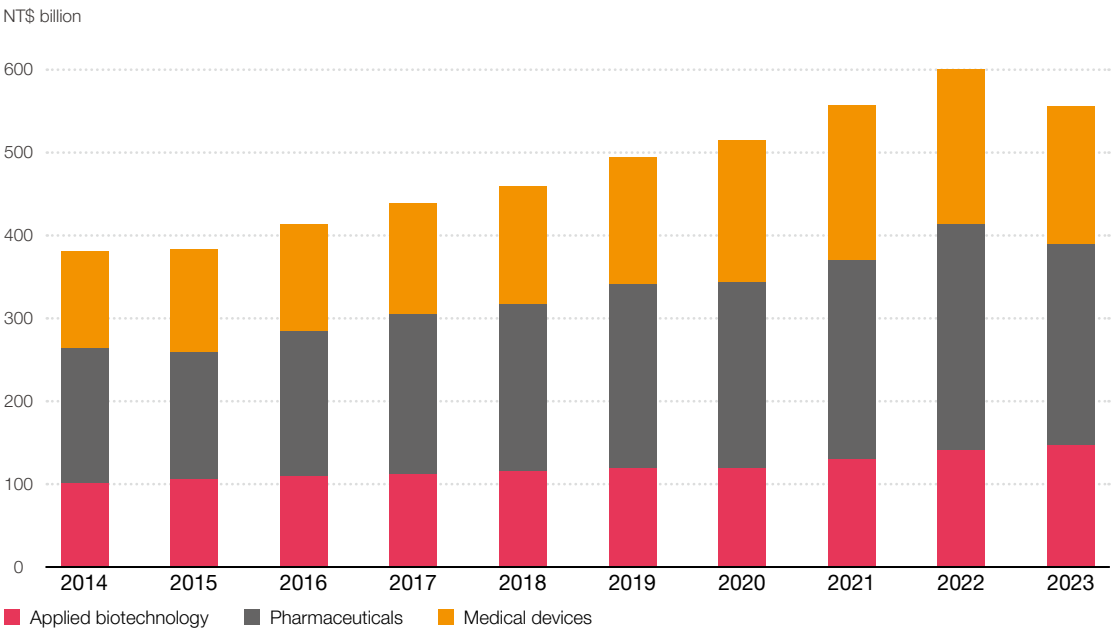
Our analysis of Taiwan's biomedical industry will primarily focus on the applied biotechnology, pharmaceuticals and medical devices sectors, as these have been the three core pillars of the industry since the late 2000s. Together, the three represented a total market size of NT$556bn (US$17.8bn) in 2023 (see Table 4 and Figure 20). The emerging fields of precision medicine, digital health and regenerative medicine are also discussed throughout, given their major importance for the future growth and direction of the overall biomedical industry.

Table 4: Status of Taiwan's biomedical industry, 2014-2023*

Unit: NT$ billion	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023#
Total revenue	**288.6**	**298.6**	**315.0**	**325.0**	**344.2**	**365.3**	**395.6**	**453.8**	**423.9**	**413.3**
- Applied biotechnology	82.2	88.4	94.0	98.6	104.7	110.6	114.2	125.8	133.9	137.2
- Pharmaceuticals	83.2	77.2	79.5	80.1	80.3	85.5	89.0	91.7	96.1	129.1
- Medical devices	123.2	133.0	141.5	146.3	159.2	169.2	192.4	236.3	193.9	147.0
Total exports	**125.2**	**141.6**	**155.2**	**157.6**	**170.8**	**184.8**	**201.0**	**230.9**	**199.2**	**197.1**
- Applied biotechnology	31.2	34.3	37.7	41.1	45.2	49.7	51.7	51.5	50.5	53.3
- Pharmaceuticals	19.7	26.1	31.4	29.2	30.1	31.0	32.2	33.3	40.3	60.8
- Medical devices	74.3	81.2	86.1	87.3	95.5	104.1	117.1	146.1	108.4	83.0
Total imports	**217.1**	**226.2**	**253.7**	**271.2**	**286.3**	**314.3**	**320.7**	**334.5**	**375.5**	**339.3**
- Applied biotechnology	50.0	51.9	53.4	54.4	56.3	57.7	56.5	55.9	57.0	62.3
- Pharmaceuticals	99.9	102.1	126.7	142.2	151.0	168.0	168.1	181.8	217.6	174.9
- Medical devices	67.2	72.2	73.6	74.6	79.0	88.6	96.1	96.8	100.9	102.1
Total market size	**380.5**	**383.2**	**413.5**	**438.6**	**459.7**	**494.8**	**515.3**	**557.4**	**600.2**	**555.5**
- Applied biotechnology	101.0	106.0	109.7	111.9	115.8	118.6	119.0	130.2	140.4	146.2
- Pharmaceuticals	163.4	153.2	174.8	193.1	201.2	222.5	224.9	240.2	273.4	243.2
- Medical devices	116.1	124.0	129.0	133.6	142.7	153.7	171.4	187.0	186.4	166.1

* Excluding the health and wellness, digital health and regenerative medicine sectors.
# Medical device revenues were adjusted downward in 2023 due to industry classification changes.
Source: Industrial Development Administration, 2024 Biotechnology Industry in Taiwan White Paper.

Figure 20: Market size of Taiwan's biomedical industry, 2014-2023*



* Excluding the health and wellness, digital health and regenerative medicine sectors.
Source: Industrial Development Administration, 2024 Biotechnology Industry in Taiwan White Paper.

2.2 Policy support and trends

Strong policy support from the government has helped create a favourable investment environment for the growth and development of Taiwan's biomedical industry. A wide range of measures has been implemented in recent decades—including special legislation and preferential tax incentives—as part of strategic initiatives to encourage biomedical R&D and investment. The government's biomedical industry policy has evolved over time, as outlined below, but it remains centred on driving forward Taiwan's next generation of industrial growth.

Biomedical Industry Innovation Programme

In 2016, the government included the biomedical industry in its '5+2' Innovative Industries Plan, which sought to advance the transformation of Taiwan's industrial base toward higher value-added activities. It launched a related development initiative, called the Biomedical Industry Innovation Programme (BIIP), which initially focused on the applied biotechnology, pharmaceuticals, medical devices and health and wellness sectors. The overarching goal of the initiative was to establish Taiwan as hub for biomedical R&D in the Asia Pacific region.

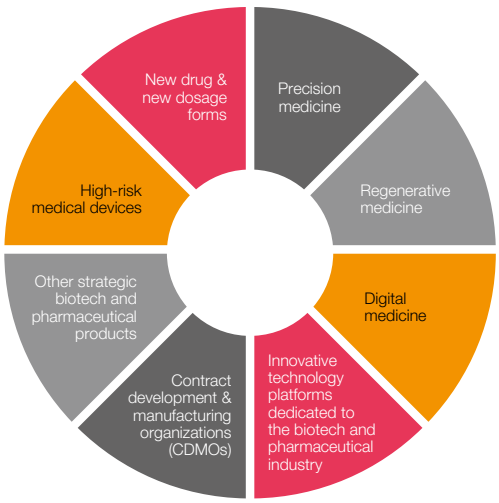
Based on the theme of creating local, global and future links, the BIIP aimed to raise the biomedical industry's output value and competitive capabilities through four action areas: establishing a comprehensive ecosystem; integrating innovation clusters; connecting to global markets; and promoting key specialty industries. The plan's targets for 2025 called for an industry output value of more than NT$1 trillion (US31bn), the development and international marketing of 20 new drugs and the introduction of 80 high-value medical devices to global markets.

Precision Health Strategy Development Programme

The BIIP laid the foundation for the next-phase promotion of precision health, with a particular focus on precision medicine, regenerative medicine and digital health (see Figure 21). In 2019, the government proposed the Taiwan Precision Health Initiative (TMI), which is a large-scale genetic study being conducted jointly by leading research institute Academia Sinica and a group of medical centres. The TMI aims to identify genetic risk factors that lead to common diseases in Taiwan and match them with the most effective medical treatments and drugs.

Since 2020, the government has promoted precision health and medical technology as a component of its Six Core Strategic Industries initiative, which builds on the '5+2' Plan. Its Precision Health Strategy Development Programme seeks to establish Taiwan as a global leader in precision health and the development of high-tech solutions to epidemics like Covid. The objective is to leverage Taiwan's digital infrastructure to accelerate the integration of technology and medical data to drive the development of personalised precision health services.

Figure 21: Current biomedical focus areas in Taiwan



Source: Biotechnology and Pharmaceutical Industries Promotion Office.

With the advent of innovative precision and digital health solutions, opportunities are being created worldwide to transform patient care and improve healthcare service delivery. In Taiwan, the government has sought to take advantage of the global trends in precision health and medical technology, by designating them as priority areas for promotion and development, to provide a new direction for the growth of the local biomedical industry.

Accelerating shift towards precision health

Precision health is a growing area of interest for healthcare systems around the world, as it has the potential to significantly improve patient care by tailoring treatments that address individual variability in genes, environment and lifestyle for each person—particularly as regards oncology. Taiwan's precision health policy aims to ensure health maintenance, disease prevention, diagnostics, therapeutics and long-term care for people of all ages.

In addition to the Precision Health Strategy Development Programme, which seeks to establish Taiwan as a global leader in the precision health field, the Ministry of Health and Welfare has set a roadmap for a precision healthcare system by 2030. Key tasks include the establishment of a large-scale gene bank, the promotion of new-born genomic sequencing and the development of new reimbursement strategies for precision medicine.

Taiwan has also improved its regulatory environment to encourage the development of precision medicine initiatives. The principal law covering biomedical innovation, the Act for the Development of Biotech and Pharmaceutical Industry, has been amended in recent years to extend R&D tax breaks to emerging biomedical fields including precision health and regenerative medicine, which are regarded as key areas for future growth.

Taiwan's massive NHI research database and strong R&D capabilities make it an attractive location for development of precision medicine applications, with the local technology and biomedical industries converging to produce personalised solutions and treatments. Taiwan's efforts to develop its precision medicine offerings are also attracting international attention, as reflected by a growing number of collaborative arrangements.

Growing demand for new medical technologies

Another significant market trend is digital health, which is an innovative, ever-changing area in healthcare. It encompasses a wide range of digital tools that can improve healthcare, enable lifestyle changes and create operational efficiencies. These cover areas such as mobile medicine, medical health information, wearable devices, telehealth and telemedicine, personalised medicine and other IT apps in the health and medical fields.

