Taiwan health industries
An introductory market overview

A concise guide to Taiwan’s healthcare, biotech, pharma and medical device sectors.
July 2018
Foreword

Across the Asia-Pacific region, a convergence of shifting economic and demographic trends, accelerating reform and transformation of health systems, and greater societal awareness of personal health and well-being issues, has created a health sector environment that is experiencing dramatic growth and change.

The related opportunities for organisations and businesses in Asia’s health systems and industries are vast as countries throughout the region search for the best way to finance, organise and deliver the highest possible quality of healthcare to the maximum number of people with the right balance of quality, cost and access.

Taiwan has one of the top-performing health systems in Asia, which is underpinned by a comprehensive national health insurance (NHI) programme offering universal coverage. However, the government faces a number of pressing health policy challenges, such as the growing strain of an ageing population on healthcare resources. In recognition of this, Taiwan’s authorities have begun planning for a next generation NHI.

Healthcare providers, drug manufacturers and medical device companies also face a challenging competitive environment in Taiwan, but one which also offers growth opportunities across the health spectrum. For instance, the government’s targeted development of the biomedical industry, with the goal of becoming a regional hub for pharma R&D, is generating interest in Taiwan as an attractive location for clinical trials.

Also, digital health has great potential to transform healthcare in Taiwan through delivering a better patient experience, with improved results, at lower costs. This trend is attracting the growing attention of companies operating at the intersection of technology and medical science, and encouraging tie-ups between medical facilities and firms involved in Taiwan’s innovative sectors like artificial intelligence and the Internet of Things.

This report, which is a revised update of our 2015 publication Taiwan health industries outlook, provides an introductory overview of Taiwan’s health industries—encompassing the healthcare, biopharmaceutical and medical device sectors—and examines the prospects, opportunities and challenges for market participants.

Our PwC health industries practice in Taiwan focuses on the healthcare, pharmaceutical and life sciences sectors. We bring industry experience as it pertains to assurance, tax and advisory services—providing a breadth of knowledge that helps us work with clients to resolve complex issues and identify opportunities.

To have a deeper conversation about Taiwan’s health industries market and how PwC can help you, please contact myself or one of my colleagues (see page 76) for assistance. We look forward to hearing from you.

Lily Wong
PwC Taiwan Health Industries Leader
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Note: The information in this report is up-to-date as of June 2018. The report has been compiled by PwC Taiwan’s Knowledge Management Director Damian Gilhawley and is based on desk research and interviews with industry stakeholders and experts. The material herein is intended for general informational purposes only and does not constitute professional advice. Please refer to the full disclaimer on the back cover.
Executive summary

Taiwan’s healthcare system

Key features

• Taiwan has a high performing healthcare system that has abundant medical resources and delivers high-quality treatment and care at affordable costs, and consistently enjoys high rates of public satisfaction.

• The universal and compulsory national health insurance (NHI) programme offers equal and easy access to a comprehensive network of contracted hospitals and clinics, most of which are privately owned.

• NHI benefits are uniform and comprehensive, with all medically necessary services covered, and patients face few limits on their choice of healthcare provider or doctor, as there is no gatekeeper referral system.

• National health expenditure represented 6.3% of GDP in 2016, which is low by OECD standards, with the NHI accounting for the majority of spending at 53%, followed by household out-of-pocket expenditure 34%.

• The relatively low spend reflects the ability of the government, as the single buyer of and payer for health-care services, to control expenditures, as well as the low-cost administrative efficiency of the NHI system.

Key challenges

• The most significant issue for the healthcare system is the NHI’s ‘all-you-can-eat’ provisions and relatively weak constraints on demand or supply, which causes excessive use and wastage of medical resources.

• Patients seeking treatment for minor illnesses are a key factor behind serious overcrowding at the larger hospitals, resulting in poor working conditions for doctors and nurses and causing a retention problem.

• Due to underfunding and fiscal constraints, the adoption of healthcare cost-containment measures has led to challenges in balancing costs and medical care, and impacted patient access to innovative drugs.

• Higher costs associated with a rapidly ageing population and growth in chronic disease cases will further strain the resources of the healthcare and long-term care systems and also impact the NHI’s finances.

• Further substantive reforms will be required to ensure the NHI’s sustainability in the longer term, and in recognition of this the government has already started planning for a next-generation healthcare system.
Taiwan’s biomedical industry

- The biomedical industry—including the applied biotechnology, pharmaceutical and medical device sectors—is a major priority focus for Taiwan, as part of the government’s “5 + 2 Innovative Industries Programme.”

- A long period of investment has produced a solid foundation, with an ecosystem that spans the entire biomedical value chain, from research, discovery and development to manufacturing and marketing.

- Combined domestic market sales (excluding exports) totalled NT$421.7bn (US$13bn) in 2016, with the pharmaceutical sector representing the largest share at 38%, followed by medical devices 36% and biotech 26%.

Biotechnology sector

- Strong government policy support has been a key contributor to the accelerated expansion of the biotech sector, which has more than doubled in size over the past decade to reach NT$109.7bn (US$3.4bn) in 2016.

- Its clinical research capacity has progressed rapidly, supported by abundant biotech talent, good medical and research infrastructures, ample clinical trials experience, and cost-competitive R&D and manufacturing.

- The growth momentum remains strong, supported by active government promotion of Taiwan as a biotech R&D base, a robust biotech IPO market, and the maturation of company pipelines and service offerings.

Pharmaceutical sector

- A well-developed healthcare infrastructure supports the sales growth of pharmaceutical drugs in Taiwan, with domestic market sales totalling NT$159.8bn (US$4.9bn) in 2016, ranking the sixth largest in Asia.

- The tight-budgeted hospital market accounts for 80% of total sales, which limits profits for drugmakers, and this is further compounded by a long reimbursement timeline and annual reviews of drug prices.

- Demographic and epidemiological trends will drive up future demand for medicines, but the continued use of drug-price controls to contain NHI spending on healthcare will limit rates of increase in market value.

Medical device sector

- Taiwan’s rapidly ageing population and related higher demand for healthcare products and services has underpinned growth in the medical device sector, with domestic sales of NT$152.2bn (US$4.7bn) in 2016.

- Taiwan depends on imports for almost 50% of local demand, mostly for high-end devices used in hospitals, while local companies rely on exports of mid-to-low-end medical equipment for over 40% of their revenues.

- A government-backed industry investment plan, announced in April 2017, aims to move Taiwan’s medical device sector up the value-added chain, and to increase its value to NT$200bn (US$6.5bn) by 2020.
Taiwan’s healthcare system

Taiwan’s healthcare system is internationally regarded for its National Health Insurance (NHI) programme,¹ which provides universal, easily accessible and affordable healthcare to a population of 23.6m people. With patients enjoying access to a comprehensive range of heavily-subsidised and high quality medical services, and facing few limits on their choice of provider, public satisfaction with the NHI system remains steadily high.²

Its many successes notwithstanding, the NHI, like any other healthcare system around the world, has had its share of challenges over the years, including serious financial deficits. The Taiwan authorities have managed those difficulties through successive policy adjustments and reforms, in particular the introduction of a so-called second-generation (2G) NHI in 2013. However, Taiwan’s healthcare system still faces several critical issues, which will necessitate further substantive reforms in order to ensure its long-term sustainability.³

The most significant issue is the NHI’s ‘all-you-can-eat’ provisions and relatively weak constraints on demand or supply, which encourage overuse and wastage of medical resources. For instance, the lack of a gatekeeper referral system enables easy access to care, with per capita outpatient visits twice the OECD average.⁴ Also, widespread overprescribing is common since prevailing fee-for-service reimbursement mechanisms and lack of proper prescribing and dispensing separation enable providers to profit from treatment of NHI patients. A rapidly ageing population and growth in chronic diseases, together with rising costs associated with new health technologies and surgical advances, are putting further strain on the healthcare system’s resources. Medical care costs for the 65 and over cohort accounted for 37.6% of total NHI spending in 2014,⁵ when the elderly share of the population was 12%. These costs will grow further in line with the projected rapid rise in seniors, with Taiwan set to formally become an ‘aged society’ in 2018 and a ‘super-aged’ society by 2026.⁶

Efforts to address some of these challenges are already being pursued by the authorities, such as the widening of differential co-payments in April 2017 to encourage patients to seek treatments for minor ailments at small hospitals and clinics.⁷ Further and deeper reforms are still needed, but healthcare reform is a politically sensitive issue in Taiwan, so it will take time to make any major changes. Health ministry officials confirmed in February 2017 that planning had begun for the 3G NHI, which is expected to take 6-8 years to complete.⁸

The rest of this chapter will look more closely at the key components of Taiwan’s healthcare sector—including its regulatory governance, infrastructure and workforce, demand status, and expenditure and financing—and analyse the related policy challenges facing the government and the likely reforms that might be introduced.
Figure 1: Overview of Taiwan’s healthcare system

**Key features**

- A government-run, single-payer health insurance scheme, the NHI, centralises the disbursement of healthcare funds.
- Healthcare providers are a mixture of public and private entities, almost all of which are contracted with the NHI.
- Compulsory health coverage for 99.6% of Taiwan’s 23.6m population, and patient freedom of provider choice.
- Universal patient accessibility, comprehensive benefit package, low out-of-pocket costs, and short waiting times.
- A central health IT system provides high administrative efficiency at low cost and near real time data monitoring.
- Positive health outcomes and consistently high rates of public satisfaction with the NHI since its inception in 1995.

**Main challenges**

- Ineffective constraints on patient access and provider overtreatment causes overuse of medical resources.
- Patients seeking treatment for minor illnesses are a key factor behind serious overcrowding at large hospitals.
- Doctor and nurse shortages and overworked working conditions for hospital personnel are a growing problem.
- Cost-containment policies are putting downward pricing pressure on healthcare providers and drugmakers.
- Taiwan’s fast-ageing population is increasing demand pressures on the provision of health and long-term care.
- Uncertainty over the long-term sustainability of the NHI amid rising healthcare costs and ageing demographics.

Source: PwC analysis
The Ministry of Health and Welfare (MOHW) is the competent government authority for all health and social welfare matters in Taiwan. It is responsible for health planning and promotion, disease prevention and control, food safety and drug management, medical care, social insurance, and social welfare, assistance and protective services. In addition, the MOHW oversees 26 public hospitals and 13 social-welfare institutions.9

Administration of Taiwan’s healthcare system is shared between the central and local levels. The MOHW is responsible for the central administration of health matters nationwide and the guidance, supervision and coordination of local health bureaus. Each of Taiwan’s municipality, city and county governments operate a health bureau, responsible for advancing health and medical operations within their respective jurisdictions.

The MOHW has five administrative agencies—the Centers for Disease Control; Food and Drug Administration; Health Promotion Administration; National Health Insurance Administration (NHIA); and the Social and Family Affairs Administration. The NHIA manages the mandatory national health insurance programme, the NHI, which provides comprehensive health and medical care coverage to virtually all of Taiwan’s population.

The MOHW closely supervises all NHI initiatives and policies. Its NHI Committee helps plan and monitor NHI-related tasks and its NHI Dispute Mediation Committee deals with NHI-related disputes. The NHIA is the single-payer for the NHI, with responsibility for premium collection, risk-pooling and provider payments, as well as oversight of utilisation, delivery and quality of services through an IT-driven administrative system.

In addition to specialised groups and offices that plan and promote various health insurance measures, the NHIA has six regional divisions across Taiwan that handle insurance enrolments, premium collections, utilisation review and reimbursements, and the management of contracted medical institutions. It has also set up 21 liaison offices in various cities and counties to serve the public. The NHIA has around 2,800 staff.10
Figure 2: Organisation of the healthcare system in Taiwan

Executive Yuan (Cabinet): Global budget target growth setting

Ministry of Health and Welfare: Policy, regulation

NHI Committee

National Health Insurance Administration: premium collection, risk pooling, payment of providers, quality assurance

Department of Social Insurance

NHIA – Taipei Division

NHIA – Northern Division

NHIA – Central Division

NHIA – Southern Division

NHIA – Kaoping Division

NHIA – Eastern Division

Hospitals and Clinics

Insured

Planning Division

Enrolment Division

Financial Analysis Division

Medical Affairs Division

Medical Review and Pharmaceutical Benefits Division

Information Management Division

Secretariat

Personnel Office

Accounting and Statistics Office

Civil Service Ethics Office

Service delivery infrastructure

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

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

Figure 3: Current healthcare systems in Taiwan

**Medical care institutions**

In 2016, Taiwan’s healthcare infrastructure included 22,384 medical care institutions (490 hospitals and 21,894 clinics), of which 93% (482 hospitals and 20,375 clinics) were contracted with the NHIA. Of the remaining 7% non-contracted healthcare providers, most have chosen not to join the NHI programme. These providers, such as renowned cosmetic surgeons and TCM doctors, must therefore rely on self-paying patients.

