# Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foreword</td>
<td>1</td>
</tr>
<tr>
<td>Executive summary</td>
<td>2</td>
</tr>
<tr>
<td>Taiwan’s healthcare system</td>
<td>5</td>
</tr>
<tr>
<td>Taiwan’s biomedical industry</td>
<td>25</td>
</tr>
<tr>
<td>• Biotechnology sector</td>
<td>29</td>
</tr>
<tr>
<td>• Pharmaceutical sector</td>
<td>35</td>
</tr>
<tr>
<td>• Medical device sector</td>
<td>43</td>
</tr>
<tr>
<td>Key health industries topics</td>
<td>49</td>
</tr>
<tr>
<td>• Digital health</td>
<td>51</td>
</tr>
<tr>
<td>• Long-term care</td>
<td>55</td>
</tr>
<tr>
<td>• Precision medicine</td>
<td>59</td>
</tr>
<tr>
<td>• International collaboration</td>
<td>63</td>
</tr>
<tr>
<td>How PwC Taiwan can help</td>
<td>67</td>
</tr>
</tbody>
</table>

The information in this report is up-to-date as of July 2020, unless otherwise stated. The report has been compiled by Darrian Gilhawley, a Knowledge Management Director at PwC Taiwan, and it is based on a mix of desk research and in-depth interviews with industry stakeholders and academics. The report is intended for informational purposes only and does not constitute professional advice.
Developed economies across the globe are facing the common challenges of ageing demographics, declining fertility rates and shrinking labour pools, which will have negative economic, budgetary and social consequences. As the number of the elderly rises, governments have started prioritising the development of new solutions and technologies that will help with the provision of healthcare and preventative measures. Taiwan is a case in point.

Taiwan is recognised as having one of the best performing health systems in Asia, underpinned by a single-payer national health insurance (NHI) programme which offers universal coverage with affordable and easy access to high-quality care. But it faces growing cost and resource pressures to meet the demands of a fast-ageing population. In recognition of this situation, the authorities have already started planning for a next-generation NHI.

Industry players—including healthcare providers, drug developers and manufacturers, and medical device companies—too face various challenges in Taiwan’s highly competitive environment, but one which also offers opportunities across the health spectrum. For instance, the government’s plans to develop the local biomedical industry to become a regional hub for drug 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 firms operating at the intersection of technology and medical science, as well as encouraging tie-ups and collaborations between medical facilities and businesses involved in innovative sectors such as Artificial Intelligence and the Internet of Things.

This publication, which is a revised update of the previous 2018 edition, provides a comprehensive introductory guide to Taiwan’s health industries—encompassing the healthcare, biopharmaceutical and medical device sectors—and examines the prospects, opportunities and challenges for market players. It also takes a look at key industry topics including digital health, long-term care, precision medicine and international pharma collaboration.

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

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

Lily Wong
Health Industries Leader
PwC Taiwan
Executive summary

Taiwan’s healthcare system

Key features

- Taiwan has a high-performing healthcare system that is internationally recognised for its compulsory, universal health coverage programme and delivery of high-quality, affordable treatment and care.

- The government-run, single-payer national health insurance (NHI) scheme provides patients easy access to a large network of contracted hospitals and clinics, most of which are privately owned.

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

- With patients enjoying universal access to high-quality healthcare services and abundant medical facilities, low-out-of-pocket costs and short waiting times, public satisfaction with the NHI is high.

- Health expenditure represented 6.6% of GDP in 2018, lower than the OECD average of 8.8%, with the NHI accounting for 53% of total spending, then household out-of-pocket expenditure at 33%.

- The relatively low spend reflects the ability of the government, as the single buyer of and payer for healthcare services, to control expenditures, as well as the NHI’s low-cost administrative efficiency.

Main challenges

- A major problem for the healthcare system is the NHI’s ‘all-you-can-eat’ provisions and relatively weak constraints on demand or supply, which encourages overuse and wastage of medical resources.

- Patients seeking treatment for minor ailments are a key factor behind overcrowding at many hospitals, resulting in poor working conditions for doctors and nurses that in turn is causing a retention problem.