In Taiwan, the government has designated medical technology as a priority sector for development. Taiwan is well placed to lead the development of innovative products and solutions across the whole digital-health ecosystem, thanks to its established strengths in the information and communications technology industry and manufacturing, as well as having one of the top healthcare systems and largest medical databases in the world.

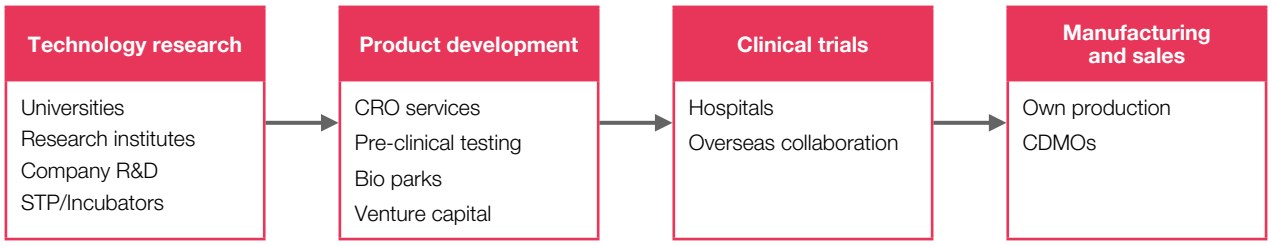
Taiwan also provides certain incentives to facilitate the development of new digital health products and services. The Act for the Development of Biotech and Pharmaceutical Industry provides R&D tax breaks to qualified companies for investments in high-risk medical devices. In addition, the Ministry of Economic Affairs offers investment subsidies to start-up enterprises to encourage development of cutting-edge medical AI solutions.

A growing number of Taiwan's renowned technology companies are diversifying into the biomedical industry, with the aim of transforming not only Taiwan's own healthcare system, but also the world's. The focus is on integrating digital health technologies with the latest medical applications to enable connected and smart healthcare. This development is expected to have a synergistic growth impact on Taiwan's biomedical industry.

2.3 Biomedical ecosystem

A long period of strong government backing and investment has laid a solid foundation for a comprehensive biomedical ecosystem in Taiwan, which spans the entire value chain of the industry, from pre-clinical and clinical research in drug discovery and development to manufacturing and marketing (see Figure 22). Much of the industry's activity takes place in bio clusters close to universities, research institutes and large hospitals.

Figure 22: Taiwan's biomedical ecosystem



Source: PwC Taiwan.

State-sponsored research institutes and universities help to nurture biomedical talent as well as technological innovation. The key bodies include Academia Sinica, Development Center for Biotechnology, National Health Research Institutes, Industrial Technology Research Institute and a number of universities, in particular National Taiwan University, China Medical University, Taipei Medical University and National Yang Ming University.

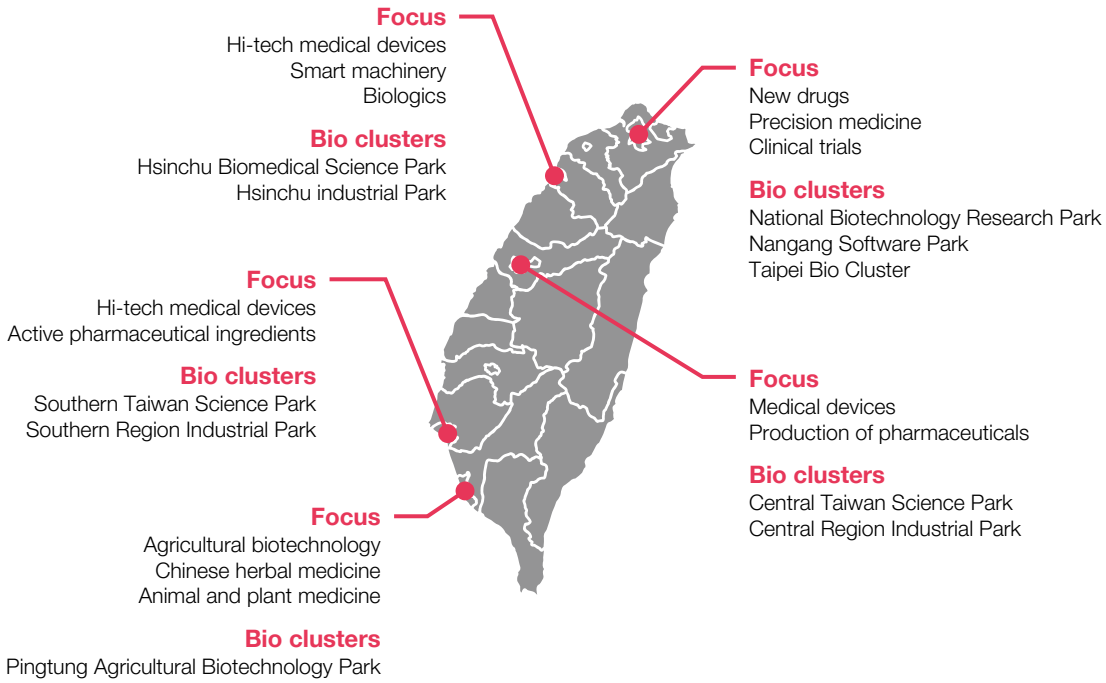
These organisations have spawned and encouraged a large number of start-ups that mainly focus on early-stage commercialisation of academic research, many of which are housed in government-funded incubators and science parks. At the other end of the ecosystem's spectrum are established biomedical companies, which produce biopharmaceutical and medical device products either for themselves or under contract to other firms.

In between the biomedical start-ups and commercial manufacturers are companies and organisations offering support services related to contract research and development, pre-clinical testing and clinical trials, among others. Taiwan thus has all the necessary elements to enable companies to collaborate both domestically and internationally across all parts of the biomedical industry from research and development through to production.

2.4 Biomedical cluster network

Taiwan has an inter-connected network of biomedical hubs from north to south of the island, centred around science and research parks, which support value creation and export growth across the industry (see Figure 23). Manufacturers of new drugs, medical devices and biologics are clustered in northern Taiwan, with pharmaceutical and medical device companies mostly grouped in the central region, and companies producing active pharmaceutical ingredients, medical implants and minimally invasive surgical instruments in the south.

Figure 23: Biomedical industry clusters in Taiwan



Source: Biotechnology and Pharmaceutical Industries Promotion Office.

In the north, the leading biomedical clusters are the National Biotechnology Research Park in Nangang, the Neihu Technology Park 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 on the west coast is home to Taiwan's precision machinery and tooling hub, which in recent years has benefited from the growth of robotics, smart applications and value-added data services. Biomedical businesses at the Central Taiwan Science Park in Taichung collaborate 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 pharmaceutical products is another focus area in central Taiwan.

In the southern part of Taiwan, the primary focus is the production of active pharmaceutical ingredients, with biomedical firms also leveraging the area's strong metal processing capabilities to develop minimally invasive surgical instruments for dentistry and orthopaedics at the Southern Taiwan Science Park. In addition, based on Taiwan's strengths in the agricultural field, the Pingtung Agricultural Biotechnology Park at the bottom of the island focuses on development of functional foods, Chinese medicines, animal vaccines and animal breeding.

2.5 International collaborations

As innovation does not come cheaply or quickly, there is a growing recognition of the value and importance of collaboration across the biomedical ecosystem. Companies globally are increasingly adopting a collaborative, multi-stakeholder approach to conducting R&D and innovation activities. They are partnering with research institutes, healthcare facilities and others to tackle scientific and technological challenges, generate greater efficiencies in R&D, and accelerate the development and delivery of new and innovative treatments for patients.

As momentum accelerates in Taiwan's biomedical industry, international companies are showing high interest in collaboration and investment opportunities across the whole value chain, looking to take advantage of the agility of local firms when it comes to identifying market niches with potential for more innovation. Similarly, Taiwanese research institutes and biomedical businesses seek collaborations with overseas counterparts and multinationals to speed up the development of their innovations and expand their market reach internationally.

The most common forms of collaboration in Taiwan's biomedical industry include the following:

- **R&D and manufacturing collaboration,** such as biopharmaceutical outsourcing to CROs (Contract Research Organisations), CMOs (Contract Manufacturing Organisations), CDMOs (Contract Development and Manufacturing Organisations) and other types of partnering arrangements and strategic alliances.
- **Licensing and distribution agreements,** such as for the in-licensing and out-licensing of research and development assets, process development know-how and certain manufacturing and distribution rights.
- **Direct investments,** including equity stakes, joint ventures and mergers and acquisitions (M&A).

Biomedical M&A in Taiwan has largely been small-scale to date and primarily driven by local consolidation and overseas expansion plans to reduce reliance on a small domestic market, with a particular focus on contract development and manufacturing organisations (CDMOs) as potential targets. At the same time, the industry is attracting increasing international investor interest, thanks to its strong positioning in the Asian clinical trials market, as well as the government's longstanding policy support for the industry's growth and development.

Furthermore, the government, academia and industry associations play an important role in promoting Taiwan's biomedical industry to international audiences through conferences, exhibitions and other events—in particular, the BIO Asia-Taiwan expo, which is one of the largest annual biomedical gatherings in Asia. They also help to foster and facilitate international collaborations with local research institutes and others, especially in the areas of biomedical R&D and talent training, as part of broader efforts to drive industry innovation and future growth.

3. Biotechnology sector

Biotechnology, or biotech in short, involves the use and manipulation of living organisms to develop or make commercial products and services, mainly for use in agriculture, food science and medicine. Taiwan's applied biotechnology sector has five segments: agricultural biotechnology products, environmental biotechnology products, food biotechnology products (including health nutrition), biotech cosmetics and bio-based specialty chemicals, and related technical services for the development of new drugs (including precision medicine).

Strong government commitment has helped drive the expansion of Taiwan's biotechnology sector since the mid-2000s. A key milestone was the passage of the 2007 Act for the Development of Biotech and Pharmaceutical Industry, which laid the foundation for future growth. Two years later, the government at that time launched a Diamond Action Plan for Biotech Take-off to strengthen the sector's basic structure, while the second phase of the industry development plan, which started in 2013, focused on growing the capabilities of its value chain.