Most of Taiwan’s hospitals (83% in 2016) and an even greater proportion of health clinics (98%) are privately owned, and many are small. According to MOHW data, Taiwan had 490 (81 public, 409 private) hospitals and 21,894 (440 public, 21,454 private) clinics in 2016. Western medicine is the predominant form of care, accounting for 53% of all registered providers, followed by dental clinics (30%) and TCM institutions (17%).

The total number of hospitals dropped from 750 in 1997 to 490 in 2016, mainly due to the closure or merging of small private hospitals unable to withstand rising operational costs. Private hospitals still outnumber public facilities by more than five to one, but district hospitals in particular have struggled in the face of growing competition from the larger, better-resourced medical centres and regional hospitals, which are favoured by many patients. The lack of an effective gatekeeper mechanism serves to encourage this excess utilisation.

Although hospital numbers have declined over the past 20 years, the remaining facilities have grown in size and opened more beds, in an effort to boost their efficiency and revenues—the total number of hospital beds increased from 108,536 in 1997 to 133,499 in 2016. Taiwan currently has 5.7 hospital beds per 1,000 people, above the OECD average of 4.7, with around two-thirds of all beds owned by privately-operated facilities.

As for health clinics, their numbers grew from 16,648 in 1997 to 21,894 in 2016, consisting of 11,395 Western medicine clinics, 6,727 dental clinics and 3,772 TCM clinics. The rise has been driven, in part, by government efforts to reduce reliance on hospitals for the provision of primary care services. It is estimated that around 40% of Taiwan’s doctors practice in their own private clinics, and 80% to 90% of clinics are solo practices.

<table>
<thead>
<tr>
<th>Table 1: Number of NHI-contracted hospitals and clinics, 2016</th>
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<tbody>
<tr>
<td><strong>Total</strong></td>
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<td>----------------</td>
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<tr>
<td>Total healthcare institutions</td>
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<td>Contracted healthcare institutions</td>
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<td>% of institutions contracted</td>
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Source: Ministry of Health and Welfare and National Health Insurance Administration
Figure 4: Number of hospitals and hospitals beds, 1997-2016

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<th>Year</th>
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<th>Public hospitals</th>
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Source: Ministry of Health and Welfare

Figure 5: Number of health clinics, 1997-2016

<table>
<thead>
<tr>
<th>Year</th>
<th>Western Clinics</th>
<th>Chinese Clinics</th>
<th>Dental Clinics</th>
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<td>20000</td>
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Source: Ministry of Health and Welfare
Private sector dominance

Largely because the public health infrastructure was not capable of meeting the increase in demand triggered by the implementation of the NHI in 1995, the programme was designed from the start to attract non-public investment. As a result, providers are primarily private and free to compete with each other. Many hospitals are organised as foundations, which allows them to enjoy tax breaks as not-for-profit medical institutions.

Yet, most private not-for-profit hospitals behave as if they were for-profit. In 2016, 114 out of the 148 hospitals that claimed more than NT$400m (US$13.7m) in reimbursements from the NHI generated a profit. As gains from healthcare services are relatively low, many hospitals depend on non-healthcare income (such as from food courts, convenience stores and parking lots) to balance fiscal gaps from insufficient NHI reimbursements.

In general, providers obtain their revenues from NHI reimbursement payments, co-pays and registration fees, and proceeds from the sales of services and devices not covered by the NHI. While the overall NHI payments to providers have increased under the global budget system, the growing medical utilisation and severity of illness have resulted in shrinking reimbursements for each service performed. As a consequence, providers are pressured to be more efficient, to compete for volume, and to provide more services with higher margins.

The competition for patients among private hospitals creates a supply-induced demand for care under the NHI’s predominantly fee-for-service payment system, and is a key contributory factor to the high utilisation of healthcare resources in Taiwan. However, ineffective constraints on either service demand or supply, provider reimbursement mechanisms, and the ability of hospitals to profit from the sale of drugs and other services have all encouraged widespread overtreatment, and this has been a major driver of NHI spending.
**Medical workforce**

Despite an extensive network of medical facilities, Taiwan faces a growing shortage of doctors and nurses due to retention issues. The situation is not helped by the fact that the population of medical personnel is controlled by government quotas, with the number of medical school enrolments restricted to 1,300 students per year. In 2016, there were a total of 51,234 doctors (both Western and TCM) and 130,785 nurses in Taiwan, or 2.2 doctors and 5.6 nurses per 1,000 people, which are lower than the respective OECD averages of 3.4 and 9.0.

The comparatively low ratios are a concern in view of the high utilisation of healthcare services in Taiwan—in the 2007-2016 period, hospital outpatient visits grew by 14.9% and inpatient numbers by 13.0%. Doctors in hospitals often complain about being overworked, underpaid and prospects of malpractice suits. Many have left to work in clinics or take up higher-paying posts overseas, creating serious shortages in the major specialty areas of internal medicine, surgery, emergency care, podiatric medicine, and obstetrics and gynaecology.

Nurses also complain about long hours, low wages and stressful working conditions. This has resulted in an increasing number of non-practicing registered nurses and ever-worsening nurse shortages and nurse-patient ratios. To address the issue, in 2012, the MOHW started to actively implement reforms aimed at increasing nurse-staffing levels and improving nurse retention. In 2015, nurse-patient ratios were officially added to the criteria for hospital evaluations in an effort to improve the labour conditions of nursing staff.

The manpower shortage in hospitals has largely been brought about by the design of the NHI scheme—and in particular by the global budget system, which caps reimbursement levels for medical services. Provider cost-containment efforts have included the imposition of increasingly heavy workloads on doctors, nurses and other staff. Coupled with declining levels of financial compensation, the deterioration in working conditions has led to serious staff shortages. Resolving these medical personnel issues is a key government priority.

The matter has taken on a pressing urgency, because doctors will start to be covered by the Labour Standards Act in 2019, possibly cutting the amount of time they can work and creating manpower shortages at major hospitals. Faced with potential staff shortages and the need to free up resources for critical and emergency care, in November 2017, the NHIA announced plans to cut outpatient visits to medical centres and regional hospitals by 10% over the next five years, by way of channelling outpatients to smaller healthcare facilities.
Figure 6: Number of doctors and nurses per capita, 2007-2016

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

The health record is entirely electronic at every level of care. Contracted providers are required to report to the NHIA, on a 24-hour basis, each patient visit and service delivered, thus enabling the tracking of individual and national aggregate service utilisation in almost real time. This provides the NHIA with a good sense of overall healthcare expenditures at any point in time and helps it to identify and manage heavy users of NHI services. The centralised data repository also serves as a useful resource for tracking health trends in the population.

Two recent personal health information innovations, both cloud-based, are worthy of note. One is the NHI PharmaCloud system, a patient-centred drug information database, which was created in 2013 and expanded in 2016 to also offer medical treatment information to help doctors and pharmacists better diagnose ailments and prescribe medicines. The other is My Health Bank, a web-based electronic medical records repository for consumers, which was introduced in 2014 and upgraded in 2016 to increase access to personal health data.

In addition, in January 2018, the NHIA launched a cloud-based file-sharing platform for diagnostic images to be shared among contracted medical facilities, which is expected to generate annual savings of NT$2bn (US$69m). The new platform allows large hospitals to upload images of computed tomography (CT) and magnetic resonance imaging (MRI) scans, which can be retrieved by smaller hospitals and clinics for follow-up diagnoses. It will gradually include the imaging results of gastroscopy, ultrasound and X-ray procedures.

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Figure 7: NHI system framework (data flow)

Source: National Health Insurance Administration
### Demand and resource utilisation

#### Disease trends

Coupled with rising incomes and advances in medical care technologies, the NHI has brought substantial health improvements to the population. Taiwan’s outcome measures compare favourably to most OECD countries in terms of life expectancy (80 years in 2016, up from 74.5 in 1995) and infant mortality rates (3.9 per 1,000 live births in 2016, down from 6.5 in 1995). However, Taiwan has much lower fertility and birth rates, a situation which has persisted for decades and led to a higher rate of ageing than the OECD average.

While the burden imposed by infectious disease has been reduced, chronic non-communicable diseases (NCDs) have emerged as a growing challenge. In 2016, chronic NCDs were responsible for approximately two-thirds of all deaths in Taiwan, with cancer alone responsible for a 28% share of overall mortality, followed by heart disease (12%), pneumonia (7%), cerebrovascular disease (7%) and diabetes (6%). Cancer treatment accounted for NT$84.5bn (US$2.9bn), or 14%, of total NHI expenditure in 2016, making this the most expensive disease area.

The rising burden of chronic NCDs has serious implications for Taiwan’s healthcare system in terms of both growing utilisation of services and associated healthcare costs, and potentially increased demand for a larger healthcare workforce. Moreover, as demographic ageing is a key driver of the increasing prevalence of NCDs, the accelerating growth of Taiwan’s elderly population (as detailed next) will put more pressure on already strained healthcare resources, and poses a major risk to the long-term sustainability of the NHI programme.

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**Figure 8: Life expectancy and infant mortality, 1995-2016**

- **Life expectancy at birth (years)**
- **Infant mortality rate**

Source: Ministry of Interior and Ministry of Health and Welfare
Taiwan’s 23.6m population is ageing rapidly due to shrinking birth rates (now barely more than one child per woman) and longer life expectancy. The annual population growth rate dwindled to 0.2% in 2016 from an average of 1.4% a year in the 1980s. Government measures to encourage people to have more babies, such as stipends for giving birth and childcare benefits, have had little impact. As a consequence, the government currently projects that negative population growth will occur in 2021 at the earliest and in 2025 at the latest.

Taiwan has one of the fastest ageing populations in the world. It formally became an ‘ageing society’—in which the proportion of people aged 65 or older accounts for at least 7% of a country’s population—in 1993. The share of the elderly segment has since nearly doubled to 13.2% in 2016. Current government estimates for 2016-2060 indicate Taiwan will likely meet the criteria for an ‘aged society’ in 2018 when senior citizens account for 14.5% of the population, and a ‘super-aged society’ in 2026 when that figure reaches 20.6%.

The latest available data show that, in 2014, medical spending on patients aged 65 and over (representing 12% of the population at that time) accounted for NT$206.5bn (US$7.1bn), or 38%, of total NHI expenditure. In per capita terms, the average amount was NT$73,898 (US$2,538) per senior citizen, some three times higher than the national average—clearly indicating that the higher the age, the more spent per person on healthcare.

With the government projecting that the size of Taiwan’s senior population could increase by as much as 50% over the next decade, to 4.9m individuals in 2026, spending on elderly healthcare will also correspondingly rise. Besides driving the NHI’s medical costs higher, an ageing population will also mean a smaller workforce and a reduced premium base, and similarly threaten the long-term sustainability of the healthcare system.
Figure 9: Total population growth trend in Taiwan, 1980-2060

![Population growth trend graph](chart1.png)

- Actual Population
- High-variant projected population
- Medium-variant projected population
- Low-variant projected population

Source: Ministry of Health and Welfare and National Development Council

Figure 10: Ageing population trend in Taiwan, 1980-2060

![Aging population trend graph](chart2.png)

- Population of population aged 65+ (%)

Source: Ministry of Health and Welfare and National Development Council
Long-term care in Taiwan

The rapid growth of the elderly population is putting pressure on the government to strengthen Taiwan’s long-term care (LTC) system. In 2015, it passed a Long-Term Care Services Act to regulate the establishment and management of care facilities. Two years later it launched a new Long-term Care Plan 2.0 to promote capacity building and widespread distribution of LTC resources, with the goal of establishing a complete chain of care, from preventative healthcare to community-based support services and finally late-life hospice care.