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

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

- The government has already taken steps to address some of these issues, such as curbing costs and reducing waste, but further and deeper reforms will be needed to ensure the NHI’s sustainability.

- Healthcare reform is a sensitive topic in Taiwan, so any major changes will be a protracted process. Planning has already begun for a next-generation NHI and will take around 6-8 years to complete.
Taiwan’s biomedical industry

- The biomedical industry (including applied biotechnology, pharmaceuticals and medical devices) is a major priority focus for Taiwan, as part of the government’s “5+2 Innovative Industries Plan.”
- A long period of investment has produced a solid foundation, with an ecosystem spanning the entire biomedical value chain, from research, discovery and development to manufacturing and marketing.
- Combined domestic market sales (excluding export revenues) totalled about US$16bn in 2019, with pharma representing the largest share at 45%, followed by medical devices 31% and biotech 24%.

Biotechnology sector

- Strong policy support has been a key contributor to the accelerated expansion of Taiwan’s biotech sector, which has more than doubled in size over the past decade to reach US$3.8bn in 2019.
- Clinical research capacity has progressed rapidly, supported by abundant talent, good research infrastructures, ample clinical trials experience, and cost-competitive R&D and manufacturing.
- Growth momentum remains strong, supported by the government’s promotion of Taiwan as a 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 US$7.2bn in 2019, ranking the 7th largest in Asia.
- The tight-budgeted hospital market accounts for 80% of total drug sales, which limits profits for drug-makers, and this is further compounded by a long reimbursement timeline and annual price reviews.
- Demographic and epidemiological trends will drive up future demand for medicines, but the continued use of drug-price controls to contain healthcare spending will limit rates of increase in market value.

Medical device sector

- A rapidly ageing population and related higher demand for healthcare products and services has underpinned growth in Taiwan’s medical device sector, with domestic sales of US$5bn in 2019.
- Imports account for 60% of domestic demand, mostly for high-end devices used in hospitals, while local companies rely on exports of mid-to-low-end medical equipment for 60% of their revenues.
- A government-backed industry investment plan, launched in April 2017, aims to move Taiwan’s medical device sector up the value-added chain and increase its value to US$6.7bn by 2020.
## Healthcare system

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare in Taiwan</td>
<td>6</td>
</tr>
<tr>
<td>Regulatory governance</td>
<td>7</td>
</tr>
<tr>
<td>Healthcare delivery infrastructure</td>
<td>8</td>
</tr>
<tr>
<td>• Hospitals and clinics</td>
<td>9</td>
</tr>
<tr>
<td>• Medical care personnel</td>
<td>11</td>
</tr>
<tr>
<td>• Health information technology</td>
<td>12</td>
</tr>
<tr>
<td>Healthcare demand and utilisation</td>
<td>13</td>
</tr>
<tr>
<td>• Major disease trends</td>
<td>13</td>
</tr>
<tr>
<td>• Ageing demographics</td>
<td>14</td>
</tr>
<tr>
<td>• Healthcare resource utilisation</td>
<td>15</td>
</tr>
<tr>
<td>• Medical tourism promotion</td>
<td>17</td>
</tr>
<tr>
<td>Healthcare expenditure and financing</td>
<td>18</td>
</tr>
<tr>
<td>• Health spending analysis</td>
<td>19</td>
</tr>
<tr>
<td>• NHI programme overview</td>
<td>21</td>
</tr>
<tr>
<td>• Cost-containment strategies</td>
<td>22</td>
</tr>
<tr>
<td>• Private health insurance</td>
<td>24</td>
</tr>
</tbody>
</table>
Healthcare in Taiwan

Taiwan has one of the best healthcare systems in the world, according to a number of international healthcare index rankings. The main reason is its National Health Insurance (NHI) scheme, which provides universal and affordable health coverage and care to all residents in Taiwan. With patients enjoying easy access to a comprehensive range of heavily-subsidised and high-quality medical care, and facing few limits on their choice of healthcare provider or doctor, the level of public satisfaction with the NHI is consistently high, at 89.7% in 2019.