The current government, which has been in power since 2016, continues to actively support and promote biotechnology as a priority sector for industrial development. In that year, it launched the Biomedical Industry Innovation Programme, with the goal of making Taiwan a regional hub for biomedical R&D. Four years later, the government introduced a Precision Health Strategy Development Programme as part of further efforts to build up Taiwan as an international leader in precision health and the development of new biomedical products.

Taiwan's biotechnology sector has almost tripled in market size since 2007 to reach NT$146bn (US$4.7bn) in 2023 (see Table 5), with the primary focus on development of new drugs and biologics. Although the sector's scale is still relatively small, its upward growth momentum is strong and expected to continue. Key drivers will be further policy and investment support and the maturation of companies' drug pipelines and service offerings. The introduction of new laws on regenerative medicine can also be expected to give the biotech sector a boost.

Table 5: Status of Taiwan's applied biotechnology sector, 2014-2023

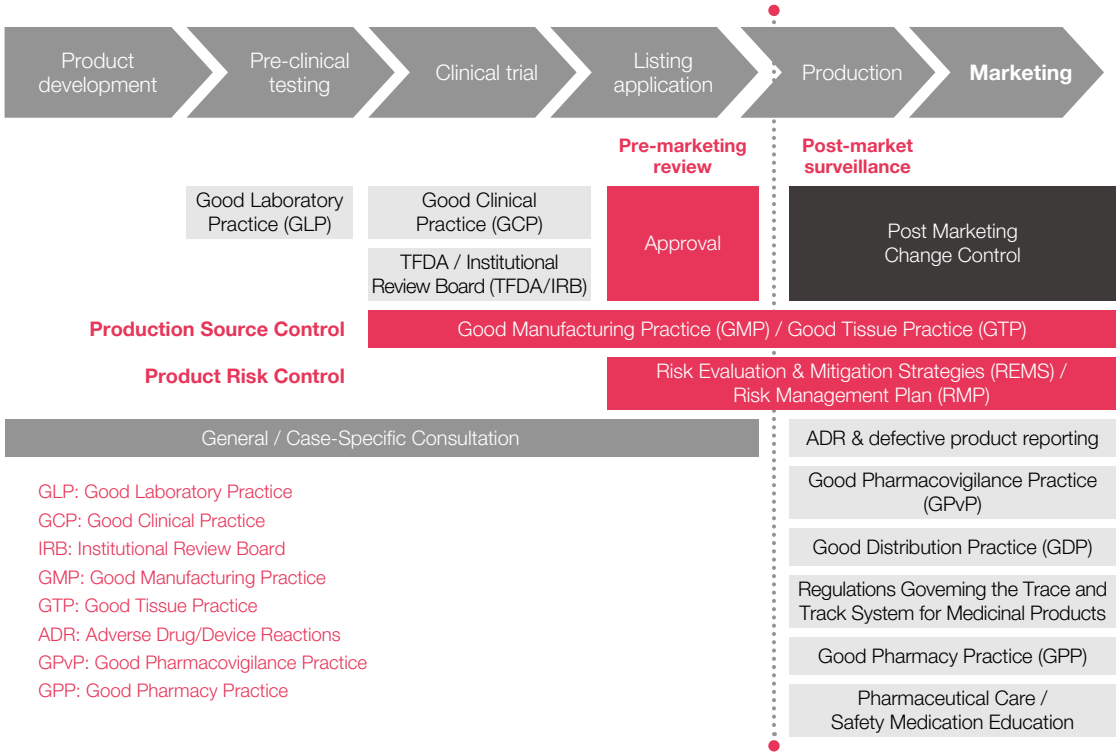
Unit: NT$ billion	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Revenue	82.2	88.4	94.0	98.6	104.7	110.6	114.2	125.8	133.9	137.2
No. of companies	500	510	525	557	596	626	651	671	684	690
Personnel	18,340	19,259	20,219	21,432	22,718	23,854	24,570	24,447	25,669	25,541
Export value	31.2	34.3	37.7	41.1	45.2	49.7	51.7	51.5	50.5	53.3
Import value	50.0	51.9	53.4	54.4	56.3	57.7	56.5	55.9	57.0	62.3
Import:Export	62:38	61:39	60:40	58:42	57:43	55:45	55:45	59:41	62:38	61:39
Domestic market size	101.0	106.0	109.7	111.9	115.8	118.6	119.0	130.2	140.4	146.2

Source: Industrial Development Administration, 2024 Biotechnology Industry in Taiwan White Paper.

3.1 Regulatory environment

The Taiwan Food and Drug Administration (TFDA), under the Ministry of Health and Welfare (MOHW), is the government body responsible for the enforcement of laws and regulations related to food, cosmetics, medicines and medical devices, in addition to the issuance of all related licences, permits and authorisations. It has established a comprehensive lifecycle management system for drug-related products (see Figure 24)—which is largely in line with international standards and practices—to effectively control their safety efficacy and quality.

Figure 24: Medicinal products management framework



Source: Taiwan Food and Drug Administration.

The TFDA conducts reviews, audits and inspections at the various stages of the drug lifecycle to monitor and ensure compliance with operating practices. The MOHW-backed Center for Drug Evaluation (CDE) assists the TFDA to conduct technical reviews of applications for clinical trials, new drugs and medical devices. Its main role is to improve the quality and speed of clinical trials as well as drug and device approval processes. The CDE also establishes regulations for new therapy treatments and ensures the transparency of review processes.

The principal governing law for the biotechnology sector is the 2007 Act for the Development of Biotech and Pharmaceutical Industry. The law has been amended in recent years to expand the R&D tax breaks available to qualified companies for investments in new and emerging biomedical technologies, including precision medicine, regenerative medicine and digital health. Furthermore, the Fundamental Science and Technology Act was revised in 2017 to facilitate the flow of biotechnology talent between academia and the private sector.

More recently, in June 2024, the Legislative Yuan passed new legislation that will facilitate the development of regenerative medicine. The Regenerative Medicine Act and the Regenerative Medicine Product Act establish a comprehensive framework for the management of regenerative medicine treatment and provide protection to patients. The new laws will give a boost to the biotechnology sector by helping expedite a wider application of research results to clinical medicine as well as speeding up approvals of regenerative medicinal products.

3.2 Conducting clinical trials

Drug development is a long and costly sequential process, from discovery and clinical development to approval and marketing. In Taiwan, for studies involving human subjects, clinical trials of investigational new drugs (INDs) conducted for marketing approval, as well as post-marketing studies on approved drug products, are mainly 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 R&D capabilities and simplify trial processes. For instance, the Taiwan Clinical Trial Consortium (TCTC) works with clinical trial sponsors to advance patient care and provide on-site clinical trial coordination services. The TCTC brings together 12 disease-specific clinical trial consortia, all of which are Asian prevalent, involving over 280 clinical trial doctors and principal investigators.

Taiwan is regarded as a favourable international site for clinical trials of new drugs. The 2019 Biotechnology Competitiveness and Investment Survey by Pugatch Consilium ranked Taiwan second among 17 fast-growing emerging biomedical markets, behind Singapore, for its investment attractiveness. However, international drugmakers contend some gaps still need to be closed for Taiwan to compete with mature markets, such as resolving drug approval delays and introducing greater predictability and holistic approaches for market access.

Research and clinical trials infrastructure

Research institutes have played an important role in Taiwan's economic development 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.

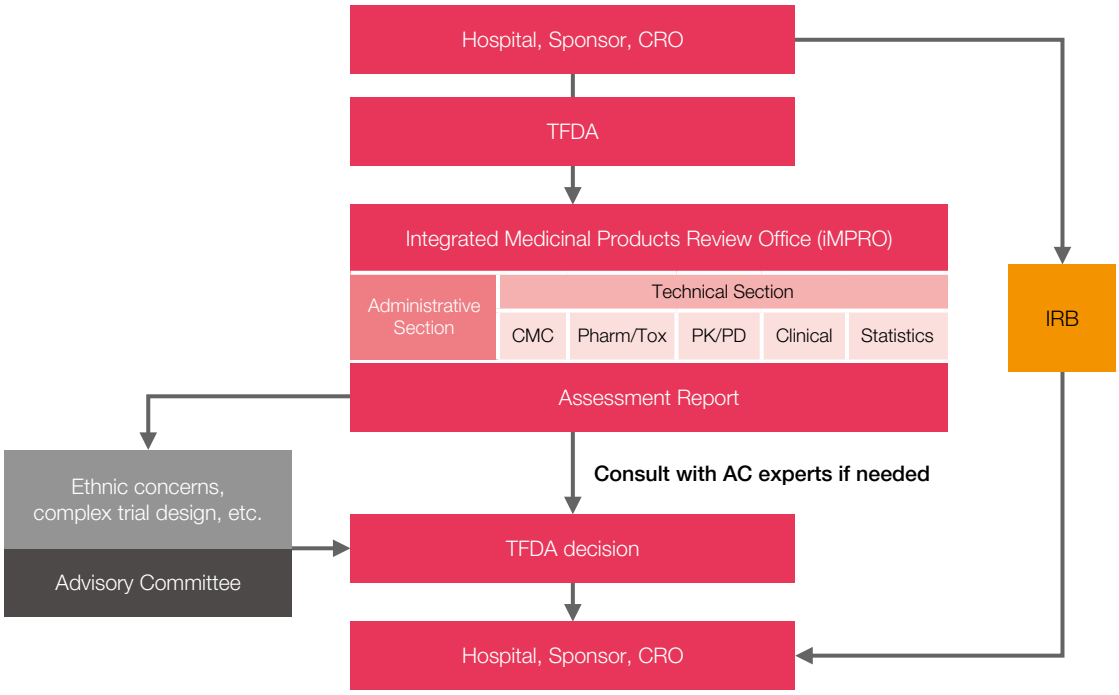
The opening of the National Biotechnology Research Park (NBRP) in the Nangang District of Taipei City in 2018 marked a key milestone for industry, as it integrated local R&D and start-up incubation capabilities, focusing all pre-clinical trial activity in a single location. The park houses the TFDA, DCB, National Laboratory Animal Center, Academia Sinica research centre, BioHub Taiwan incubation base and private firms. The NBRP has helped increase the scale and scope of local R&D and attracted multinationals 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, 25 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. Moreover, the MOHW has funded new clinical trial centres at certain hospitals.