The ten-year LTC Plan 2.0 is a key plank of the government’s efforts to expand the amount and quality of care available to Taiwan’s elderly and disabled population. It is an extension of the original plan that was launched in 2008, with this version designed to have a more local-level focus and provide for more flexible services. Meanwhile, through its integrated home care programme, the NHI provides home care for the elderly and disabled, including visits by physicians and nurses, community services, and end-of-life care.

The implementation of the LTC Plan 2.0 is expected to benefit 738,000 people, compared with 511,000 under the previous scheme, but it will also place greater demands on funding and the workforce. The government budgeted NT$20.7bn (US$711m) for the new programme in 2017, but as the ageing population increases over the next ten years, the MOHW estimates annual LTC costs could reach NT$73.6bn (US$2.5bn) by 2026. In addition, Taiwan has a shortage of care workers and many more will need to be recruited in the next few years.

Aside from government budget allocations, the LTC Plan 2.0 relies on supplementary revenue sources, such as inheritance, gift and cigarette taxes, which may not be stable. With aged-care expenditure expected to rapidly increase over the coming years, the government will have to find additional revenue streams to fund long-term care. Given current public budget constraints, the expansion of Taiwan’s LTC system will offer opportunities for private investment in facilities and services to meet the needs of the elderly population.

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Figure 11: Projection of long-term care needs in Taiwan, 2017-2026

<table>
<thead>
<tr>
<th>Year</th>
<th>Under 65 years old</th>
<th>Above 65 years old</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>800,000</td>
<td>800,000</td>
<td>1,600,000</td>
</tr>
<tr>
<td>2018</td>
<td>700,000</td>
<td>700,000</td>
<td>1,400,000</td>
</tr>
<tr>
<td>2019</td>
<td>600,000</td>
<td>600,000</td>
<td>1,200,000</td>
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<tr>
<td>2020</td>
<td>500,000</td>
<td>500,000</td>
<td>1,000,000</td>
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<tr>
<td>2022</td>
<td>300,000</td>
<td>300,000</td>
<td>600,000</td>
</tr>
<tr>
<td>2023</td>
<td>200,000</td>
<td>200,000</td>
<td>400,000</td>
</tr>
<tr>
<td>2024</td>
<td>100,000</td>
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<td>200,000</td>
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<td>2025</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2026</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Source: Ministry of Health and Welfare
Utilisation of healthcare resources

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

Outpatient visits to Taiwan's hospitals increased by 14.9% over the 2007-2016 period, and the average annual number of outpatient visits per NHI beneficiary rose from 14.0 to 15.3 times, which is more than two times the current OECD average of 6.9 per capita outpatient visits. The high rate of visits can be attributed to the easy accessibility to affordable healthcare services in Taiwan and its ageing demographics, as older people typically use more medical services and have more chronic illnesses than other segments of the populace.

The issue is becoming particularly acute for the larger hospitals, according to NHIA data. In 2006, the ratio of outpatient services was 70.2% for primary clinics, 11.2% for district hospitals, 10.2% for regional hospitals and 8.4% for medical centres. Ten years on, in 2016, the figures were 64.7% for primary clinics, 9.7% for district hospitals, 14.8% for regional hospitals and 10.8% for medical centres. The NHIA projects that by 2020 the percentages for regional hospitals and medical centres will rise to 11.5% and 15.2% respectively.

The number of hospital inpatients grew by 13.0% between 2007 and 2016, while the average length of stay fell from 9.4 to 8.7 days, though still higher than the current OECD average of 7.8 days. The rise in inpatient numbers has been driven by several factors, including the lack of an effective gatekeeper referral system for specialty care and hospitalisation, more elderly and chronic cases, and insufficient long-term care facilities.

Figure 12: Medical service volume of hospitals, 2007-2016
Patients in Taiwan can visit any number of doctors without restrictions, which encourages doctor- and hospital-shopping, even for minor ailments. They generally trust the quality of outpatient care provided at hospitals more than that of clinics, and this has led to overcrowding issues in many hospital outpatient departments, especially at large hospitals and major medical centres. While convenient for patients, the high volume of outpatient visits inevitably increases doctors’ workloads and limits the time they spend on each patient.

Supply-induced demand for hospital care is also an influential factor, as the larger hospitals are incentivised to compete for patient and service volume in the outpatient setting, which is more profitable than the provision of inpatient care under the current NHI reimbursement payment system. Payments to hospitals accounted for 45.6% of all spending on personal healthcare in 2016, with clinic payments responsible for a further 23.6%, underlining the dominant role played by hospitals in outpatient as well as inpatient provision.\(^{35}\)

Efforts to curb the moral hazard behaviour of both patients and healthcare providers have been stepped up in recent years, with a view to improving integration between primary and secondary care. These include measures designed to encourage more widespread use of family doctors—partly through the imposition of punitive co-pays on non-referrals to hospitals and specialist clinics. Opposition to measures that threaten patient choice is strong, however, while hospitals are reluctant to relinquish their hold on the lucrative outpatient business.

**Patient cost sharing**

Taiwan’s NHI programme guarantees health access to patients regardless of their financial means. But in order to optimise the use of resources and reduce NHI costs, all enrollees are required to co-pay for most medical services, though some categories of patients are exempt from such payments. Co-pays include fixed fees for outpatient visits, which range from NT$50 (US$1.7) at local clinics to NT$550 (US$18.9) at medical centres, and 5%-30% of hospital costs for inpatients, depending on the type of illness and the length of stay.\(^{36}\)

Since the NHI’s inception, co-payment levels have been adjusted several times to help reduce moral hazard and ration excess healthcare utilisation, yet the resulting rates are still relatively low. Most recently, in April 2017, the NHIA increased outpatient fees for visits to medical centres without a prior referral from NT$360 to NT$420; if patients have a referral, the fee has been reduced from NT$210 to NT$170. In addition, patients seeking emergency-room treatment for conditions classified as minor most now pay an additional NT$100.\(^{37}\)

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### Table 2: Basic co-payments for outpatient visits under NHI system

<table>
<thead>
<tr>
<th>Institution class</th>
<th>Western medicine Outpatient care</th>
<th>Emergency care ER examination</th>
<th>Dental care</th>
<th>Traditional Chinese medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of institution</td>
<td>With referral</td>
<td>Without referral</td>
<td>Level 1, 2</td>
<td>Level 3 to 5</td>
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<tr>
<td>Medical centres</td>
<td>170</td>
<td>420</td>
<td>450</td>
<td>550</td>
</tr>
<tr>
<td>Regional hospitals</td>
<td>100</td>
<td>240</td>
<td>300</td>
<td>300</td>
</tr>
<tr>
<td>District hospitals</td>
<td>50</td>
<td>80</td>
<td>150</td>
<td>150</td>
</tr>
<tr>
<td>Clinics</td>
<td>50</td>
<td>50</td>
<td>150</td>
<td>150</td>
</tr>
</tbody>
</table>

Source: National Health Insurance Administration
**Medical tourism promotion**

Another driver of healthcare demand is the promotion of Taiwan as a destination for medical tourism.\[38\] Since 2007, the government has been actively promoting the internationalisation of medical services as part of its efforts to attract more tourists. Proponents of the policy view it as benefitting the healthcare sector by providing hospitals with another source of income to reduce their reliance on the cash-strapped NHI. The focus has been on personalised services such as health check-ups, plastic surgery, and treatment for serious diseases.

The quality of medical care in Taiwan is on a par with more developed countries but less expensive—the cost of heart bypass surgery or a hip-joint replacement in Taiwan is about one-fifth of identical procedures in the US.\[39\] Its other attractive advantages include the availability of highly qualified personnel and state-of-the-art facilities and procedures. As of 2017, 15 medical facilities in Taiwan had received accreditation from the US-based Joint Commission International, which is considered the gold standard in international healthcare.\[40\]

Taiwan’s medical tourism industry has enjoyed steady growth over the past decade.\[41\] According to MOHW data, the number of visitors coming to Taiwan for medical or cosmetic treatment increased from 68,545 in 2008 to 279,281 in 2016, with the majority of patients coming from Greater China and Southeast Asia. Its output value rose from NT$2bn (US$69m) to NT$14bn (US$481m) over the same period. The government’s New Southbound Policy targeting Southeast Asia countries will give the industry a further boost going forward.

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**Figure 13: International healthcare promotion results, 2008-2016**

<table>
<thead>
<tr>
<th>Year</th>
<th>No. of patients</th>
<th>Industry output value</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>2009</td>
<td>3.4</td>
<td>5.4</td>
</tr>
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<td>2010</td>
<td>4.1</td>
<td>9.6</td>
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<tr>
<td>2011</td>
<td>5.4</td>
<td>13.6</td>
</tr>
<tr>
<td>2012</td>
<td>9.6</td>
<td>14.1</td>
</tr>
<tr>
<td>2013</td>
<td>14.1</td>
<td>15.9</td>
</tr>
<tr>
<td>2014</td>
<td>15</td>
<td>14</td>
</tr>
<tr>
<td>2015</td>
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<td></td>
</tr>
<tr>
<td>2016</td>
<td>14</td>
<td></td>
</tr>
</tbody>
</table>

Source: Ministry of Health and Welfare
Health expenditure and financing

National healthcare expenditure

Healthcare expenditure in Taiwan has increased steadily in the past two decades following the introduction of the NHI system. It grew at a 5.1% CAGR in local currency terms from NT$378.8bn (US$13bn) in 1995 to NT$1,086.9bn (US$37.3bn) in 2016, and as a proportion of GDP from 5.1% to 6.3%. On a per capita basis, it rose from NT$17,809 (US$612) to NT$46,219 (US$1,587) over the same period. National healthcare spending is expected to continue growing in line with an ageing population and a rising prevalence of chronic diseases.

Consulting firm BMI Research forecasts total healthcare expenditure in Taiwan will increase to NT$1,381bn (US$47.4bn) by 2022, and NT$1,755bn (US$60.3bn) by 2027, which implies a ten-year compound annual growth rate of 4.7% in local currency terms. It expects national healthcare expenditure as a proportion of GDP to remain between 6% and 7% in the forecast period, which would still be lower than in other advanced Asian economies such as Japan (10.9%) and South Korea (7.7%), and below the current OECD average of 9.0%.

A key reason for Taiwan’s relatively low healthcare spend is the ability of the government, as the single buyer of and payer for healthcare services, to set and regulate fees, and impose a global budget system that caps total NHI expenditure. Another important factor is the high administrative efficiency of the NHI’s IT-driven system, which is characterised by administrative simplicity and low overheads. General administration costs accounted for 2.3% of national healthcare expenditure in 2016, which is among the lowest levels in the world.

Figure 14: Healthcare expenditure in Taiwan, 1995-2022

<table>
<thead>
<tr>
<th>Year</th>
<th>National health expenditure (NT$bn)</th>
<th>% of GDP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995</td>
<td></td>
<td>5.1%</td>
</tr>
<tr>
<td>2000</td>
<td></td>
<td>6.3%</td>
</tr>
<tr>
<td>2005</td>
<td></td>
<td>6%</td>
</tr>
<tr>
<td>2010</td>
<td></td>
<td>6%</td>
</tr>
<tr>
<td>2015</td>
<td></td>
<td>6%</td>
</tr>
<tr>
<td>2020</td>
<td></td>
<td>6%</td>
</tr>
<tr>
<td>2025</td>
<td></td>
<td>6%</td>
</tr>
</tbody>
</table>

Source: Ministry of Health and Welfare and BMI Research
Healthcare financing analysis

Analysing healthcare expenditure by financial resources, private households accounted for 52.4% of the 2016 total, followed by the government sector 25.7%, and private enterprises and non-profits 21.1%. The bulk of private spending on healthcare was accounted for by NHI premium payments and household out-of-pocket expenses—largely co-payments, registration fees, or for medical care services and products not covered by the NHI. Almost 60% of government spending on healthcare was directed into the NHI in the form of subsidies.