Some of the very best features of Taiwan’s healthcare system were on display during the COVID-19 pandemic crisis in early 2020. The virus outbreak had a much more moderate impact in Taiwan than in other areas across the globe with relatively few infections overall. Taiwan, learning from its SARS experience, was among the quickest to recognise and counteract the potential dangers of the virus. Its effective controls have been attributed to the use of technology, a central command centre, the single-payer NHI system and swift decision making.

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

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

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

The government is already taking steps to address some of these challenges, such as the launch of a new policy in 2018 to reduce the total number of outpatients in major hospitals by 2% per year, and the expanded use of cloud data-sharing systems to reduce waste. Further and deeper reforms will be needed over the longer term as demographic and epidemiological trends add growing pressure on the NHI’s finances. However, healthcare reform is a highly sensitive topic in Taiwan, so any major policy changes will likely be a protracted process.

The health ministry confirmed as much in 2017, when it announced that planning had begun for a third-generation NHI and would take 6-8 years to complete. Meanwhile, a hike in premium rates is likely at some point in the near term. Controlling costs and waste will also remain a priority, with provider and patient behaviour being scrutinised more closely, and the likely imposition of further constraints, such as through higher co-payments. Moreover, efforts to shift some of the burden of primary care away from big hospitals will continue.

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

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

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

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

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

Figure 1: Healthcare system governance in Taiwan

Source: The Commonwealth Fund, International Health Care System Profiles.
Healthcare delivery infrastructure

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

In general, the provider licensing by local health authorities and hospital accreditation by the Joint Commission of Taiwan are trusted to assure an acceptable standard of care, and serve as the basis for contracting with the NHIA. 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. Also, medical treatment and care is divided into Western and traditional Chinese medicine (TCM).

Figure 2: Status of medical institutions in Taiwan, 2018-2019

<table>
<thead>
<tr>
<th>Medical care institutions</th>
<th>22,992</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>480</td>
</tr>
<tr>
<td>Clinics</td>
<td>22,512</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>8,048</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>8,048</td>
</tr>
<tr>
<td>Nursing institutions</td>
<td>1,471</td>
</tr>
<tr>
<td>General nursing homes</td>
<td>542</td>
</tr>
<tr>
<td>Psychiatric nursing homes</td>
<td>44</td>
</tr>
<tr>
<td>Home care practices</td>
<td>618</td>
</tr>
<tr>
<td>Post-natal nursing institutions</td>
<td>267</td>
</tr>
<tr>
<td>Blood donation institutions</td>
<td>18</td>
</tr>
<tr>
<td>Blood donation centres</td>
<td>5</td>
</tr>
<tr>
<td>Blood donation stations</td>
<td>13</td>
</tr>
<tr>
<td>Pathology institutions</td>
<td>11</td>
</tr>
<tr>
<td>Pathology institutions</td>
<td>11</td>
</tr>
<tr>
<td>Other medical institutions</td>
<td>1,940</td>
</tr>
<tr>
<td>Midwifery practices</td>
<td>23</td>
</tr>
<tr>
<td>Medical laboratories</td>
<td>376</td>
</tr>
<tr>
<td>Medical radiological institutions</td>
<td>53</td>
</tr>
<tr>
<td>Physical therapy practices</td>
<td>228</td>
</tr>
<tr>
<td>Occupational therapy practices</td>
<td>76</td>
</tr>
<tr>
<td>Denture clinics</td>
<td>33</td>
</tr>
<tr>
<td>Mental counselling clinics</td>
<td>80</td>
</tr>
<tr>
<td>Psychotherapy clinics</td>
<td>54</td>
</tr>
<tr>
<td>Speech therapy centres</td>
<td>36</td>
</tr>
<tr>
<td>Dental technology centres</td>
<td>901</td>
</tr>
<tr>
<td>Hearing centres</td>
<td>21</td>
</tr>
<tr>
<td>Home respiratory care practices</td>
<td>3</td>
</tr>
<tr>
<td>Optometry practices</td>
<td>28</td>
</tr>
<tr>
<td>Nutrition advisory organisations</td>
<td>28</td>
</tr>
</tbody>
</table>

Note: The medical care institution data is for 2019 and all other data is for 2018.
Source: Ministry of Health and Welfare.
Hospitals and clinics

As of 2019, Taiwan had a total of 22,992 medical care institutions, which consisted of 480 hospitals and 22,512 clinics, the vast majority of which were contracted with the NHIA (see Table 1). Most of the hospitals (83% in 2019) and an even greater proportion of the health clinics (98%) are privately owned, and many are small. Western medicine is the predominant form of treatment, accounting for 53% of all registered care providers, followed by dental clinics (30%) and TCM institutions (17%).