Clinical trial review and approval process

Clinical trials of new drugs typically proceed through four phases and require prior approvals from both the TFDA and the relevant Institutional Review Board (IRB) (see Figure 25). Taiwan has a central IRB system consisting of nine 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, and the IRB one is filed in the name of the principal investigator.

Figure 25: Standard review process for IND applications



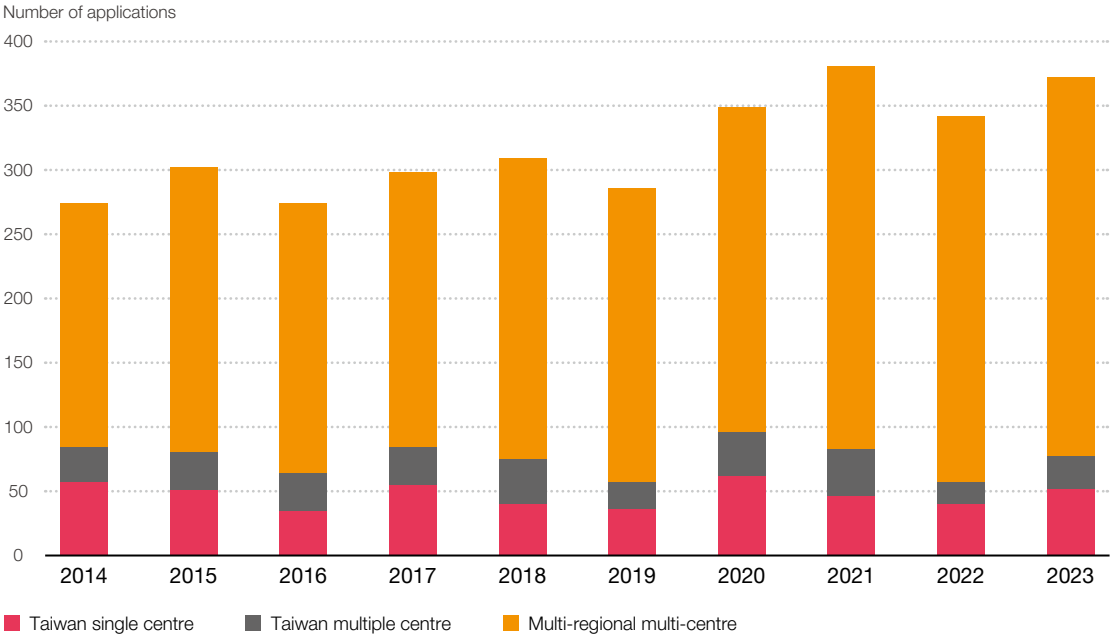
Source: Taiwan Drug and Food Administration.

Once a sponsor submits a clinical trial application to the TFDA, the supporting dossier is assessed. If required, a review meeting will be held with the TFDA, which may request supplementary documents. The standard review time for an IND application is 45 calendar days, while that for fast-track pathways for regional and global trials is 15 days. For cases where a multinational protocol has been approved by at least one of ten reference markets, the TFDA will conduct an administrative review without requiring a technical evaluation from the CDE.

The TFDA made enhancements in 2017 to its review processes for clinical trial protocols, which were aimed at helping accelerate the development of new drugs and facilitating 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 and refining the review process for clinical trial protocol amendments based on degree of changes.

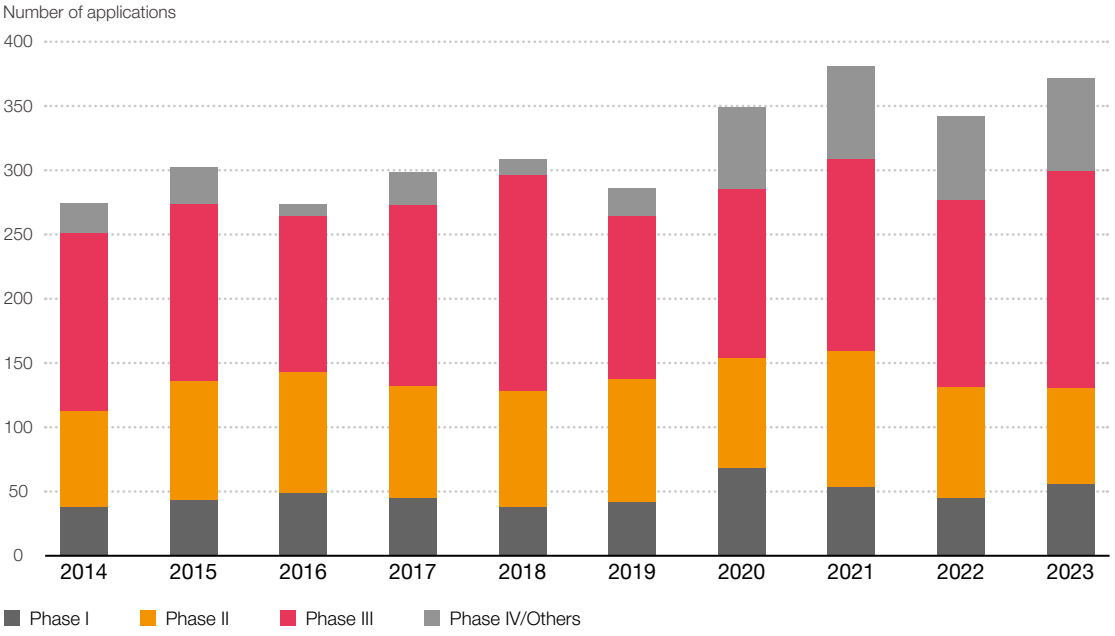
The number of clinical trials conducted in Taiwan has increased steadily in recent years (see Figures 26 and 27). The TFDA handles 300-400 new IND applications every year, mostly for multi-regional, multi-centre Phase II and III trials. Because of the high quality, speed and relatively low cost of conducting clinical trials in Taiwan, most of the major global pharmaceutical firms have set up local clinical trial offices, which mainly focus on Phase III global multi-centre studies. Even so, Taiwan faces stiff challenges from several regional competitors.

Figure 26: IND applications in Taiwan by clinical trial type, 2014-2023



Source: Taiwan Food and Drug Administration.

Figure 27: IND applications in Taiwan by study phases, 2014-2023



Source: Taiwan Food and Drug Administration.

3.3 Business environment

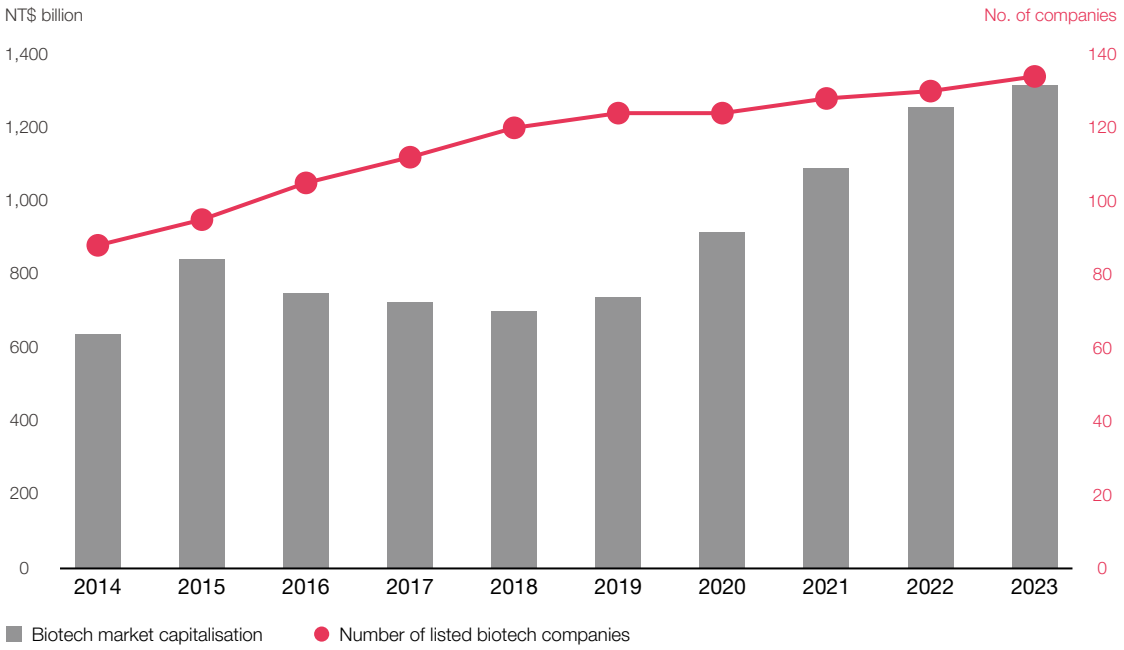
Taiwan's biotechnology sector is small in scale and has a fragmented structure. Around 690 enterprises are classified as biotech companies and their combined revenue totalled NT$137bn (US$4.4bn) in 2023. Due to a small domestic market size, local drug developers often work with outsourcing partners and Big Pharma to develop high-end drugs and expand abroad. 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.

The use of CDMOs has become increasingly popular among biopharmaceutical firms as a way to outsource various stages of drug development and manufacturing. Taiwan is keen to take advantage of these market changes. To better facilitate such partnerships, the Act for the Development of Biotech and Pharmaceutical Industry was amended in 2021 to extend its remit to CDMOs. The government has also taken other steps to boost the local biotech CDMO market, including support for firms to jointly develop key technology platforms.

As funding is a persistent challenge for both biotechnology start-ups and development-stage companies, the government has encouraged the creation of small and medium biotechnology venture capital funds to provide financing. The state-run National Development Fund also provides significant funding support by investing in biotechnology companies and biotechnology-related venture capital firms. Moreover, initial public offering (IPO) rules have been relaxed in recent years to make it easier for biotechnology firms to raise funds through listings.

As a result, the number of listed biotechnology and medical care companies in Taiwan has risen steadily (see Figure 28) to reach 134 in 2023—including 26 from the biotechnology sector, 55 from the pharmaceuticals sector and 53 from the medical devices sector—with a combined market cap of NT$1,317bn (US$42bn). As Taiwan's biotechnology sector is in the late incubation stage, the maturation of companies' clinical pipelines and the approval of new drugs has attracted growing investor attention and given a boost to biomedical stocks.

Figure 28: Market value of listed biomedical stocks in Taiwan, 2014-2023



Source: Industrial Development Administration, 2024 Biotechnology Industry in Taiwan White Paper.