Looking at the flow of funding through financial agents, the public sector accounted for 59.5% of total healthcare expenditure in 2016, versus 40.5% from private sources. The NHI programme represented the majority of total healthcare spending at 52.8%, followed by out-of-pocket expenditure at 34.0%, mostly co-payments for doctor visits, hospitalisations and prescription drugs. With future NHI spending expected to outpace revenues as the population rapidly ages, policymakers may have to consider shifting a larger share of costs onto patients.

In terms of financial allocation, personal healthcare accounted for 87.7% total healthcare expenditure in 2016, followed by capital formation 5.8%, public health 4.2%, and general administration 2.3%. Spending on personal healthcare included payments to hospitals (45.6%, comprising outpatient care 24.7% and inpatient care 20.9%), health clinics (23.6%, comprising Western medicine 11.5%, dentistry 10.0% and TCM 2.2%) and other specialty institutions 2.8%, plus other costs associated with the purchase of medical supplies and equipment 15.6%.

Spending on medicines has consistently accounted for around a quarter of healthcare costs over the past decade or so. In 2015, pharmaceutical expenditure totalled NT$262bn (US$9bn), accounting for 25.5% of national healthcare expenditure, higher than the OECD average of 16%. On a per capita basis, it amounted to NT$11,164 (US$383), of which 48.1% was financed by the NHI and 51.9% by out-of-pocket (co-payment and self-pay). Over the years, such expenditure has trended upward, making drugs a key target for cost-containment efforts.
Figure 16: Healthcare expenditure by financial allocation, 2016

- Hospitals: 45.6%
- Personal healthcare: 87.7%
- Clinics: 23.6%
- Medical articles, equipment and healthy goods: 15.6%
- Other specialty institutions and NHI xeno payment: 2.8%
- Capital formation: 5.8%
- Public health: 4.2%
- General administration: 2.3%
- Public health: 4.2%
- Capital formation: 5.8%

Source: Ministry of Health and Welfare

Figure 17: Pharmaceutical expenditure, 2006-2015

Source: Ministry of Health and Welfare
National health insurance programme

The NHI is predominantly a premium-based social health insurance programme. It was established in March 1995 by merging and expanding existing health insurance schemes, which at that time only covered around half of the population. The mandatory nature of NHI affiliation—with the government funding premiums for vulnerable patient groups—has seen coverage become almost universal. Currently, 99.6% of Taiwan’s 23.6m population (including qualified foreign residents) are enrolled in the government-run, single payer scheme.

NHI benefits are uniform and comprehensive, all medically necessary services with covered. The package covers inpatient and outpatient care (both primary and specialist care), prescription drugs (over 16,000 items), dental care, traditional Chinese medicine, child birth care, physical rehabilitation, home care, chronic mental healthcare, and end-of-life care. The NHIA determines which services are covered in consultation with a broad spectrum of stakeholders, and such decisions are subject to considerations of budget impact.

The NHI programme is funded primarily through premiums jointly paid by the insured, their employers and the government, in addition to subsidies for low income and disadvantaged people. The 2G NHI reforms of 2013 broadened the premium base to include supplemental sources of income. The current rates for payroll-based and supplementary premiums are 4.69% and 1.91%, respectively. Other revenues come from fines on overdue premiums, public welfare lottery contributions, and a health and welfare surcharge on tobacco products.

Financial status and pressures

In 2016, the NHI had total revenues (on an accrual basis) of NT$591bn (US$20.3bn), of which insurance premiums accounted for 94.2%. Payroll-based premiums totalled NT$470bn—with employers (including governmental agencies and enterprises) contributing 38.7%, households 38.2%, and government subsidies 23.1%—and supplementary premiums were NT$44bn. Total NHI expenditure was NT$572bn (US$19.6bn), giving a surplus of NT$19bn. Its accumulated reserve fund balance was NT$247bn (US$8.5bn) at end-2016.

Over the period from 1996 to 2016, NHI revenues rose by an average of 4.7% a year, while its expenditures grew by an average of 4.8% per annum, driven by both greater utilisation and higher cost of care. The NHI began experiencing financial deficits as early as 1998 and this has forced policymakers to pursue both cost-containment measures and the periodic imposition of premium hikes (in September 2002 and April 2010) in a bid to ensure that revenues keep pace with rising healthcare costs, and to bolster dwindling NHI reserves.

Financial reforms implemented in 2013, including the introduction of supplementary premiums, helped to stabilise the NHI’s finances. However, the reduction of both basic and supplementary rates at the beginning of 2016 have contributed to a fall in revenues and eroded the NHI budget surplus. With a deficit projected for 2017, a hike in current health insurance premium rates is deemed inevitable at some point in the next few years, but more fundamental reforms will be required to ensure the NHI system’s long term sustainability.
Figure 18: NHI financial revenue and expenditure (accrual basis), 1995-2016
**Healthcare cost-containment**

Balancing the NHI budget has been a constant challenge. Besides various revenue boosting initiatives, efforts to rein in spending have also been pursued. These include the implementation of various cost-containment measures designed to curb both demand and supply. While patients incur higher co-payments for overuse or misuse of resources, policymakers have been reluctant to impose other additional costs on users of the NHI system. Instead, government efforts to balance the NHI budget have focused primarily on the supply side.

**Global budget payment system**

The establishment of a global budget payment system is the most significant supply-side cost-containment mechanism implemented to date. Phased in between 1998 and 2003, the system was adopted to constrain rapid expenditure growth under the fee-for-service payment model. Global budget caps are set for hospitals, primary care, dental, and the provision of TCM and kidney dialysis. The system, in turn, forces providers to decide for themselves as to how to use their limited funds to satisfy the medical needs of their patients.

Within the global budget, providers are paid through a mix of fee-for-service and other payment systems using a “floating” point-value scale. The point values used to pay for services are reviewed every quarter during the year and are reduced if service volumes increase too much. This ensures that total payments stay under the cap in each sector. Since its implementation, the system has consistently kept medical expenditure growth below 5% a year, compared with rates of 8% that prevailed before the rollout of global budgeting.

Taiwan’s global budgeting system for healthcare involves an annual negotiations on discrete budgets for NHI spending in the five sectoral areas. These involve the NHIA, provider representatives and, since 2013, the MOHW’s multi-stakeholder NHI Committee. Once draft budgets have been approved by the Executive Yuan (Cabinet), budgets for each medical sector are split between the NHI’s six healthcare regions, with shares determined by a combination of historical expenditure and the application of a risk adjustment mechanism.

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**Figure 19: Annual growth rate of NHI medical expenditures, 2008-2017**

![Graph showing annual growth rate of NHI medical expenditures, 2008-2017](image-url)

**Source:** National Health Insurance Administration
Alternative reimbursement mechanisms

The NHIA is also pursuing alternative ways to pay providers to help control rising healthcare expenditures. Reimbursement is generally on a fee-for-service basis, according to national uniform fee schedules. However, financial incentives inherent in the payment system help drive supply-induced demand for care, which partly explains the high utilisation of healthcare resources in Taiwan. Accordingly, the NHIA has adopted some other reimbursement methods in recent years to encourage more efficient, cost-conscious behaviour by providers.

These include the expanding use of diagnosis-related group payments for inpatient care, known as Tw-DRG and first introduced in 2010, which caps reimbursement for specific services at defined levels. The NHIA had planned in 2016 to extend the application of flat-sum payments from 401 to 1,663 items (about 58% of all inpatient treatments), but the move was shelved in the face of strong opposition from providers. The NHIA has further introduced pay-for-performance, capitation and bundled payment models for certain episodes.

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

Annual drug price adjustments

Efforts to curb healthcare spending include the imposition of tighter controls on the price of inputs such as pharmaceutical drugs, which currently account for around a quarter of NHI costs. To date, these have been dominated by policies designed to limit reimbursement prices, and have done little to address overprescribing. Regular price cuts have forced the removal of some products from the NHI reimbursement schedule, while restrictions on the reimbursement of costly new drugs have delayed the launch of some innovative medicines.

Taiwan uses a drug expenditure target (DET) system to adjust pharmaceutical prices on an annual basis. It was implemented in 2013 and replaced the previous system of biennial price cuts using price-volume surveys. Under the DET scheme, the NHIA sets a target for NHI drug spending for the year, and should expenditure exceed the amount allocated, price adjustments will be implemented. In the 2018 review, for example, a total of 7,476 drugs received an average price cut of 4.6%, generating estimated savings of NT$7.4bn (US$250m).

Table 3: Drug price adjustments under DET, 2013-2017

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
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<tbody>
<tr>
<td>DET growth rate (%)</td>
<td>4.528</td>
<td>3.309</td>
<td>3.481</td>
<td>4.950</td>
<td>4.280</td>
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<td>Target expenditure (NT$bn)</td>
<td>138.0</td>
<td>142.6</td>
<td>147.5</td>
<td>154.8</td>
<td>151.1</td>
</tr>
<tr>
<td>Overspend amount (NT$bn)</td>
<td>5.7</td>
<td>8.2</td>
<td>3.2</td>
<td>5.7</td>
<td>7.4</td>
</tr>
<tr>
<td>Effective date of price cut</td>
<td>1 May 2014</td>
<td>1 April 2015</td>
<td>1 April 2016</td>
<td>1 April 2017</td>
<td>1 May 2018</td>
</tr>
<tr>
<td>Average price reduction (%)</td>
<td>3.9</td>
<td>5.3</td>
<td>2.1</td>
<td>3.5</td>
<td>4.6</td>
</tr>
<tr>
<td>Number of drugs reduced in price</td>
<td>7,583</td>
<td>6,821</td>
<td>7,392</td>
<td>7,331</td>
<td>7,476</td>
</tr>
</tbody>
</table>

Source: National Health Insurance Administration
The price cuts are also aimed at reducing the gap between drug procurement and reimbursement prices from which hospitals profit. Most hospitals in Taiwan operate in-house pharmacies and are allowed to purchase medicines at discounted rates, whilst charging for dispensing them at NHI reimbursement prices which are often significantly higher. It is estimated that hospitals make a profit of NT$25bn (US$859m) from the so-called ‘NHI drug price black-hole’ every year, and drugmakers claim this artificially inflates NHI’s drug costs.

**Tackling waste and fraud**

The NHIA has also been taking aim at wastage of medical resources, notably prescription drugs. Patients in Taiwan dump some 70 tonnes of drugs each year, mostly medication for chronic diseases. To reduce such waste, the NHIA has expanded its cloud-based medication and treatment information system to more closely monitor drug usage and prescribing practices. It is also considering to stop reimbursing duplicate prescriptions, raising the current NT$200 (US$6.9) ceiling for drug co-payments, and switching more drugs to OTC status.

Claims monitoring has also been stepped up in a bid to tackle waste and fraud. NHIA audits and inspections have been used to monitor the veracity of NHI claims, and to pinpoint providers and patients guilty of overtreatment, overuse or abuse of the system. Provider charges are also subject to closer scrutiny, with hospitals claiming more than NT$400m in reimbursements from the NHI required to submit detailed accounts to the NHIA. The reporting requirement threshold will be reduced to NT$200m starting from the 2018 fiscal year.
Alternative private health insurance

The universal coverage and comprehensive benefits package of the NHI scheme has constrained demand for supplementary private health insurance in Taiwan. At present, private coverage is limited to disease-specific cash indemnity policies or life insurance with health riders, and mostly offer one-time, event-trigger payments for certain occurrences, such as cancer or hospitalisation. Private policies do not cover medical services covered by the NHI, nor do they buy faster access to any type of care, or increased choice of specialists or hospitals.

Notwithstanding universal access to subsidised provision through the NHI programme, households currently foot 34.0% of total healthcare costs on an out-of-pocket basis, up from 22.3% in 1995. The growing share of the rising cost of healthcare and increasing patient cost-shifting, as population ageing puts the NHI under increasing strain, impose a growing financial burden on households. And this could lead to more demand for private health insurance in order to protect patients against downside risks and drive better care decisions.