The total number of hospitals dropped from 669 in 2000 to 480 in 2019, largely due to the closure or merging of small hospitals. District hospitals in particular have struggled in the face of increasing competition from the larger and better-resourced regional hospitals and medical centres. Existing facilities have grown in size and opened more beds in a bid to boost efficiency and revenues—the total number of hospital beds increased from 114,179 in 2000 to 135,257 in 2019. Taiwan currently has 5.7 hospital beds per 1,000 population, above the OECD average of 4.7, with around two-thirds of all beds owned by privately-operated health facilities.

As for primary care clinics, their total number grew from 17,413 in 2000 to 22,512 in 2019, consisting of 11,663 Western medicine clinics, 6,874 dental clinics and 3,975 TCM clinics. The rise has been boosted, in part, by more cosmetic and aesthetic medicine clinics, and the government’s efforts to reduce patient reliance on hospitals for provision of primary care services. Around 40% of Taiwan’s doctors work as private practitioners in their own clinics, and 80%-90% of clinics are solo practices.

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

In 2017, 133 out of the 150 hospitals that claimed more than NT$400m (US$13m) in reimbursements from the NHI turned a profit. In general, hospitals generate revenue from reimbursement payments, co-pays and registration fees, and proceeds from sales of services and devices not covered by the NHI. Many also depend on non-healthcare income (such as from food courts, convenience stores and parking lots) to balance fiscal gaps from shrinking NHI reimbursements for services performed. As a result, hospitals are under increasing pressure to be more efficient, to compete for patient volume, and to provide more services with higher margins. This heightened competition for patients creates a supply-induced demand for healthcare services under the predominantly fee-for-service payment system, and is a major contributory factor to the high utilisation of healthcare resources in Taiwan. However, weak constraints on service demand or supply, provider reimbursement mechanisms, and the ability of hospitals to gain profit from the sale of drugs and other services all serve to encourage overtreatment, which is a driver of NHI spending.

Table 1: Number of NHI-contracted hospitals and clinics, 2019

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Western medicine hospitals</th>
<th>Chinese medicine hospitals</th>
<th>Western medicine clinics</th>
<th>Chinese medicine clinics</th>
<th>Dental clinics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical care institutions</td>
<td>22,992</td>
<td>476</td>
<td>4</td>
<td>11,663</td>
<td>3,975</td>
<td>6,874</td>
</tr>
<tr>
<td>Contracted hospitals and clinics</td>
<td>21,435</td>
<td>473</td>
<td>4</td>
<td>10,497</td>
<td>3,724</td>
<td>6,737</td>
</tr>
<tr>
<td>% of contracted health facilities</td>
<td>93.2</td>
<td>99.0</td>
<td>100</td>
<td>90.1</td>
<td>93.5</td>
<td>98.3</td>
</tr>
</tbody>
</table>

Source: Ministry of Health and Welfare and National Health Insurance Administration.
Figure 3: Number of hospitals and hospital beds in Taiwan, 2000-2019

No. of hospitals

Source: Ministry of Health and Welfare.

Figure 4: Number of primary care clinics in Taiwan, 2000-2019

No. of clinics

Source: Ministry of Health and Welfare.
Medical care personnel

Despite an extensive network of medical facilities, Taiwan faces a growing shortage of doctors and nurses due to retention issues. As of 2019, Taiwan had a total of 56,587 doctors (both Western and TCM) and 143,590 nurses, or 2.4 doctors and 6.1 nurses per 1,000 population, which are both well below the respective OECD averages of 3.5 and 8.8. These low ratios are a concern in view of the high utilisation of healthcare services in Taiwan — in the 2010-2019 period, hospital outpatient visits grew by 15.8%, and inpatient numbers by 14.0%.