4. Pharmaceuticals sector

Taiwan's pharmaceuticals sector covers a broad range of drug-related products, including small-molecule drugs, biologics, active pharmaceutical ingredients (APIs) and Chinese herbal medicine. The domestic market grew at a five-year CAGR of 3.9% to reach NT$243bn (US$7.8bn) in 2023 (see Table 6), with chemical drugs and APIs accounting for most of the sales. Around 70% of demand is fulfilled by growing imports of innovative brand drugs and the rest by local pharmaceutical companies, mostly for APIs and finished drug formulations.

Market growth has been, and will continue to be, supported by the rapid ageing of Taiwan's population and the related high demand for chronic disease treatments and new advanced drugs. A key constraint, however, is the government's continued reliance on cost-containment policies, such as drug price controls, to curb NHI spending on pharmaceuticals. International research firm BMI forecasts that Taiwan's pharmaceutical sector will expand at a five-year CAGR of 5.8% from 2023 to 2028 and at a ten-year compound rate of 5.5% to 2033.

Taiwan's 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. Prescription drugs dominate the local market, accounting for 89% of total pharmaceutical sales in 2023, made up of patented (60%) and generic (29%) drugs. The lack of proper drug prescribing and dispensing, which allows hospitals to operate their own in-house pharmacies for profit and encourages over-prescribing, is also beneficial to pharmaceutical suppliers.

The over-the-counter (OTC) medicine segment is small and under-developed, representing the balance of the market with a 11% share. This is due to the comprehensive nature of the NHI drug reimbursement schedule, which lists more than 14,000 items. But with reimbursed price cuts stifling growth of prescription drugs, drugmakers may look to the OTC segment 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, 2014-2023

Unit: NT$ billion	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Revenue	83.2	77.2	79.5	80.1	80.3	85.5	89.0	91.7	96.1	129.1
No. of companies	350	320	320	357	358	360	375	378	372	366
Personnel	19,000	18,500	18,500	19,000	19,055	19,100	19,500	19,800	20,380	27,500
Export value	19.7	26.1	31.4	29.2	30.1	31.0	32.2	33.3	40.3	60.8
Import value	99.9	102.1	126.7	142.2	151.0	168.0	168.1	181.8	217.6	174.9
Import:Export	76:24	66:34	61:39	64:36	63:37	63:37	62:38	64:36	58:42	53:47
Domestic market size	163.4	153.2	174.8	193.1	201.2	222.4	224.9	240.2	273.4	243.2

Source: Industrial Development Administration, 2024 Biotechnology Industry in Taiwan White Paper.

4.1 Regulatory environment

The TFDA is responsible for ensuring the quality and safety of pharmaceutical drugs for use in Taiwan, with its Division of Medicinal Products handling the registration, approval and monitoring of drug products. The CDE assists the TFDA with technical dossier reviews of new drugs and APIs. it was also previously responsible for conducting Health Technology Assessments (HTAs) to support the NHIA's reimbursement policy on new drugs, but since 2013 this role has been taken over by the National Institute for Health Technology Assessment.

The Pharmaceutical Affairs Act (PAA) provides the basic structure for the regulation of medicines, and there are also a raft of subordinate regulations, guidelines and standards to clarify the implementation of the PAA. The Act divides pharmaceuticals into raw materials (APIs) and finished formulation products, with the latter category further separated into new drugs, biological agents, generic drugs and orphan drugs. A new Medical Devices Act was enacted in 2020 to separate the regulation of medical devices from that of pharmaceuticals.

Taiwan's regulatory framework for pharmaceuticals is accredited by the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). This guarantees Taiwan's Good Manufacturing Practice (GMP) standards follow international norms and enables the 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 seeks to unify the processes for drug registration worldwide.

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 efforts to join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership on trade. The revised PAA established a new patent linkage system, which was officially implemented in 2019. It marked a positive step forward for Taiwan in its ongoing efforts to develop a more innovative pharmaceutical sector.

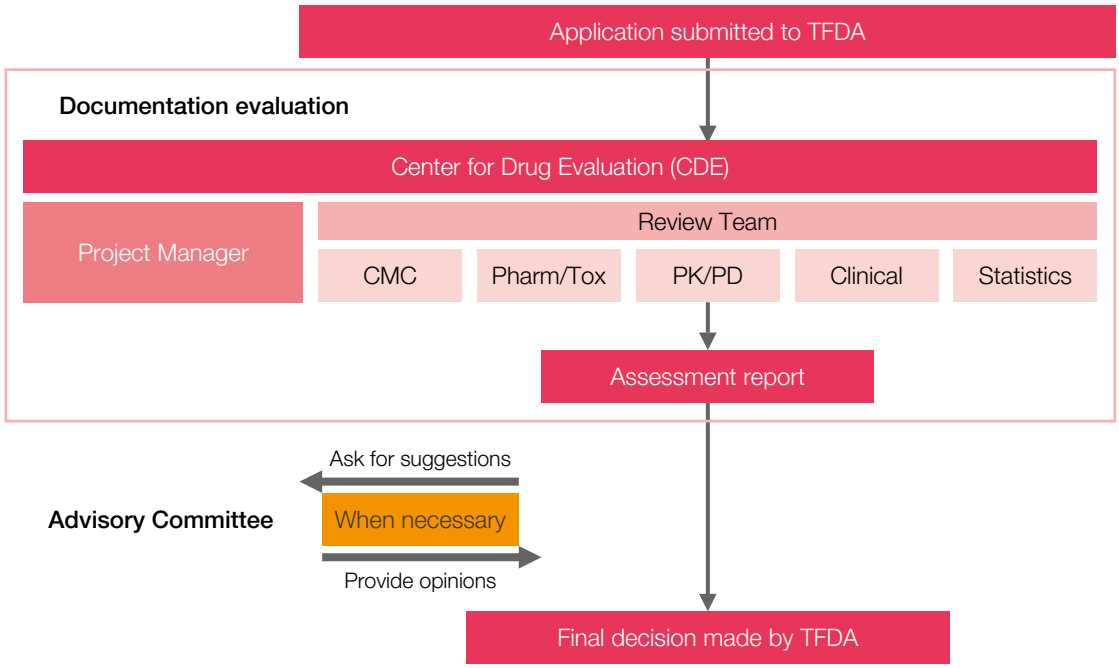
The patent linkage system aims to ensure that new generics are not launched in Taiwan while the original patent is still valid, as it makes potential patent infringement a mandatory consideration and an examination basis during the review process for generic drug applications. The TFDA checks such applications against a list of patented drugs with therapeutic equivalence, but concerns have been voiced that it's narrowly interpreting the new linkage 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) and 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 may be extended to five years.

4.2 Registration and approval

All domestically-produced and imported pharmaceutical drugs must be reviewed and approved by the TFDA to be able sell and market the product in Taiwan. The common types of applications are a new drug application (NDA), an abbreviated new drug application (ANDA) and an Over-the-Counter (OTC) application. For the NDA review process (see Figure 29), applicants must submit relevant information and data relating to the safety, efficacy and quality of the product, such as clinical trial results, manufacturing records and quality control data.

Figure 29: Review process for new drug applications



Source: Taiwan Food and Drug Administration.

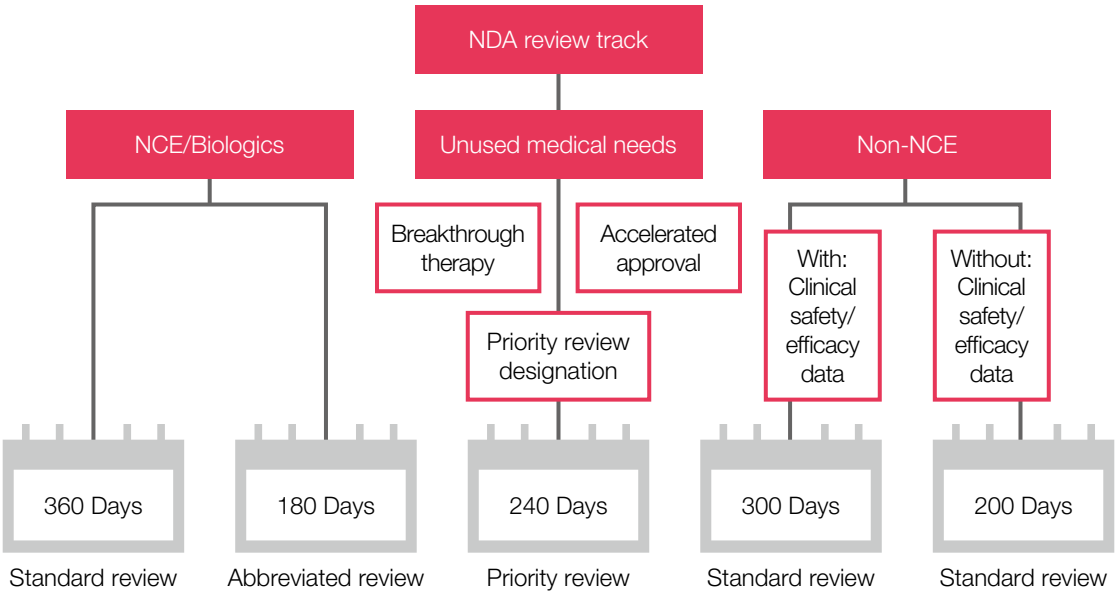
The TFDA and CDE review teams examine the submitted data related to an application and make a decision to approve it or not. The approval timeline for an NDA varies depending on the pathway (see Figure 30), ranging from six months (ANDA) to one year (standard NDA). In recent years, the TFDA has developed 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.

Nevertheless, the actual review timeline is still relatively lengthy. According to TFDA statistics, the median review time for NCE and biological applications was 330 days in 2023, just 29 days fewer than a decade earlier in 2014 (see Figure 31), while the average review time for applications under the priority review mechanism actually increased from 207 days in 2017 to 226 days in 2023. This highlights that the regulatory process for drug approval can be complex and time consuming, potentially hindering the speed to market for new products.

The recent introduction of a parallel review mechanism should expedite the drug review process. Previously all new drugs needed to pass a review and obtain a drug licence from the TFDA before applying to the NHIA for reimbursement listing. In January 2024, the NHIA set up a new HTA office to speed up the process of adding new drugs to NHI coverage. With the TFDA and the specialist unit reviewing new drugs simultaneously, the goal is to reduce the general time needed for review and NHI coverage of new drugs from two years to one year.