Private coverage is already growing in Taiwan. Health insurance accounted for NT$355bn (US$11.9bn), or 9.9%, of total insurance premiums in 2016, having expanded at a CAGR of 6.1% in 2008-2017. Property and casualty insurers have marketed yearly renewable insurance contracts since 2008, and these have seen strong growth. Individual health products, primarily medical insurance, with a fixed payment scheme dominate the market, while reimbursement-based health insurance products have only been rolled out in recent years.

Figure 20: Private health insurance premium income, 2008-2017
Recognising the major challenges facing the NHI, health ministry officials confirmed in February 2017 that planning had begun for a third-generation (3G) NHI, a process that is expected to take 6-8 years to complete. In the meantime, with the NHI having slipped back into deficit in 2017, a hike in health insurance premium rates is inevitable at some point in the next few years. Curbing costs will also continue to be a priority, which will see provider and patient behaviour scrutinised more closely, and the likely imposition of further constraints.

Policymakers can also be expected to consider shifting a larger portion of the NHI’s costs onto patients, such as through higher co-payments or the expansion of balance billing. Efforts to implement a graded healthcare and referral system, by shifting the provision of primary care and management of chronic diseases out of medical centres and regional hospitals, will continue apace. And with the implementation of the LTC Plan 2.0, investment in facilities providing long-term care to the elderly and disabled will increase. Further and deeper reforms will be required to secure the NHI’s viability in the longer term, as demographic and epidemiological trends impose growing pressure on its finances, and as policymakers pursue improvements in care quality. However, the subject of healthcare reform is a politically charged issue in Taiwan, as potential cuts in coverage offered by the NHI—which is widely regarded as a form of ‘welfare’ rather than ‘insurance’—will likely meet strong public opposition, meaning that any major policy changes will be a protracted process.

To support and inform the government’s policy planning for the 3G NHI, PwC was commissioned in 2016 by the International Research-based Pharmaceutical Manufacturers Association (IRPMA) to produce a White Paper on the future of the healthcare system. The report, *Taiwan’s healthcare system: A look to the future*, is publicly available on IRPMA’s website. It focuses on three issue areas—system structure, access to innovative drugs, and healthcare funding—and provides a comprehensive set of recommendations, as summarised below.
Figure 21: PwC recommendations on the future direction of healthcare in Taiwan

**Healthcare system structure**

**Key challenges**
- Overuse and wastage of medical resources resulting from the lack of an effective gatekeeper mechanism.
- Distorted resource allocations that create challenges for healthcare providers and the quality of patient care.
- A rapidly ageing population and rise in chronic disease cases will further exacerbate the current situation.

**Recommendations**
- Accelerate implementation of a multi-tiered healthcare delivery system and institute a gatekeeper referral system that encourages patients to use clinics for primary care and relieves pressure on overburdened large hospitals.
- Fully separate the prescribing and dispensing of drugs, currently dominated by hospitals’ in-house pharmacies, to remove the possible compromising of patient interests and provide an expanded role for community pharmacists.
- Promote general health awareness and encourage patient self-care as preventative measures, as well as self-monitoring and self-medication under appropriate conditions, with doctor visits only when really necessary.
- Make more extensive use of cloud computing capabilities to reduce misuse of resources and big data analytics to optimise resource allocation and make more abundant information available to patients and stakeholders.

**Patient access to innovative drugs**

**Key challenges**
- A lengthy drug approval (FDA) and reimbursement (NHI) process, which primarily focuses on the cost impact rather than the value aspect of new drugs, which risks delaying or discouraging the launch of innovative drugs in Taiwan.

**Recommendations**
- Maintain a drug approval and reimbursement process that is based on internationally accepted standards, is competitive relative to peer countries, and actively encourages the launch of new and innovative medications.
- Ensure a transparent, timely and efficient approval and reimbursement process that balances the costs and benefits of new drugs, emphasises the quality of care outcomes, and prioritises the interests of patients.
- Reform the current decision-making process to increase the involvement of patient and medical interest groups.

**Enhance healthcare funding**

**Key challenges**
- Limited funding is a major challenge for Taiwan’s healthcare system and its long-term sustainability. With the financial pressures on the NHI set to grow further, the system’s current funding model needs to be adjusted.

**Recommendations**
- Expand the involvement of Taiwan’s top economic planning agency, the National Development Council in the healthcare budget-setting process to ensure that broad economic and social needs are taken into account.
- Shift a larger portion of medical costs onto patients by expanding the scope of medication co-payments.
- Establish special public health budgets/funds to cover life-saving drugs, such as expensive cancer treatments.
- Engage in more public-private risk-sharing schemes along the lines of outcome-based managed entry agreements.
- Encourage the development and take-up of more private health insurance products to supplement NHI coverage.

Source: PwC Taiwan, “Taiwan’s healthcare system: A look to the future,” September 2017
Taiwan’s biomedical industry

The biomedical industry—encompassing applied biotechnology, pharmaceuticals and medical devices—is a major priority focus for Taiwan, as part of the government’s “5+2 Innovative Industries Programme” unveiled in 2016.\(^6\) A long period of investment has produced a solid foundation, with an ecosystem that spans the entire biomedical value chain. Taiwan is well equipped for research, drug discovery, development, manufacturing and marketing, and is already a global manufacturing leader in several medical device product categories.\(^6\)

In November 2016, the government launched a new policy initiative, the “Biomedical Industry Innovation Promotion Programme,” which focuses on biopharmaceuticals, medical devices, and health and well-being.\(^6\) The aim is to position Taiwan as a hub for biomedical R&D, based on four action plans to create links locally, globally and to the future, in order to achieve the goals of developing 20 new drugs, bringing 80 high-value medical devices to market, and building biomedicine into a NT-trillion-dollar (US$33bn) industry by 2025.

Another goal of the industry promotion plan is to establish at least 10 biotech and health-related flagship brands, by encouraging domestic enterprises to acquire or form strategic alliances with high-potential international businesses—such as small and medium-sized pharmaceutical companies, medical supply companies, distributors and service providers—and to expand into overseas markets. The state run National Development Fund has established an industrial innovation fund to support such M&A activities.\(^6\)

As momentum continues to build, investors are taking note. Thanks to its long-term cultivation by both the government and private sectors, Taiwan’s biomedical industry has progressively expanded in scale. Total sales in the domestic market (excluding exports) grew by 4.1% on-year to NT$421.7bn (US$13bn) in 2016.\(^6\) The pharmaceutical sector represented the largest share at NT$159.8bn (38%), followed by medical devices NT$152.2bn (36%) and biotechnology NT$109.7bn (26%). Each sector will now be analysed in more detail.

---

**Figure 22: Scope of Taiwan’s biomedical industry**

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<thead>
<tr>
<th>Biomedical Industry</th>
<th>Applied Biotechnology</th>
<th>Pharmaceuticals</th>
<th>Medical Devices</th>
</tr>
</thead>
<tbody>
<tr>
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<td>Agriculture, Food, Environment New Biopharmaceuticals, Contract Services</td>
<td>Small Molecule Drugs, Biologics Active Pharmaceutical Ingredients Traditional Chinese Medicine</td>
<td>In vitro Diagnostics Assistance and Compensatory Surgery and Treatment Diagnosis and Monitoring Disease Prevention and Health Promotion and Miscellaneous Devices</td>
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Source: Ministry of Economic Affairs, 2018 Introduction to Biotechnology and Pharmaceutical Industries in Taiwan
### Table 4: Current status of Taiwan's biomedical industry

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### Figure 23: Domestic market size of Taiwan's biomedical industry, 2007-2016

Source: Ministry of Economic Affairs, 2008-2017 Biotechnology Industry White Papers
Biotechnology sector

Market overview

Taiwan’s applied biotechnology sector—which includes agricultural, food and environmental biotechnology, as well as new biopharmaceuticals, regenerative medicine, and contract services—has been developing steadily over the past decade, backed by strong government policies. The 2009 national plan for biotech development helped kick-start the domestic market, which has since almost doubled in size to reach NT$109.7bn (US$3.4bn) in 2016. The main focus of most sector companies is the development of new drugs and biological products.

Government policy support has been the key contributor to the biotech expansion. In 2007, the Act for the Development of Biotech and New Pharmaceuticals Industry was enacted to lay the foundation for accelerated growth. Two years later, the government launched its Diamond Action Plan for Biotech Take-off to strengthen the basic industrial structure. In 2013, the second phase of the strategic policy initiative, renamed the Biotech Industrialisation Take-off Action Plan, focused on building up the capability of the biotechnology value chain.

More recently, in 2016, the government designated biomedicine as one of its “5+2” innovative industries for priority development, and launched the “Biomedical Industry Innovation Programme”. The overall goal is to make Taiwan a regional hub for biomedical R&D and to boost the industry’s value to NT$1tn (US$33bn) by 2025. Supporting measures include, among other items, the creation of a “biomedical corridor” between Taiwan’s science parks, a tax incentive scheme for biomedical start-ups, and relaxed investment regulations.

Taiwan indeed has many of the conditions essential to be a major biomedical R&D hub. Its clinical research capacity has progressed rapidly in recent years, supported by an abundance of talented scientists, good medical and research infrastructures, ample clinical trial experience focusing on Asia-prevalent diseases, and cost-competitive R&D and manufacturing. Even so, Taiwan still has a way to go—especially in such areas as its drug approval and reimbursement systems—before it will be in a position to challenge for the “top spot.”

Although the size of Taiwan’s biotech sector is still relatively small, its growth momentum is strong. Key drivers for future growth include the government’s continuing strong policy support, and the maturation of company pipelines and service offerings—some of Taiwan’s most innovative biopharmaceutical firms are on the cusp of bringing to market first-in-class, breakthrough drugs targeting some of society’s worst diseases.
Table 5: Status of Taiwan’s biotechnology sector, 2007-2016

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<td>3.3</td>
<td>3.3</td>
<td>3.4</td>
</tr>
</tbody>
</table>

Source: Ministry of Economic Affairs, 2008-2017 Biotechnology Industry White Papers

Figure 24: Domestic market size of Taiwan’s biotechnology sector, 2007-2016

Source: Ministry of Economic Affairs, 2008-2017 Biotechnology Industry White Papers
Regulatory environment

The Taiwan Food and Drug Administration (TFDA) is responsible for the enforcement of laws and regulations related to medicines, and the issuance of all licences, permits and authorisations. The medicinal product life cycle from R&D to market release includes fundamental drug research, non-clinical studies, clinical trials, registrations, manufacturing and market distribution. Reviews, audits, and inspections are conducted at each step to ensure compliance with various standards, forming a comprehensive life cycle management system.60

The Center for Drug Evaluation (CDE), a non-profit organisation supported by the MOHW, 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 and drug approval processes. It also sets regulations for new therapeutic treatments such as cell therapy and ensures the transparency of review processes. A bill is under review to upgrade the CDE to take over responsibility for all evaluation reviews of drugs and medical devices.60

Successive governments have made the continuing development of biotech a priority. Regulatory support is directed primarily by the 2007 Act for the Development of Biotech and New Pharmaceuticals Industry, which was enacted to provide tax incentives, special rules favouring investment in start-ups, and funding through the state-run National Development Fund. It also mandated the establishment of the Nangang Biotechnology Park, the Hsinchu Biomedical Science Park, and a biotech corridor in the Southern Taiwan Science Park.

Taiwan’s biotech statute was amended in January 2017 to extend the tax incentive scheme for biotech and new pharmaceutical companies approved by the Ministry of Economic Affairs. Previously, only new drugs and high-risk medical devices were eligible. Now, a third category has been added, emerging biotech and pharmaceutical products, which includes precision medicine and cell and gene therapy technologies. The government is particularly keen to accelerate research and development activities in precision medicine.72

Figure 25: Medicinal product life cycle management framework

![Diagram showing the medicinal product life cycle management framework]

CTD: Common Technical Document
GLP: Good Laboratory Practice
GCP: Good Clinical Practice
GTP: Good Tissue Practice
GPvP: Good Pharmacovigilance Practice
GMP: Good Manufacturing Practice
GDP: Good Distribution Practice

Source: Taiwan Food and Drug Administration, 2017 Annual Report
New drug development often takes more than ten years, as developers must conduct a series of clinical trials and pass approval procedures. Clinical research trials are broken up into four phases that build on one another. The earliest phase trials may look at whether a drug is safe or the side effects it causes, while a later phase trial aims to test whether a new treatment is better than existing treatments. In Taiwan, all clinical trials must be conducted in compliance with the Good Clinical Practice Standards for Medicinal Products.