Hospital-based doctors often complain about being overworked, underpaid and potential malpractice suits. Many have left to work in clinics or take up higher-paying posts abroad, leading to shortages in the specialty areas of internal medicine, surgery, emergency care, podiatric medicine, and obstetrics and gynaecology. To help prevent physicians from occupational burnout, and to protect their rights, doctors are now covered by the Labour Standards Act, beginning from 1 September 2019, which sets limits on the number of hours that they may work.

Nurses also protest about long hours, low wages and stressful working conditions. This has resulted in an increase in the number of registered nurses not practicing and a rising shortage of nurses. To address the issue, the MOHW has in recent years implemented various reforms aimed at increasing nurse-staffing levels and improving retention rates. From 2015, nurse-to-patient ratios are included in the criteria for hospital care evaluations as part of efforts to ameliorate widespread labour violations at hospitals and improve nurses’ work conditions.

The medical care personnel shortages in Taiwan have largely been brought about by the design of the NHI scheme — and in particular by the global budget system, which caps reimbursement levels for medical services. Providers’ cost-containment efforts have included increasing the workloads of doctors, nurses and other medical staff. Coupled with low and declining levels of pay and salary, the deterioration in hospital working conditions has led to serious manpower shortages. Resolving these personnel issues is a key priority for the MOHW.

Figure 5: Number of doctors and nurses per capita in Taiwan, 2000-2019

Per 1,000 people

Source: Ministry of Health and Welfare.
Health information technology

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

The 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 data in almost real time. This provides the NHIA with a good sense of overall healthcare expenditure at any point in time, and also helps it to identify and manage heavy users of NHI services. Several innovative applications have been developed to leverage this data source.

The NHIA has expanded its use of cloud-based data-sharing systems in recent years to reduce waste and improve the quality of care services. NHI MediCloud allows doctors to quickly retrieve a patient’s medical records from other hospitals and facilities to prevent any duplication of drugs and tests, and My Health Bank is an electronic medical records repository that helps patients to better manage their personal health. In June 2019, the NHIA launched a pilot access programme for the development of AI applications using NHI data.

The NHI’s huge medical database also serves as a useful resource for tracking health and disease trends across the population. This was exemplified during the COVID-19 pandemic health crisis in early 2020, when the government integrated data from the NHI, immigration and customs systems to trace potential cases and contain the outbreak. This big data innovation allowed hospitals, clinics and pharmacies access to patients’ medical and travel histories in order to identify individuals for testing who had travelled to high-risk locations.

Figure 6: NHI MediCloud system

Source: National Health Insurance Administration.
Healthcare demand and utilisation

Coupled with rising incomes and advances in medical care technologies, the NHI has brought substantive healthcare improvements to Taiwan’s population since its introduction in 1995. Health outcome measures compare favourably to most OECD countries with regards to life expectancy (80.9 years in 2019, up from 74.5 years in 1995) and infant mortality rates (4.2 per 1,000 live births in 2018, down from 6.5 in 1995). However, Taiwan has much lower fertility and birth rates, a situation which has persisted for decades and given rise to a higher rate of ageing than the OECD average.

Major disease trends

While the burden imposed by infectious diseases has been reduced due to a national immunisation programme, non-communicable chronic diseases (NCDs) have become a growing health challenge in Taiwan. According to MOHW statistics, in 2019, the top ten leading causes of death accounted for 77.5% of all deaths and were primarily NCDs. Cancer was the main cause of death for the 38th year, accounting for 28.6% of all deaths, followed by heart disease (11.3%) and pneumonia (8.7%).

The medical journal, *The Lancet*, reported in 2018 that Taiwan has one of the world’s lowest mortality rates from NCDs among 30-70 year olds; just 17.6% of men and 9% of women of this age die from NCDs. All the same, the financial costs of treating chronic conditions are substantial. Acute and chronic kidney disease (affecting 397,000 patients) was Taiwan’s most expensive illness in 2019, costing NT$3.3bn (around US$1.8bn) in NHI payments. Taiwan has the highest incidence and prevalence of end-stage renal disease in the world, especially among the elderly population.