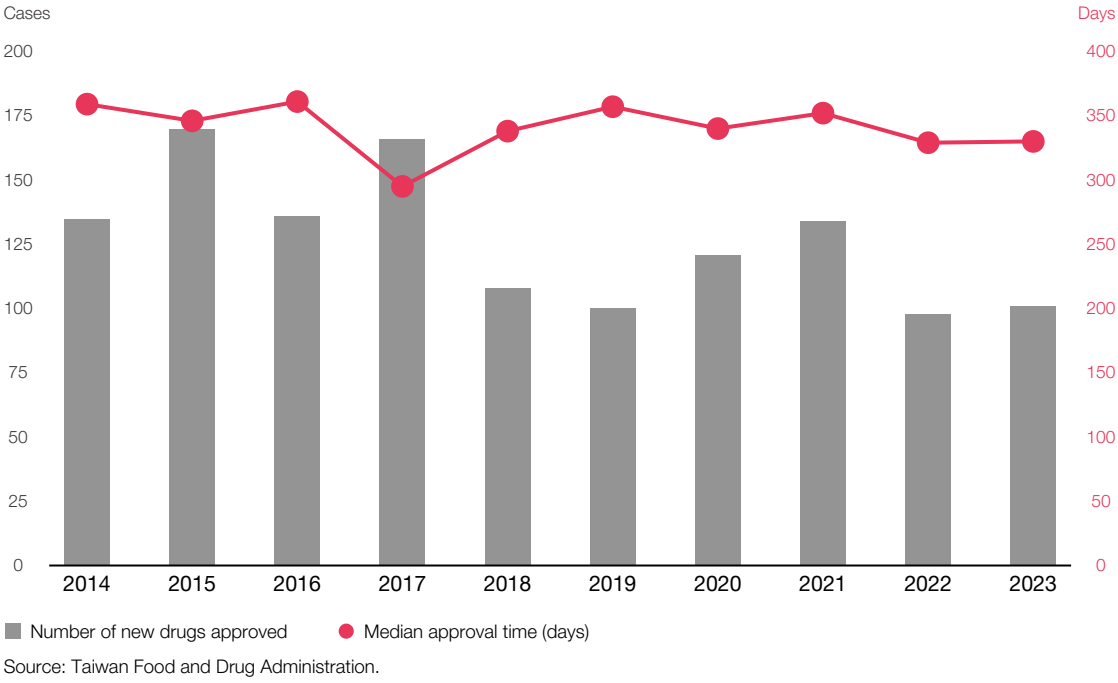
The parallel assessment pathway will enable pharmaceutical companies to apply for new drug approval and NHI listing at the same time. It will be made available for five major drug categories, including those granted with TFDA's priority review designation, accelerated review designation, paediatric drugs, drugs for rare diseases and new drugs not yet launched in other countries. Also, the NHIA has said it plans to digitise its NHI drug review process in 2024, which will enable applicants to keep track of the schedule and progress of reviews.

Figure 30: Review pathways for new drug applications



Source: Taiwan Food and Drug Administration.

Figure 31: New drugs approved in Taiwan, 2014-2023



Source: Taiwan Food and Drug Administration.

4.3 Reimbursement and pricing

As the vast majority of newly licensed drugs are required to be covered under the compulsory universal NHI programme, the NHIA administrator plays a key role in the reimbursement and pricing process (see Figure 32). Generally, after marketing approval for a new drug has been granted by the TFDA, the manufacturer must submit a separate application to the NHIA for inclusion in its comprehensive drug reimbursement schedule. Obtaining a positive reimbursement decision is seen as a prerequisite for the commercial success of new drugs.

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

Reimbursement listing approval

The NHI listing process involves a preliminary assessment by an Expert Advisory Meeting, followed by the recommendations of the Pharmaceutical Benefits and Reimbursement Scheme (PBRS) Joint Committee on a drug's benefit status and a final endorsement decision by the NHIA. The PBRS Joint committee consists of various different stakeholders and it is tasked with reaching a resolution on the listing and pricing of a new drug, which is supported by a HTA report that provides an evaluation of its therapeutic and economic value.

The new drug listing process has long been criticised for its slow pace. Currently, the average waiting time for all new drugs to receive approval for reimbursement listing is 729 days, and the average for oncology drugs is 783 days, according to NHIA data. Pharma multinationals regularly advocate the need for greater transparency and efficiency in the reimbursement approval process, highlighting, for example, the delays caused by the sequential drug reviews by the TFDA and NHIA for their respective registration and reimbursement processes.

To facilitate more timely patient access to innovative new drugs, in 2023, the NHIA introduced multiple policy reforms regarding NHI-covered drugs, which include provisional listing, increasing budgets for new drugs and implementing a new parallel review mechanism. It also established a designated agency, the Center for Health Policy and Technology Assessment, with additional funding and workforce to conduct parallel HTA reviews, among other tasks. Together, these measures should help speed up the inclusion of new drugs in NHI coverage.

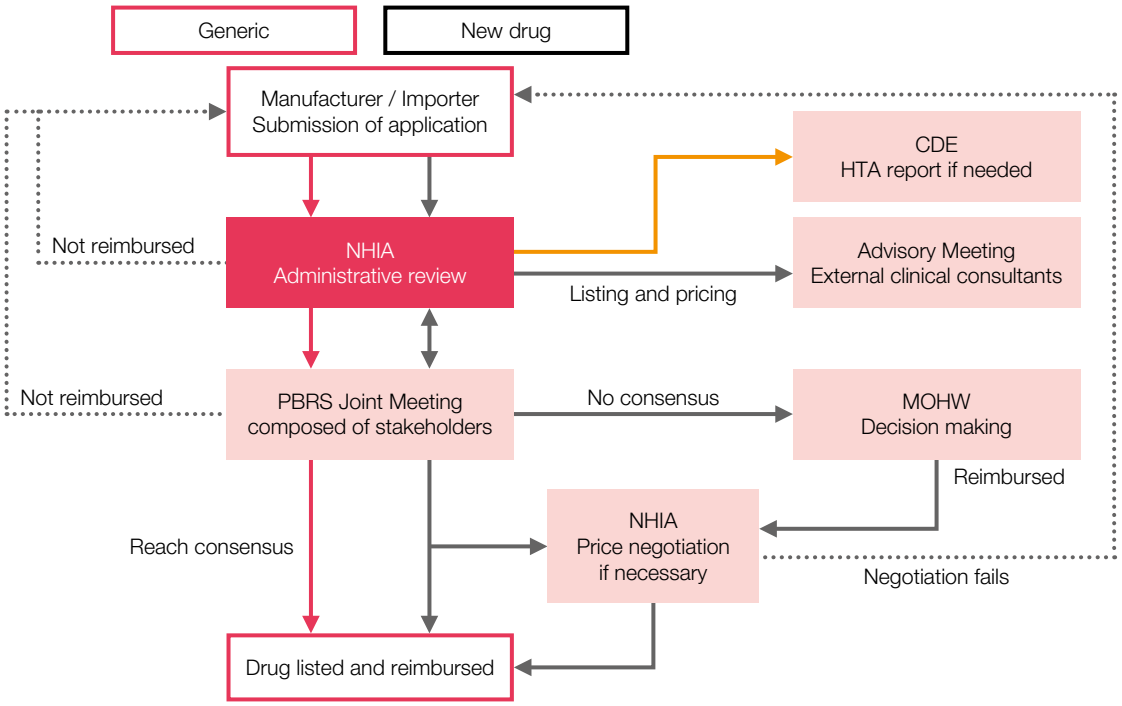
Reimbursement price setting

The NHIA typically acts to reduce the price it is willing to reimburse for new drugs in order to control spending on pharmaceuticals. In general, the reimbursement price of a brand-name drug is determined with reference to the prices of the product in ten advanced countries (A10) (see Figure 33). 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 drug expenditure, the cost of most new drugs is reviewed on an annual basis under a Drug Expenditure Target mechanism (see page 24). The NHIA sets an annual target for NHI drug spending, and if actual expenditure exceeds it, price adjustments will be made in the following year. This has resulted in several price reductions in recent years. Low drug reimbursement prices and annual price cuts are a contentious issue for pharma multinationals and may affect their willingness to launch new and innovative medicines in Taiwan.

Although NHIA has used price-volume agreements with drug manufacturers to a limited extent as part of its reimbursement model, it recently started to adopt risk-sharing agreements—also known as managed entry agreements (MEAs). In 2018, the NHIA set out guidelines for entering into MEAs, 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 drugmakers have expressed concerns about the implementation and execution of MEAs.

Figure 32: Pharmaceutical listing and pricing flowchart



Source: National Health Insurance Administration.

Figure 33: Reimbursement pricing of new drugs

Category		Pricing	Mark-ups
1	Breakthrough	Median price of A-10 countries	• 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 • Lowest price in A10 • Price in original country • International price ratio • Treatment-course dosage ratio • A combination drug is priced at 70% of the sum of each ingredient's price, or at the price of the single active ingredient.	
2B	Me-too		

Note: A-10 countries include Australia, Belgium, Canada, France, Germany, Japan, Sweden, Switzerland, UK and US.
Source: National Health Insurance Administration.

4.4 Business environment

Taiwan is a net importer of pharmaceuticals, with international suppliers attracted by its high level of per capita drug spending (of around US$265 in 2023), which reflects a large and growing demand for chronic disease treatments as the population ages rapidly. A well-developed healthcare system also serves to support the sale of patented drugs. The downside risks to pharma multinationals looking to launch innovative medicines in Taiwan include a longstanding policy focus on cost containment and use of price controls to curb healthcare spending.

The patented drug market is dominated by international drugmakers, but local companies have started to invest more heavily in new drug R&D. Most of the leading foreign players are active in Taiwan, mainly focusing on sales and marketing, and they generally use a local specialist distributor. Around 370 Taiwanese firms are engaged in pharmaceutical manufacturing, mainly production of APIs, finished generics or both. Phased-in compliance with global PIC/S GMP standards in recent years 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 novel medicines is also growing, attracting both academic institutions and local biotech companies.

In recent years, the government has implemented several strategic initiatives and policies to make Taiwan an attractive destination for investment in biomedical R&D. The Biomedical Industry Innovation Programme, which launched in 2016, 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 companies and encourages and supports them to set up R&D centres in Taiwan.