Taiwan has over the past decades put in place a number of initiatives to boost its biopharmaceutical R&D and clinical research capabilities and today these are rated as some of the strongest among newcomer markets. The 2017 Biopharmaceutical Competitiveness Index (BCI) survey ranked Taiwan third after Singapore and Israel. However, some gaps still remain to be closed for Taiwan to compete with mature markets, including resolving approval delays, and introducing greater predictability and holistic approaches in market access.

Research infrastructure

Research institutes have played an important role in the development of Taiwan’s economy, and nine currently focus on the biomedical industry. The lead institute is the Development Center for Biotechnology (DCB), which is tasked with advancing the biotech sector by building infrastructure, developing key technologies, and training talent in coordination with government, industry, and academia. It specialises in developing biologics and small molecule drugs, botanical drugs, as well as technologies required for preclinical testing.

A recent key development was the completion in March 2018 of the National Biotechnology Research Park in Taipei’s Nangang District, which will integrate Taiwan’s currently fragmented R&D and start-up incubation capabilities, focusing all pre-clinical trial activity in a single location. The DCB has since relocated to the Park and plans to set up a commercialisation office to assist with transferring biotech findings by government-funded research institutes to prospective investors and firms aiming to develop new innovative products.

Robust government support for clinical research is integral to Taiwan’s attractiveness as a site for clinical trials. To help grow the biomedical industry, the government has subsidised the establishment of general clinical research centres in regional teaching hospitals, with the aim of forming research management units and improving the quality of research. Centres of excellence in clinical trials have also been established at leading research-hospital institutions to enhance Taiwan’s capacity to conduct early-stage clinical trials.
Clinical trials review process

Also, regulatory processes have been accelerated, which adds to Taiwan’s attractiveness as a clinical trials site. The TFDA reviews investigational new drug (IND) applications. Its approval timeline for a standard review is 30 days, while a fast track pathway for global and regional trials delivers approvals in 15 days. Provided that a multinational clinical trial protocol has been approved by at least one of 10 reference countries, then the TFDA will undertake only an administrative review without requiring technical evaluation from the CDE. In August 2017, the TFDA announced enhancement measures for its clinical trial protocol review process. These include the introduction of a new 30-day fast-track review mechanism for cell therapy/gene therapy clinical trials which meet one of the following requirements: multi-regional and non-first in human clinical trials (conducted in both one A10 reference country and Taiwan), or investigator-initiated academic clinical trials with the same investigational products that had been used in other clinical trials conducted in Taiwan.

At present, a total of 19 medical centres and 124 hospitals are qualified by the TFDA to conduct clinical trials in Taiwan, while networks linking facilities capable of conducting studies in particular therapeutic areas—including oncology—have also been established. Domestic drug developers can conduct early and mid-phase trials in Taiwan and use this data for a Phase III study in the US or EU, while spending by pharmaceutical multinationals on clinical trials in Taiwan has primarily focused on Phase III global multi-centre studies.

The number of clinical trials conducted in Taiwan has risen steadily in recent years. The TFDA currently handles around 250-300 (298 for 2017) new trial applications every year, mostly for multi-national, multi-centre Phase II and III trials.

Figure 26: Review process for investigational new drug applications
Figure 27: IND applications in Taiwan by clinical trial type

Number of applications

Source: Taiwan Food and Drug Administration

Figure 28: IND applications in Taiwan by study phases

Number of applications

Source: Taiwan Food and Drug Administration
**Gateway to China**

Taiwan’s biotech R&D programmes are highly relevant to the China market, focusing on diseases common in ethnic-Chinese populations in China and elsewhere. Reflective of this exposure, there has been a steady stream of publicly reported Taiwan-based drugmaker activity in the China market. In addition, recent developments in regulatory harmonisation for new drug development across the Taiwan Strait offer significant opportunities for Taiwanese drug developers, such as by helping them to gain faster market access to the China market.

Facilitated by the Cross-Strait Co-operation Agreement on Medicine and Public Health Affairs signed in 2010, local drug developers can simultaneously submit applications for new drugs in Taiwan and China. Under the pact, the two sides reached a formal consensus four years later on cooperation in clinical trials of new drugs. In April 2016, Taiwan and China mutually recognised for the first time the results of clinical drug tests conducted by eight hospitals—four from each side of the Taiwan Strait—that conform to ICH GCP guidelines.

The cross-Strait mutual acceptance of clinical trial data for certain new drug categories will cut costs for drug developers in both Taiwan and China, as the new policy will reduce overlapping trials and shorten the timeline for getting new drugs to market. As Taiwan has a solid reputation for well-run clinical trials, the accord could substantially boost clinical investment in Taiwan by multinational pharmaceutical companies.
**Business environment**

Taiwan’s applied biotechnology sector is still small and has a fragmented structure. About 500 companies (mostly small and medium sized) are categorised as "biotechnology" (across all subsectors, including services) firms, but their combined revenues total only about NT$94bn (US$2.9bn), according to the latest government data.\(^8\) As of the end of May 2017, a total of 118 firms had been approved as biotech and new pharmaceutical companies, 283 drugs had been approved as biotech new pharmaceuticals, and 38 of these had received sales permits.\(^8\)

Taiwan’s favourable clinical trial conditions, and the prevalence of smaller-sized companies make it well suited to the “acquire, develop, transfer” biotech business model, whereby companies in-license assets at the preclinical or early clinical phase, and develop them locally in the clinic for later out-licensing to larger partners for marketing.\(^8\) Because of the small domestic market, Taiwanese drug developers often ally with contract research organisations and pharma multinationals to develop high-end drugs and expand overseas.

A recent significant achievement was the approval of the first locally-developed new drug to be reimbursed by Taiwan’s NHI scheme. In December 2017, the NHIA approved the reimbursement listing and pricing for Taigexyn (nemonoxacin), a new antibiotic developed by TaiGen Biopharmaceuticals, which is now available for prescription under the NHI.\(^9\) While other local new drug developers have gained regulatory approval to introduce new products to the market, prescription volumes have been limited due to a lack of NHI coverage.

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**Figure 29: Collaboration business model for Taiwanese drug developers**

![Collaboration business model](source: PwC analysis)
Biotec IPO market

Funding is still a challenge for both biotech start-ups and development-stage companies, so government support takes on special importance. Its 2013 revised action plan for the biotech sector encouraged the formation of small and medium biotech venture capital funds. The state-run National Development Fund also provides significant funding support to the sector. As of the end of 2016, it had invested in 14 biotech companies and 16 biotech venture capital firms, and these investments totalled over NT$10bn (US$335m).90

The government has also relaxed initial public offering (IPO) rules to make it easier for companies defined as “biotech” by the government to raise funds through listing on Taiwan’s stock exchanges.91 Being able to go public before registering profits has encouraged early stage companies to IPO for access to financing, and the biotech statute was amended in 2017 to include more biomedical start-up firms. As of the end of May 2018, a total of 114 biotechnology and medical care companies were listed on Taiwan’s main and secondary boards.

With the biotech sector in the late incubation stage, the maturation of company pipelines is attracting investors looking for “the next big thing.”92 Biotech stocks began to take off in 2009, with the value of the sector in terms of market capitalization increasing dramatically, from about US$2.6bn in 2009 to US$23.8bn at the end of 2017.93 To help manage the gap between sector performance and investor expectations, a new biotech stock index, the TIP Taiwan Market Biotechnology and Medical Care Index, was launched in July 2017.94

Figure 30: Stock market capitalisation of Taiwan’s biotech sector, 2007-2017
Taiwan’s pharmaceutical sector encompasses chemical drugs (Western medicine), active pharmaceutical ingredients (APIs), Chinese herbal medicine, and biologics. Domestic market sales (including imports) totalled NT$159.8bn (US$4.9bn) in 2016, according to the latest government data. Chemical drugs and APIs account for the majority of pharmaceutical revenues, with 30% of demand fulfilled by Taiwanese drugmakers, mostly for APIs and finished formulations, and the rest supplied by pharmaceutical imports. A well-developed healthcare infrastructure supports the sales growth of pharmaceuticals in Taiwan, with an extensive network of hospitals and physician clinics serving as the primary access points. The lack of proper prescribing and dispensing separation also benefits drug manufacturers. As with most developed countries, prescription drugs are dominant in the market, accounting for 92% of total drug sales in 2016—the bulk of which (around 70%) came from patented drugs, and the rest from locally-produced generic drugs. The over-the-counter (OTC) medicine sector is underdeveloped with just 8% of the overall pharmaceutical market. This is largely due to the comprehensive nature of the NHI reimbursement schedule, which lists more than 16,000 drug items; there are only a select group of treatments that are not reimbursed by the scheme. Even so, the OTC market may offer growth opportunities for pharmaceutical companies as price cuts weigh on prescription medicines and as authorities take a more proactive approach to Rx-OTC switching.

Revenue growth has been slowing down in the domestic market in recent years, due to the continued use of drug-price controls by the authorities and the efforts to contain public spending on medicines. Nevertheless, the sector is expected to resume a growth trend over the next five to ten years, driven by ageing demographics and related epidemiological factors. BMI Research forecasts total drug sales in Taiwan will grow to NT$223.3bn (US$8.0bn) in 2022 and NT$262.2bn (US$9.7bn) by 2027, which equates to a ten-year CAGR of 3.4%.

### Table 6: Status of Taiwan’s pharmaceutical sector, 2007-2016

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</tr>
</tbody>
</table>

Source: Ministry of Economic Affairs, 2008-2017 Biotechnology Industry White Papers
Figure 31: Domestic market size of Taiwan’s pharmaceutical sector, 2007-2016

Source: Ministry of Economic Affairs, 2008-2017 Biotechnology Industry White Papers
Regulatory environment

The TFDA, an administrative agency of the Ministry of Health and Welfare, is responsible for ensuring the quality and safety of pharmaceutical drugs and medical devices for use in Taiwan. Its Division of Medicinal Products is responsible for the registration, approval and management of drug products. The non-profit, non-governmental CDE assists the TFDA with technical dossier reviews of new drugs, APIs and medical devices.

A legislative bill is currently under review to upgrade the CDE into an independent, national-level organisation to take over responsibility for all evaluation reviews of drugs and medical devices. The move is aimed at streamlining the review process for obtaining licences to market pharmaceuticals and medical devices in Taiwan. The upgraded CDE will also provide clinical and non-clinical guidance and consultation services to domestic drug developers.

Taiwan's Pharmaceutical Affairs Act currently provides the basis for market regulation of both medicines and medical devices, but given their different characteristics the TFDA has proposed a separate statute to govern medical device products. The law divides pharmaceuticals into APIs or their finished products, with the latter further divided into new drugs, biological agents, generic drugs and orphan drugs.

Taiwan is a member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) since 2013. This means its Good Manufacturing Practice (GMP) standards are aligned with international norms, and enables the mutual recognition of pharmaceutical certification. The enforcement of the PIC/S manufacturing standard has triggered a degree of consolidation within Taiwan’s pharma sector.

Intellectual property issues

As Taiwan strives to join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership and other free-trade accords, the authorities have taken measures to strengthen IPR protection for drug products. In January 2018, the Pharmaceutical Affairs Act was amended to introduce a new drug approval-patent linkage system, to take effect in late 2018 or early 2019, and provide data exclusivity protection for new indications.

Once implemented, the patent linkage system will provide a mechanism for pharmaceutical innovators to list and update their relevant patents, similar to the US Orange Book, and make potential patent infringement a mandatory consideration and an examination basis during the review and approval process for generic drug applications. This will help ensure generics are not launched in Taiwan while the original patent is still valid.

The revised law also broadened data exclusivity provisions to further include new indications of an existing drug. Initially, NCEs and biologics are granted five-years of data exclusivity in Taiwan, the first three years of which are absolute regulatory exclusivity. An additional three years of exclusivity will now be provided for new indications with international data, or five years for those cases with clinical trials conducted in Taiwan.