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

Figure 7: Top ten leading causes of death in Taiwan, 2019

<table>
<thead>
<tr>
<th>Cause</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>28.6%</td>
</tr>
<tr>
<td>Heart disease</td>
<td>11.3%</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>8.7%</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>6.9%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>5.7%</td>
</tr>
<tr>
<td>Accidents (unintentional injuries)</td>
<td>3.8%</td>
</tr>
<tr>
<td>Chronic lower respiratory disease</td>
<td>3.6%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>3.6%</td>
</tr>
<tr>
<td>Kidney disease</td>
<td>2.9%</td>
</tr>
<tr>
<td>Liver disease</td>
<td>2.4%</td>
</tr>
</tbody>
</table>

Source: Ministry of Health and Welfare.
**Ageing demographics**

Taiwan’s 23.6m population is ageing quickly due to a shrinking fertility rate (just 1.06 children per woman in 2018) and longer life expectancy. The population growth rate dwindled to around 0.1% in 2019, down from an average of 1.4% a year during the 1980s. Government measures to encourage people to have more babies, such as stipends for new parents and more childcare benefits, have had little effect on raising the low birth rate. As a consequence, the government projects that the population could start to decline as early as 2020.

Taiwan has one of the fastest-ageing populations in the world. It has gone very quickly through the stages of an ageing society (in 1993) and now an aged society (in 2018). The proportion of people aged 65 or older accounted for 15.3% of Taiwan’s population in 2019, which means one out of every seven people is a senior citizen, and the old-age dependency ratio was 21.2%. Current government population estimates predict Taiwan will become a super-aged society in 2025 when the number of elderly people will exceed 20% of the population.

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

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

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

Population of population aged 65+ (%)

Healthcare resource utilisation

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

The total number of outpatient visits to hospitals in Taiwan grew 15.8% between 2010 and 2019, while the annual average outpatient visit rate per person increased from 14.6 to 15.0 times over the period, more than double the current OECD average of 6.8 doctor consultations per person. The high visit rate can be attributed to the easy accessibility to affordable care in Taiwan, as well as its ageing demographic profile, as older people typically use more medical care services and suffer from more serious chronic illnesses than other age groups.

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

In addition to outpatient treatment, the number of hospital inpatient cases increased 14.0% between 2010 and 2019, while the average length of stay declined from 9.2 to 8.4 days, though still higher than the current OECD average of 7.7 days. The growth in inpatient numbers has been driven by a combination of several factors, including the lack of an effective patient referral mechanism (similar to the gatekeeper system in the UK) for specialist care and hospitalisation, more elderly and chronic cases, and insufficient facilities for long-term care.

Figure 9: Medical service volume of hospitals in Taiwan, 2010-2019

![Graph showing medical service volume of hospitals in Taiwan, 2010-2019](image)

Source: Ministry of Health and Welfare and National Health Insurance Administration.
Supply-induced demand for medical care is also an influential factor, as hospitals are incentivised to compete for patient and service volume in the outpatient setting, which is more profitable than the provision of inpatient services under the NHI’s medical fee reimbursement system. Payments to hospitals represented 45.7% of all spending on personal healthcare in 2018, including 25.3% for inpatient care and 20.4% for outpatient care. This underlines the dominant role played by hospitals in the provision of outpatient as well as inpatient care.

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

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

Patient co-pay levels have been adjusted several times since the NHI’s implementation in an effort to reduce moral hazard behaviour and to improve patients’ use of health resources. Yet, the resulting co-payment rates are still relatively low. As part of measures to reduce hospital outpatient visits, in 2017, the NHIA increased the outpatient fees for visits to medical centres without a prior referral from NT$360 to NT$420. Also, patients visiting emergency departments for treatment of minor ailments now have to pay an additional NT$100.