Certain tax incentives are available to inbound investors under the Act for the Development of Biotech and Pharmaceutical Industry. Qualifying companies undertaking R&D on new drugs or technologies are entitled to a deduction from their corporate income tax liability. The deduction is limited to 35% within five years from the year the tax liability is incurred. When expenditure on research and development for the current year exceeds the mean R&D budget for the preceding two years, a tax deduction of up to 50% of the excess may be taken.

Pharmaceutical retail sector

The principal sales channels for pharmaceuticals in Taiwan are hospitals, clinics and pharmacies. Taiwan has 36,336 pharmacists, of which 48% work in hospitals and clinics. The rest work at 8,665 community pharmacies, of which 7,184 are contracted with the NHIA and allowed to dispense reimbursed prescription drugs. But only around 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 own in-house pharmacies.

Community pharmacies therefore have to rely on sale of non-prescription (OTC) medicines and consumer health products. The market share of OTC drugs is low at 11%, yet pharmaceutical companies see potential growth opportunities, as the NHIA continues to cut the prices of prescription drugs and is more proactive toward the switching of prescription (Rx) drugs to OTC status. Also, changing consumer behaviours, such as higher awareness of personal health issues and a greater willingness to self-medicate, will be another influential factor.

5. Medical devices sector

Taiwan's medical devices sector encompasses a wide range of equipment and products used for diagnosis or therapy with patients, which have become increasingly crucial in the digital transformation of healthcare. In Taiwan, medical devices are classified into five groups: diagnosis and monitoring, surgery and treatment, in vitro diagnosis, assistance and compensatory and other devices. Taiwan is a leader in a number of products, such as contact lenses, blood glucose and pressure meters, electronic thermometers and electric wheelchairs.

The domestic market for medical devices grew at a five-year CAGR of 3.1% to reach NT$166bn (US$5.3bn) in 2023 (see Table 7). Due to its limited size, Taiwanese manufacturers rely on exports for about 60% of their revenues, mostly for mid-to-low-end medical equipment and contracted manufacturing for multinationals. At the same time, Taiwan is highly dependent on imports for around 60% of domestic demand, mostly for high-end surgical, therapeutic and medical imaging devices used in hospitals and supplied from the US, Europe and Japan.

Market growth is supported by Taiwan's growing elderly population and related higher demand for assistive devices and bone implants, as well as a government-backed initiative to increase higher-value manufacturing and greater uptake of innovative medical technology. BMI forecasts Taiwan's medical devices sector will grow at a CAGR of 6.9% in the 2022-2028 period. The key constraint on growth will be the cost containment policies used to control public healthcare expenditure, which, in turn, will increase pricing pressures on device makers.

The sector's development is underpinned by strong policy 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 encourage domestic companies to manufacture higher-end medical devices. Also, the new Medical Devices Act, which provides separate regulation of medical devices for the first time, is expected to bring greater regulatory efficiency as well as stimulate innovation in the medical devices sector.

Table 7: Status of Taiwan's medical device sector, 2014-2023*

Unit: NT$ billion	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Revenue	123.2	133.0	141.5	146.3	159.2	169.2	192.4	236.3	193.9	147.0
No. of companies	781	1,041	1,073	1,090	1,128	1,157	1,219	1,243	1,294	1,220
Personnel	36,429	38,400	39,300	40,300	43,850	46,953	48,365	49,916	50,936	49,539
Export value	74.3	81.2	86.1	87.3	95.5	104.1	117.1	146.1	108.4	83.0
Import value	67.2	72.2	73.6	74.6	79.0	88.6	96.1	96.8	100.9	102.1
Import:Export	40:60	39:61	39:61	40:60	40:60	40:60	39:61	38:62	39:61	43:57
Domestic market size	116.1	124.0	128.9	133.6	142.7	153.8	170.9	187.0	186.4	166.0

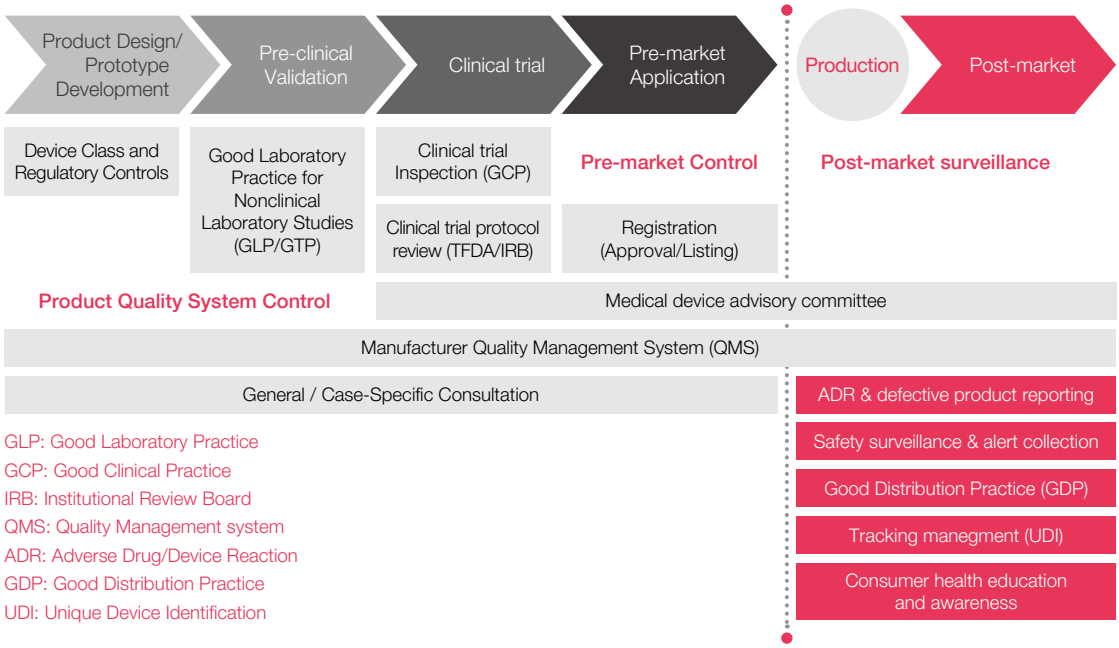
* Medical device revenues for 2023 were adjusted downward due to industry classification changes.

Source: Industrial Development Administration, 2024 Biotechnology Industry in Taiwan White Paper.

5.1 Regulatory environment

The TFDA is the regulatory authority for medical devices. It manages the medical device lifecycle by auditing manufacturers' quality control systems, performing pre-market evaluations and conducting post-market monitoring and surveillance (see Figure 34). 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 technical reviews.

Figure 34: Medical device management framework



Source: Taiwan Food and Drug Administration.

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

The new law provides a more robust regulatory framework for the lifecycle 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, it has helped rationalise the regulatory process and resolved many of the difficulties medical device makers faced before in meeting local legal requirements.

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

5.2 Registration and approval

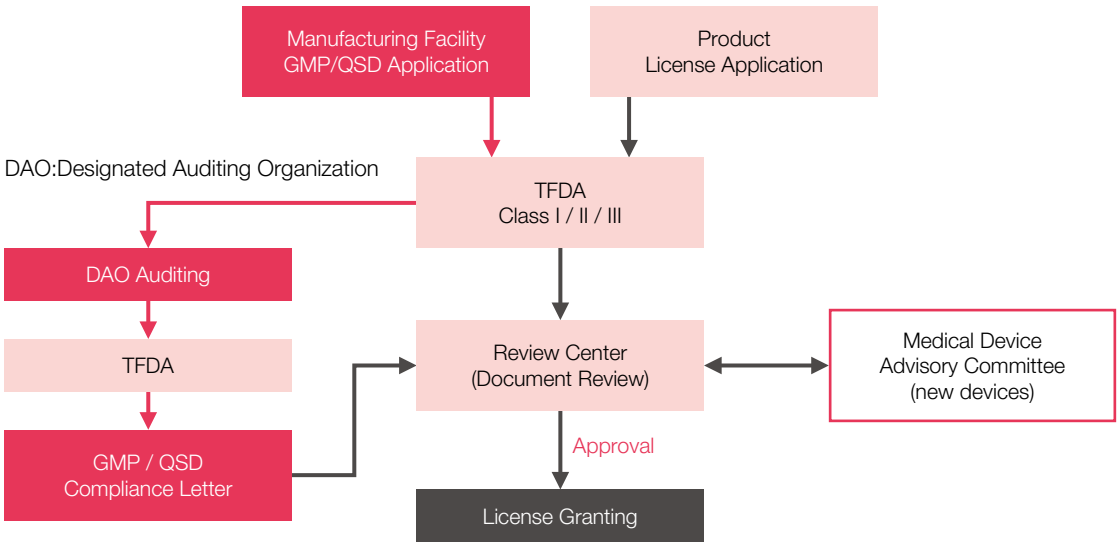
The local manufacturing or importation of medical devices is only allowed after a permit license—which grants registration and market approval—is issued by the TFDA. Medical devices are classified into low- (Class I), moderate- (Class II) and high-risk (Class III) groups. Devices that include materials 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; and they will be subject to an extended review.

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. Since 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 an expedited pathway.

Under the current review process (see Figure 35), applicants first need to submit all administrative documents for review of their completeness. Then the TFDA will perform a technical review of the required pre-clinical testing documents pertaining to the safety and performance of Class II and Class III devices; clinical reports may be needed for certain new 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.