Furthermore, Taiwan has a formal agreement with China regarding intellectual property rights protection that allows for mutual recognition of patent priority claims. Also, under a Cross-Strait Medical and Healthcare Co-operation Agreement signed in 2010, Taiwanese drug developers can simultaneously submit applications for new drugs in Taiwan and China. In 2016, the two sides initiated mutual acceptance of clinical-trial data.
Registration and approval

All newly produced and imported drug products must be reviewed and approved by the TFDA before being eligible for NHI listing, except for orphan drugs. In general, applicants of new chemical entity (NCE) drugs must submit relevant information and data relating to, inter alia: clinical trials; formulation basis; testing specifications; methods and certificates of analysis of raw materials and finished products; and manufacturing.

The regulatory review timeline for a new drug application differs according to each pathway. For NCEs and biologics, it is 360 days for standard reviews and 180 days for abbreviated reviews. For non-NCEs, the timeline is 200 days for standard reviews and 100 days for domestic innovative product reviews. The TFDA has also introduced an accelerated approval pathway, including priority (240 days) and abbreviated (150 days) reviews, to address unmet medical needs in relation to serious or life-threatening conditions.

The actual review timeline for new drugs has improved slightly in recent years, but is still relatively lengthy. In 2017, the median review time for NCE and biologics applications was 295 days, with 50-60% of the cases meeting the TFDA’s review-time target of 360 days. The upgrading of the CDE is expected to speed up the drug review process, with the percentage of reviews completed for NCE drug applications within 360 days projected to rise from 50% to 90%, and for generic drug applications within 180 days from 41% to 90%.

Continued improvements to Taiwan’s drug approval process will help support the expansion of the country’s patented drug market. In 2017, the TFDA approved a total of 45 new drug treatments, up from 40 a year earlier, and the median approval time was 295 days, 66 days less than in 2016. It also issued a total of 166 new drug permit licenses (58 NCEs, 33 biologics and 75 non-NCEs), an increase of 20% compared with 2016.

Figure 32: Review process for new drug applications

Source: Center for Drug Evaluation
Figure 33: Review process for new drug applications

Source: Taiwan Food and Drug Administration

Figure 34: Number of new drugs approved in Taiwan

Source: Taiwan Food and Drug Administration
The NHIA controls the reimbursement and pricing of new drugs in Taiwan. Once marketing approval has been granted by the TFDA, a drug manufacturer must submit an application to the NHIA for further evaluation, review and pricing by the appropriate committees. If the NHIA approves reimbursement of a new drug, it will then determine its reimbursement price, and the product can be used at any healthcare facility in Taiwan.

While reimbursement and pricing reviews now take over a year to complete, NHI schedule listings are just part of a more lengthy process required to obtain widespread access to the Taiwan market. Once approved for NHI reimbursement, drug manufacturers must then begin pursuing listings on healthcare providers’ formularies, which can often take a further two to three years before a new drug can be formally included.109

As the prescribing and dispensing functions are not separated in most hospitals and clinics in Taiwan, this means access to hospital formularies is vital for drug manufacturers. However, with more than 16,000 drug items listed on the NHI reimbursement schedule, competition for space on hospital formularies—which seldom contain more than 1,000 products—is intense. Price is usually the key to securing formulary space.

Reimbursement listing

A listing on the NHI reimbursement schedule is a prerequisite for the commercial success of new drugs in Taiwan. The reimbursement decision-making process involves initial scrutiny by expert groups, formal recommendations on the benefit status of a drug product by a Pharmaceutical Benefit and Reimbursement Scheme (PBRS) committee of stakeholder representatives, and a final endorsement decision by the NHIA. The PBRS Committee meets every month, and its focus alternates between drugs and medical devices.110 It is tasked with reaching a resolution on a product’s listing and pricing for the NHI, which is based on a Health Technology Assessment (HTA) analysis report and other data provided by the applicant manufacturers. The HTA report is conducted by the CDE and includes a comprehensive evaluation of the therapeutic and pharma-economic aspects of a new drug. The categorisation of the drug is also determined during this stage.

New pharmaceutical drugs are accorded one of three classification categories for reimbursement listing and pricing: Category 1 includes medicines that offer substantial improvement of therapeutic value in head-to-head or indirect comparisons; Category 2A offers moderate improvement of value compared to the current best comparator; and Category 2B offers similar therapeutic value compared to the current best comparator.

Changes to reimbursement listing procedures as part of the 2G NHI reforms in 2013 have resulted in longer review times and lower approval rates for new drugs and new indications. On average, the review for new drugs takes 429 days (782 days for new cancer drugs), up from 382 days under the first generation NHI.111 The approval rate of new drugs is only 62%, with just 37% of these cases having been effectively reimbursed.112
Figure 35: Pharmaceutical listing and pricing flowchart

Source: National Health Insurance Administration
**Drug pricing**

The NHIA typically acts to reduce the price it is willing to reimburse for drugs made available under the NHI programme, as part of ongoing efforts to control healthcare and pharmaceutical expenditures. Even though it uses a variety of pricing methods for new drugs, the vast majority of drug prices in Taiwan are still much cheaper than most international reference markets, and this is a major source of contention for drugmakers.

When setting drug reimbursement prices, the NHIA references the prices of ten benchmark developed countries (referred to as A10). However, the price is usually set at the lower end of the comparative scale. Average NHI prices for new drugs have declined progressively over the twenty years since the programme was first established—from around 89% of the A10 median price in 1995 to little more than 50% of the A10 median price since 2006. It has also introduced several price adjustment mechanisms—including the Drug Expenditure Target (DET) and R-zone method—to further control drug expenditure. Since 2013, the cost of most new drugs is reviewed annually under the DET system. While this approach means cuts are more predictable than under previous price-volume surveys, it has not relieved pressure on the prices of reimbursed drugs appreciably (see page 32).

The NHIA also uses price-volume agreements with manufacturers to a limited extent to help keep a cap on drug expenditure, through a claw-back mechanism, but it has not adopted so-called risk-sharing agreements used in many other developed countries—in which manufacturers negotiate a price with payers subject to outcome-based guarantees, with failure to meet these guarantees resulting in compensatory payments.

![Figure 36: Drug reimbursement pricing process](source: National Health Insurance Administration)
Business environment

Structural trends

Healthcare and pharmaceutical needs continue to rise in Taiwan as a result of universal access to and overuse of medical care services. On average, Taiwanese patients visit doctors more than a dozen times a year. The vast majority of consultations result in the generation of prescriptions for multiple drugs. This is a reflection in part of the fact that healthcare providers can generate substantial profits on the purchase and sale of drugs.

Demographic and epidemiological trends will continue to drive up demand for medicines. Along with Japan and South Korea, Taiwan has one of the fastest ageing populations in Asia, which will lead to higher demand for the treatment of chronic, age-related diseases, such as diabetes, hypertension and dementia. With few effective constraints on patient access to medicines, this will drive up sales volumes of pharmaceutical drugs.

However, pharmaceutical cost-containment measures—including new controls on NHI drug spending and an increasingly restrictive approach to the reimbursement of costly new medicines—will limit rates of increase in market value. Nevertheless, market forecasters expect innovative, high-cost products for the treatment of cancer and other serious, life-threatening diseases will continue to act as strong drivers of total market value.

Competitive landscape

Taiwan has the sixth largest pharmaceutical market in the Asia-Pacific region by sales. Its status as a target for multinational drug companies has been enhanced by universal health insurance coverage provided under the NHI, high levels of drug consumption, and access to reimbursement for a broad range of original brands. Most Big Pharma firms are active in Taiwan, and the majority of them concentrate on sales and marketing.

Some 320 domestic companies are engaged in pharmaceutical manufacturing, and most focus on production of APIs, finished generics or both. Phased-in compliance with PIC/S GMP standards has helped to sharpen their international competitiveness. Also, leading generic drugmakers have started to seek a more diversified pipeline with higher entry barriers, in addition to targeting overseas markets to support future growth.

Although the Taiwan government actively promotes the nation’s health industries, its policies tend to favour domestic generic drugmakers. This has long been criticised by international research-based pharmaceutical companies firms as negatively impacting innovation. For instance, hospitals use discounts received on high priced generics to cover low reimbursements for medical services, which hinders their use of patented drugs.
Research and development

Most Taiwanese drug manufacturers still focus on the development of generic versions of existing drugs, but some have begun to pursue the creation of added value products through the development and application of new formulation or delivery techniques. Interest in the research and development of novel medicines has also risen, and involves both academic institutions and a growing number of local biotechnology companies. The development status of Taiwan’s biotechnology sector is covered in more detail on pages 40-49.

Recent moves to bring local drugmakers up to international standards, in compliance with PIC/S rules, should help to improve pharmaceutical product quality. Also, the government is currently promoting the biomedical industry under its “5+2 Innovative Industries Programme,” with the aim of establishing Taiwan as a regional hub for biopharmaceutical R&D. A “Biomedical Industry Innovation Promotion Programme,” launched in late 2016, includes proposals to encourage international pharma companies to set up research centres in Taiwan.\(^{116}\)

Retail pharmacy in Taiwan

The retail sector comprises almost 10,000 community pharmacies, of which around 6,000 are contracted with the NHIA, enabling them to dispense reimbursed prescription drugs.\(^{117}\) However, the proportion of scripts filled in the retail sector remains limited, at only 10%,\(^{118}\) reflecting the reluctance of hospitals and physician clinics to forfeit profits made on the purchase and sale of medicines by their in-house pharmacies.

As a result, the revenues of community pharmacies are dominated by the sale of OTC medicines, which may be sold in licensed premises without a prescription, and consumer health products. The market share of OTC drugs in Taiwan, at 8%, is comparatively low by international standards.\(^{119}\) But with the NHIA continuing to cut the prices of prescription drugs, pharma companies see potential growth opportunities in the OTC market.

Future OTC growth will likely be driven by the NHIA’s more proactive approach to Rx-OTC switching, with reimbursements having been discontinued for low-potency drugs and some health supplements, and the removal of some OTC drugs from the NHI reimbursement schedule. Changing consumer behaviours, such as more awareness of health issues and a greater willingness to self-medicate, is another influential factor.
Medical device sector

Market overview

Taiwan’s medical device sector covers a wide range of equipment and products used for diagnosis or therapy in patients – everything from simple tapes and adhesives to apparatus used in surgical procedures to sophisticated testing and diagnostic equipment. Thanks to its background in information and communications technology (ICT) and manufacturing, Taiwan is a world leader in a number of medical device products, including digital blood pressure monitors, electric wheelchairs and scooters, and electronic thermometers.  

Domestic market sales (including imports) totalled NT$152.2bn (US$4.7bn) in 2016. Due to the limited market size, local medical-device makers are reliant on exports for over 40% of their revenue, which consist primarily of mid-to-low-end medical equipment and contracted manufacturing for multinationals. At the same time, Taiwan is dependent on imports for some 47% of domestic demand, mostly for high-end surgical, therapeutic, and medical imaging devices used in hospitals and supplied from the US, the EU and Japan. 

Further steady growth is expected in the coming years, on account of Taiwan’s rapidly increasing population and related higher demand for healthcare products and services, as well as the government-backed industry investment plan to increase higher-value medical device manufacturing. BMI Research forecasts the market will register a CAGR of 6.8% in local currency terms in 2017-2022. However, product pricing pressures will increase due to the authorities’ use of cost containment measures to control rising healthcare expenditure. 