### Table 2: NHI co-payments for outpatient visits

<table>
<thead>
<tr>
<th>Institution class</th>
<th>Western medicine</th>
<th>Emergency care</th>
<th>Dental care</th>
<th>Traditional Chinese medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>outpatient care</td>
<td>Triage classification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of institution</td>
<td>With referral</td>
<td>Without referral</td>
<td>Grades 1 &amp; 2</td>
<td>Grades 3 to 5</td>
</tr>
<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 demand for healthcare services is medical tourism. Since 2007, the government has promoted the internationalisation of medical services as part of broader efforts to attract more tourists to Taiwan. Supported by the MOHW, the Taiwan Task Force on Medical Travel coordinates an alliance of 74 qualified hospitals and clinics to promote medical services to patients from all over the world. The focus is primarily on personalised healthcare services, including health check-ups, cosmetic surgery and serious disease treatment.

Taiwan has emerged as a favourable destination for medical tourism, due in part to its competitive costs. The quality of medical care in Taiwan is on a par with developed countries, but less expensive. For example, the cost of heart bypass surgery or a hip replacement in Taiwan is about one-fifth of similar procedures in the US. Its other advantages include an abundance of high-quality hospitals and doctors and sophisticated medical technology. As of July 2020, there were 13 facilities in Taiwan accredited by the Joint Commission International.

Taiwan’s medical tourism sector has recorded steady growth since the late 2000s. According to MOHW statistics, the number of medical visits to Taiwan jumped from 68,545 in 2008 to 414,369 in 2018, with the majority of the medical tourists coming from Southeast Asia (boosted in part by the government’s New Southbound Policy) and China, followed by visitors from the Americas and East Asia. The total output value of international medical services increased from NT$2bn (about US$66m) in 2008 to NT$17bn (US$562m) in 2018.

In 2019, the government set a target of doubling the output value of the medical tourism sector to NT$35bn (about US$1.2bn) in four years. A one-stop promotion programme based on clinics has been launched and will initially focus on boosting business from health examinations and cosmetic medicine, as these currently account for just 20% of international medical care services. The second stage will focus on attracting medical tourists from Europe and the Americas, and potential customers would be referred by private insurance companies.

Figure 10: International healthcare promotion results, 2008-2018

Source: Ministry of Health and Welfare.
Healthcare expenditure and financing

Healthcare expenditure in Taiwan has increased steadily in nominal terms over the recent decades, following the implementation of the NHI scheme. It expanded from NT$378.7bn (US$13bn) in 1995 to NT$1,207bn (US$40bn) in 2018, at a CAGR of 4.9%, and on a per capita basis from NT$17,805 (US$672) to NT$51,186 (US$1,697). National healthcare expenditure as a share of GDP rose from 5.1% to 6.6% over the same period, but still lower than in other advanced Asian economies such as Japan (10.9%) and South Korea (8.1%), and also below the current OECD average of 8.8%.

A key reason for Taiwan’s relatively low level of health spending is the monopsony power of the government, as the single buyer of and payer for healthcare services through the NHI, to set and regulate service fees, and impose a global budget system that caps total NHI expenditure. Another key contributory factor is the high administrative efficiency of the NHI’s IT-driven system, which is characterised by administrative simplicity and low overheads. General administration costs took up just 2.1% of total healthcare expenditure in 2018, which ranks among the lowest levels in the world. Taiwan’s rapidly ageing population and a rising prevalence of chronic diseases will continue to push up healthcare expenditure and also drive innovative solutions. Some cost-containment is inevitable, though the overall expenditure trend will continue on its upward trajectory. Research firm Fitch Solutions estimates total healthcare spend will grow at a five-year CAGR of 4.9% to reach NT$1,596bn (US$53bn) by 2024, and at a ten-year CAGR of 5.2% to NT$2,090bn (US$69bn) by 2029. As a proportion of GDP, it will remain at between 6% and 7% over the full forecast period.

Around 60% of healthcare funding comes from the public sector, with the government-operated NHI responsible for 53% of funding. Enrolment in the NHI is mandatory for all residents in Taiwan, and its funding primarily comes from premiums paid by insured individuals and employers as well as from government subsidies. As patient co-payments are required for both out-and in-patient care, out-of-pocket spending accounted for 32.9% of total healthcare expenditure in 2018. Taiwan’s private health insurance market is very small, and consists mostly of policies to supplement NHI coverage.