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

Figure 35: Medical device registration process

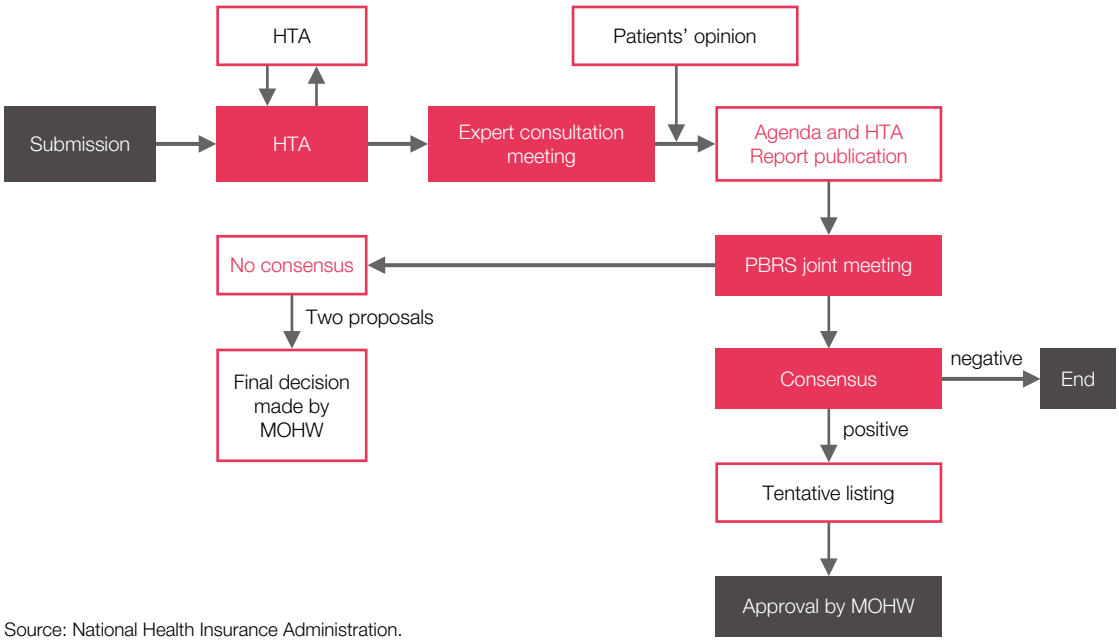


Source: Taiwan Food and Drug Administration.

5.3 Reimbursement and pricing

After marketing approval is granted by the TFDA, medical device makers are then required to submit a new product application to the NHIA. All devices must apply for reimbursement review (see Figure 36) even if a self-paid product is desired, with the listing and pricing of new devices determined by the NHIA. It decides whether or not to list a new device for NHI reimbursement as well as any restrictions on coverage. If listed, the price of the medical device will be set by the NHIA and it can then be used at any healthcare facility in Taiwan.

Figure 36: Reimbursement listing process for new medical devices



Source: National Health Insurance Administration.

Medical devices are either paid for under a fee-for-service or a diagnosis related group (DRG)-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. Moreover, the NHIA typically sets low reimbursement prices for new medical devices.

Because of the expenditure caps imposed by global budgets and DRG systems, hospitals bargain to obtain cheaper prices than the reimbursement prices for medical devices to make up for shrinking payments for patient care. To ensure reimbursement rates reflect the actual prices paid to vendors, the NHIA makes periodic price adjustments to reimbursable medical devices using price-volume surveys. As products may undergo several rounds of price cuts, this may 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. 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 balance. Furthermore, patients have the option to self-pay, out of pocket for devices not approved for reimbursement. In order for the device to qualify for this option, however, it must first be assigned a self-pay code by the NHIA.

5.4 Business environment

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

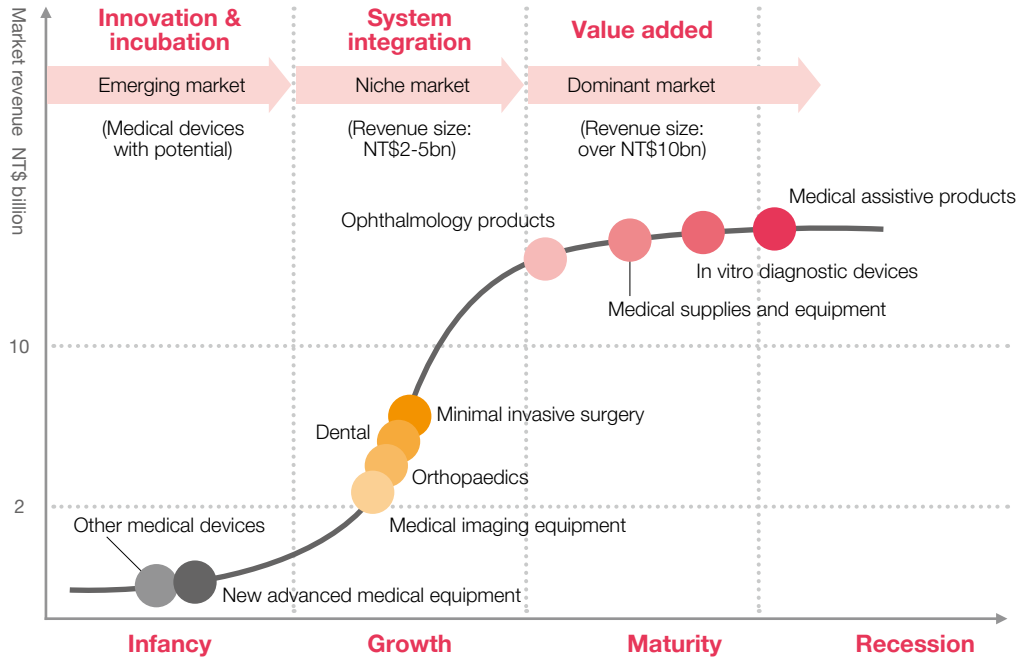
The government seeks to move the sector up the value-added chain (see Figure 37), as part of its goal to establish Taiwan as a regional biomedical R&D hub, while also addressing the growing needs of a fast ageing population. Special medical device clusters across Taiwan support new product development efforts. Also, the authorities facilitate upstream and downstream integration across the 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 significant opportunities for the medical device sector to take healthcare to the next level. This is attracting a growing number of Taiwanese technology companies to diversify into the biomedical industry to develop 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 patient care and outcomes.

The TFDA in 2021 set up a smart medical device office to support these efforts through coordinating regulations for advanced healthcare equipment and promoting development of AI- and machine learning-based medical devices. The office provides consultation, assistance, training and a matchmaking facility. To encourage R&D of domestic products, the TFDA has also set several digital health guidelines, including for AI and machine learning, software as a medical device, cybersecurity and computer-aided detection and diagnosis devices.

Most of the items that have undergone review by the smart medical device office are AI-assisted software for screening, detecting and diagnosis, listed as Class 2 (moderate risk) devices. Those that have obtained TFDA approval include ones that analyse images to diagnose cardiovascular diseases, tumours, eye disorders, bone fractures and chest and abdominal abnormalities, and many hospitals have been collaborating with medical device firms. However, the use of generative AI, such as ChatGPT, is prohibited from producing health records.

Figure 37: Development status of Taiwan's medical device sector



Source: Industrial Development Administration, 2019 Biotechnology Industry in Taiwan White Paper.

6. Key links and resources

Key government bodies

- Executive Yuan: www.ey.gov.tw
  - Biomedical Industry Innovation Program: https://biiptaiwan.org.tw
- Ministry of Health and Welfare: www.mohw.gov.tw
  - Food and Drug Administration: www.fda.gov.tw
  - National Health Insurance Administration: www.nhi.gov.tw
  - Center for Drug Evaluation: www.cde.org.tw
- Ministry of Economic Affairs: www.moea.gov.tw
  - Industrial Development Administration: www.ida.gov.tw
  - Biotechnology and Pharmaceutical Industries Promotion Office: www.biopharm.org.tw
  - Smart Electronics Industry Project Promotion Office (Smart Care SIG): www.sipo.org.tw

Research institutes

- Development Center for Biotechnology: www.dcb.org.tw
- Industrial Technology Research Institute: www.itri.org.tw
- Medical and Pharmaceutical Industry Technology and Development Center: www.pitdc.org.tw
- National Health Research Institutes: www.nhri.edu.tw

Biomedical parks

- National Biotechnology Research Park: https://nbrp.sinica.edu.tw
- Hsinchu Biomedical Science Park: www.hbspic.org.tw
- Central Taiwan Science Park: www.ctsp.gov.tw
- Southern Taiwan Science Park: www.stsp.gov.tw

Industry bodies and associations

- Institute for Biotechnology and Medicine Industry: https://ibmi.taiwan-healthcare.org
- International Research-Based Pharmaceutical Manufacturers Association: www.irpma.org.tw
- Taiwan Bio Industry Organization: https://taiwanbio.org.tw
- Taiwan Bio-Medical Care Association: www.tbmca.com.tw
- Taiwan Federation of Medical Devices Commercial Associations: www.tfmdca.org.tw
- Taiwan Medical And Biotech Industry Association: www.tmbia.org.tw
- Taiwan Research-based Biopharmaceutical Manufacturers Association: https://trpma.org.tw

Trade shows and expos

- BIO Asia-Taiwan: www.bioasiataiwan.com
- Healthcare+ Expo: https://expo.taiwan-healthcare.org
- Medical Taiwan: www.medicaltaiwan.com.tw
- Taiwan Healthcare Hub (TAITRA): https://healthcare.taiwantrade.com

7. How PwC can help

At PwC, our purpose is to build trust in society and solve important problems.

It is this focus which informs the professional services we provide and the decisions we make, and shows our commitment to working towards the highest quality outcomes for our clients, people and society.

About PwC Taiwan

We are a member of the PwC global network of firms in 151 countries with over 360,000 people who are committed to delivering quality in assurance, advisory and tax services.

PwC Taiwan was established in 1970 under the original name of Chen & Chu, and our firm has since grown steadily in size and strength to become one of the leading professional service providers in Taiwan.

We have over 3,700 people in six offices—in Taipei, Taoyuan, Hsinchu, Taichung, Tainan and Kaohsiung—who provide industry-focused services to private and public entities of all sizes and backgrounds.

Our health industries practice

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.

This breadth of knowledge and expertise, backed by the resources of our PwC global network, enables us to provide comprehensive advice and solutions to health and biomedical businesses and organisations.

Assurance services

We provide audit and assurance services and capital market and accounting advisory services to a broad spectrum of health industries clients, including emerging and early stage biotechnology companies preparing to go public on Taiwan's stock exchanges. Our services can support your ability to provide your stakeholders with accurate and understandable financial and operational information about your business activities.

Tax and legal services

We deliver practical tax and legal advice and solutions to health industries clients, and provide support ranging from tax structuring and strategy through to tax and regulatory compliance services. We intimately understand the health industries and how tax concerns impact a wide range of areas such as R&D credits, transfer pricing, intellectual property management, as well as mergers, acquisitions and divestitures.

Advisory services

We help health industries clients determine the right strategic priorities to grow profitably and maximise value, and offer advisory 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 all aspects of the M&A deals process.

To have a deeper conversation about Taiwan's health industries market, please contact:

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