Government policy support will play a critical role in boosting growth. Its “Biomedical Industry Innovation Promotion Programme” aims to build Taiwan into a regional biomedical R&D hub, and offers incentives to push local companies towards the manufacture of higher-end products. Also, in April 2017, the government announced plans to invest NT$20bn (US$65m) in the medical device sector with the aim of increasing its value to NT$200bn (US$6.5bn) by 2020, which would represent average annual growth of around 10%.
**Table 7: Status of Taiwan’s medical device sector, 2007-2016**

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<thead>
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<tr>
<td>Revenue</td>
<td>2.3</td>
<td>2.5</td>
<td>2.5</td>
<td>2.9</td>
<td>3.4</td>
<td>3.7</td>
<td>3.9</td>
<td>4.1</td>
<td>4.2</td>
<td>4.4</td>
</tr>
<tr>
<td>No. of companies</td>
<td>501</td>
<td>544</td>
<td>553</td>
<td>580</td>
<td>626</td>
<td>705</td>
<td>761</td>
<td>781</td>
<td>1,041</td>
<td>1,073</td>
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<tr>
<td>Personnel</td>
<td>20,200</td>
<td>21,923</td>
<td>22,900</td>
<td>25,800</td>
<td>30,250</td>
<td>34,200</td>
<td>35,040</td>
<td>36,429</td>
<td>38,400</td>
<td>39,500</td>
</tr>
<tr>
<td>Export value</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
<td>1.3</td>
<td>1.4</td>
<td>1.6</td>
<td>1.6</td>
<td>1.7</td>
<td>1.8</td>
<td>1.9</td>
</tr>
<tr>
<td>Import value</td>
<td>1.4</td>
<td>1.5</td>
<td>1.5</td>
<td>1.7</td>
<td>1.9</td>
<td>1.9</td>
<td>2.0</td>
<td>2.0</td>
<td>2.2</td>
<td>2.2</td>
</tr>
<tr>
<td>Domestic market demand</td>
<td>2.7</td>
<td>3.0</td>
<td>2.9</td>
<td>3.4</td>
<td>3.8</td>
<td>4.1</td>
<td>4.3</td>
<td>4.4</td>
<td>4.6</td>
<td>4.7</td>
</tr>
</tbody>
</table>

Source: Ministry of Economic Affairs, 2008-2017 Biotechnology Industry White Papers

**Figure 37: Domestic market size of Taiwan’s medical device sector, 2007-2016**

Source: Ministry of Economic Affairs, 2008-2017 Biotechnology Industry White Papers
Regulatory environment

The TDFA is the controlling authority in Taiwan for medical devices products. Its Division of Medical Devices and Cosmetics is responsible for supervision and administration of medical devices, and its Division of Risk Management enforces GMP inspections for medical device manufacturers. The CDE, an independent not-for-profit agency, assists the TFDA to carry out pre- and post-market technical dossier reviews of medical devices.

Taiwan currently regulates both medicines and medical devices under the 1993 Pharmaceutical Affairs Act. It governs the manufacturing, importation, and sale of medical devices in Taiwan, and also establishes basic requirements regarding the packaging, labelling, and sale of medical devices. Under the law, the TFDA issues registration certificates, while the MOHW performs on-site inspections of medical-device manufacturers.

Because of the different characteristics of medicinal products and medical devices, in 2017, the TFDA put forward a draft Medical Devices Act that will establish a separate, dedicated regulatory framework for medical devices. Among other items, the proposed new legislation will implement a more sophisticated classification system for medical devices, strengthen the management of medical-device manufacturers, upgrade the quality management systems of medical devices, and formulate regulations for clinical trials.

The draft bill was submitted to Taiwan’s parliament in December 2017 for its review and final approval. The TFDA anticipates the Act will help to improve the life cycle management of medical devices and, in so doing, promote the development of Taiwan’s biomedical industry, which has been identified as an important driver of growth under the government’s “5 + 2 Innovative Industries Programme.” In the meantime, the TFDA has pledged to continue working to develop a globally harmonised and transparent regulatory environment.

In terms of the future direction of medical device regulations, the TFDA aims to enhance GMP compliance, optimise the pre-market registration review process, enhance post-market regulation and border control, enhance the regulation of distribution and distributor inspections, and promote international regulatory harmonisation, among others. As a member of the AHWP (Asian Harmonisation Working Party), the TFDA is already working to bring its medical device rules more in line with international regulatory practice.
Pre-market approval from the TFDA is required for all classes of medical devices before being domestically manufactured or imported from abroad.\(^ {127}\) It only grants permit licenses to individual medical devices and not to product lines. Medical devices are classified into 17 categories and three classes (I, III and III) based on risk levels. Subject devices without predicate devices in the Taiwan market are regarded as new devices.

While registration of Class I (low risk) medical devices merely involves a simple paper review, the registration of Classes II (moderate risk) and III (high risk) medical devices requires submission of detailed documents, particularly the free-sale certificate and clinical trials data. Also, most manufacturers are required to submit quality system documentation (QSD) that meets Taiwan’s good manufacturing practice (GMP) requirements.

The TFDA has entered into technical co-operation programmes with the US FDA and EU certification bodies, which help expedite the registration process for devices already approved for sale in the US and EU markets. However, if the applicant device is not used in exactly the same way in both the US and EU, it does not qualify for the simplified review. Indeed, companies frequently find that utilising the simplified procedure is not to their benefit if having to wait for both US and EU accreditation actually delays their market entry.\(^ {128}\)

Under a new ‘two-step’ review programme, launched by the TFDA in November 2015, the administrative and technical device reviews for medical devices are no longer conducted in parallel.\(^ {129}\) Medical device registrants first need to undergo administrative reviews of their market applications. Once complete, the TFDA will then perform a technical review of the product. Previously, administrative and technical reviews could sometimes be conducted concurrently, meaning registration applicants may now experience lengthier review timeframes.

The TFDA issues a medical device permit license upon a product’s registration approval. The official timeline to obtain approval for Class I, II and III devices are 2-3 months, 6-8 months and 12-18 months, respectively.\(^ {130}\) Clinical data or clinical trials might be required for Class III devices and New Medical Devices. In response to industry complaints about the length of the approval timeline under the two-step review process,\(^ {131}\) the TFDA is working to simplify documentation requirements and shorten the registration process for medical devices.

In October 2017, the TFDA announced a pilot scheme for the online review and submission of documents through an electronic platform known as E-PRESS, which aims to enhance the medical device registration process and shorten product review times.\(^ {132}\) It is also expected to help mitigate delays resulting from the November 2015 implementation of a two-step review process, which resulted in lengthier review times, despite the introduction of higher registration fees meant to fund more staff to expedite the review process.
Figure 38: Medical device registration process

Source: Qualtech, Taiwan Medical Device Registration
Reimbursement and pricing

The reimbursement and pricing for medical devices in Taiwan are set by the NHIA. The submission process requires manufacturers to submit a new product application form after obtaining marketing approval from the TFDA. The NHIA then decides whether or not a new medical device will be listed for reimbursement. If a medical device is added to the reimbursement list, its reimbursement price will be determined by the NHIA’s Medical Device Division, and it can then be used at any healthcare facility in Taiwan.

All medical devices must apply for reimbursement review, which can take up to 18 months to process. Pricing is usually decided by a biennial price-volume survey. The aim is to ensure that reimbursement rates reflect the real prices that hospitals are paying vendors. In practice, however, this is not always the case. Hospitals tend to profit from the difference of reimbursement price that is set higher than the actual price paid to the vendor to cover their logistic and administrative costs for handling the devices.

Medical device manufacturers have long expressed concern over the NHIA’s procedures for reimbursement and product pricing. It typically sets prices low for new products, as with drugs, but also specifies a single purchase price for all medical devices that treat a given indication. Industry players argue that this does not distinguish between lower-cost devices and more advanced, higher quality ones (often accompanied by additional services), and so may discourage the introduction of innovative products into Taiwan.

Although some new devices offer improved functions, they are often far more expensive than similar items in the NHI fee schedule. Balanced billing, which shifts a larger proportion of costs onto patients, has been adopted for some costly medical devices. The NHIA has so far listed six categories (seven items) as balance billing items. In this case, a patient wishing to use a more costly medical device may pay the difference, out of their own pocket, between the existing payment standards for similar items and the actual price charged.

Medical device manufacturers can expect to face a more challenging market environment as the NHIA seeks to expand the Tw-DRG payment system to contain healthcare expenditure. As the DRG reimburses a fixed fee for an inpatient case, all additional costs incurred during the treatment falls onto the hospital operator. This represents a shift in the cost burden away from the payer towards the healthcare provider and exposes them to significant risks. This in turn will likely increase pricing pressure on medical device purchasing.

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Figure 39: Classification for medical devices payment

<table>
<thead>
<tr>
<th>Medical Devices</th>
<th>Not be covered materials by NHI according NHI Act</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>e.g. dentures, artificial eyes, spectacles, hearing aids, wheelchairs, canes</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General materials</th>
<th>Fully reimbursed or balance-billing items</th>
</tr>
</thead>
<tbody>
<tr>
<td>e.g. consumed during surgery, treatment, anesthesia Or examination (such as disposables)</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Special Devices</th>
<th>Not reimbursed or Not yet reimbursed items</th>
</tr>
</thead>
<tbody>
<tr>
<td>(implantable/specific non-implantable)</td>
<td></td>
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</table>
Figure 40: Flowchart for new medical device listing

Source: National Health Insurance Administration
Business environment

Taiwan’s medical device sector largely comprises small to medium enterprises which mainly produce and export low and mid-level medical equipment and products, such as contact lenses, disposable medical materials, diabetes products and mobility vehicles. Many local medical-device makers also undertake contract manufacturing for multinationals. This collaborative relationship has grown from the supply of components to a level where Taiwan is now a producer of upstream devices and a key link in the global supply chain.

In recent years, the government has endeavoured to move the local medical device sector up the value-added chain. In January 2017, a Biomedical Industry Innovation Centre was established in the Hsinchu Biomedical Science Park. The medical device component will invest in R&D centres and precision manufacturing to develop high-value products, which are viewed as offering greater opportunities over biopharmaceutical development due to their much shorter product development timeframe and faster-to-market metrics.

Furthermore, in April 2017, the Ministry of Economic Affairs revealed plans to invest NT$2.0bn (US$64.5m) in the medical device sector with the aim of increasing its value to NT$200bn (US$6.5bn) by 2020. Eyeing healthcare needs accompanying the escalating global elderly population, the ministry identified three key focus areas for priority development, including medical imaging equipment (such as ultrasound images, digital x-rays, and magnetic resonance imaging), intensive therapy equipment, and aesthetic medicine devices.

The government also aims to establish a positive environment for the development of the 3D printed medical device manufacturing sector in Taiwan. In January 2018, the TFDA issued new guidance on the scope of regulations in relation to 3D printed medical devices to help manufacturers to determine what information to include when making submissions. The clarification will help accelerate market entry of 3D printed medical devices, which have a growing presence in a number of product areas, including orthopaedics and dentistry.

In a sign of progress, 55 locally developed medical devices received 510(k) pre-market clearances from the US FDA in 2017, with the majority being high-value items such as dental, ophthalmological and orthopaedic materials as well as those for minimally invasive surgeries. Also, with many of Taiwan’s high-tech companies increasingly diversifying into the biomedical industry, the future growth of the medical device sector will be supported by the development of innovative smart medical devices that leverage digitalisation technology.

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**Figure 41: Current phase of Taiwan’s medical device sector**

Source: Ministry of Economic Affairs, Biotechnology & Pharmaceutical Industries Promotion Office
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PwC’s health industries services

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Our health industries practice focuses on the healthcare, pharmaceutical and life science sectors, and our people bring industry experience as it pertains to assurance, tax and advisory services. This breadth of knowledge and expertise enables us work with clients to resolve complex issues and identify opportunities.

Assurance services
We provide audit and assurance, and capital market and accounting advisory services to a broad range of health sector clients, including helping emerging and early stage biotechnology companies prepare for IPOs on Taiwan’s stock exchanges. Our aim is to deliver professional services that support your ability to provide stakeholders with accurate and understandable financial and operational information about your business.

Tax and legal services
We deliver practical tax and legal advice and solutions to health industries clients. Our specialists provide support from tax structuring and strategy through to tax and regulatory compliance services. We intimately understand the health sector 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 sector clients determine the right strategic priorities to grow profitably and maximise value in Taiwan, and offer support and practical solutions to achieve these objectives. We are focused in a range of areas including strategy, operations, technology, finance, people and change, risk and forensics. We can assist you with strategic planning and market analysis, as well as with all aspects of the M&A deals process.

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

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