![Figure 11: Healthcare expenditure in Taiwan, 1995-2024](chart)

Health spending analysis

Looking at the breakdown of national healthcare expenditure by financial resources, households represented 50.2% of the total in 2018, followed by the government sector at 26.9%, and private enterprises and non-profits 22.1%. The majority of private spending on healthcare was accounted for by NHI premium payments and household out-of-pocket expenses—largely patient co-payments, registration fees, or for healthcare services and products not covered by the NHI. Almost 60% of government spending on healthcare was directed into the NHI programme in the form of subsidies.

Analysing the flow of healthcare funding through financial agents, the public sector accounted for 59.2% of overall healthcare expenditure in 2018, against 40.8% from private-sector sources. The NHI programme represented the majority of total healthcare spending at 52.9%, followed by out-of-pocket expenses at 32.9%, mostly co-payments for doctor visits, hospitalisations and prescription drugs. With future NHI expenditure on healthcare expected to outpace revenues due to the impact of population ageing, policymakers may have to consider increasing the patients’ share of costs.

In terms of financial allocation, personal healthcare accounted for 86.7% of overall healthcare expenditure in 2018, then capital formation 7.2%, public health 4.0%, and general administration 2.1% (which is one of the lowest cost levels in the world). The expenditures on personal healthcare included hospital care (45.7%—inpatient 25.3% and outpatient 20.4%), general clinic care (22.9%, comprising Western medicine 10.9%, dentistry 9.9% and Chinese medicine 2.1%), specialty care (2.6%) and other costs related to the purchase of medical supplies, equipment and goods (15.5%).

Pharmaceutical spending on prescription drugs and self-medication accounted for 19.4% of all healthcare expenditure in 2018, higher than the OECD average of 16.2%, and represented the third largest spending component after inpatient and outpatient care. NHI reimbursement of drug expenditures doubled from 1998 to 2018, when it totalled NT$186bn (US$5.5bn), and consistently accounts for about one quarter of NHI spending.

As part of cost-containment efforts, the NHIA has targeted drug expenditures and pushed through regular price cuts for medicines to reduce costs.

Figure 12: National healthcare expenditure by financial agents, 2009-2018

![Graph showing national healthcare expenditure by financial agents, 2009-2018](image-url)

Source: Ministry of Health and Welfare.
Figure 13: National healthcare expenditure by financial allocation, 2018

- Hospitals: 45.6%
- Personal healthcare: 87.7%
- Clinics: 22.9%
- Capital formation: 7.2%
- Other specialty institutions and NHI xeno payment: 2.6%
- Medical articles, equipment and healthy goods: 15.5%

Source: Ministry of Health and Welfare.

Figure 14: NHI financial revenue and expenditure, 1995-2018

Source: National Health Insurance Administration.
NHI programme overview

The NHI is a compulsory social health insurance programme. It was established in March 1995 by merging and expanding existing health insurance schemes, which at that time only covered around half of Taiwan’s population. The mandatory nature of NHI affiliation—with the government subsidising the premiums for vulnerable patient groups—has seen health insurance coverage become universal. As of 2019, 99.9% of Taiwan’s 23.6m population (including qualified foreign residents) were enrolled in the government-run, single payer NHI system.

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

The NHI is funded primarily through payroll-based premiums jointly paid by the insured, employers and the government, in addition to subsidies for low income and disadvantaged people. Reforms to the NHI in 2013 broadened the premium base to include supplemental sources of income. The rates for the basic and supplementary premiums currently are 4.69% and 1.91%. The NHI’s other revenues come from fines on overdue premiums, public welfare lottery contributions, and a health and welfare surcharge levy on tobacco products. In 2018, the NHI had insurance revenues (on an accrual basis) of NT$611bn (around US$20bn), of which the largest share was premium revenues at 97%. General NHI premiums totalled NT$494bn (which were contributed collectively by the insured, group insurance applicants and the government), and supplementary premiums were NT$46bn. Its insurance costs totalled NT$637bn (US$21bn), of which medical benefits accounted for 99.3%. The resultant deficit of NT$27bn was offset using the reserve fund, which stood at NT$211bn (US$7bn).

Insurance revenues grew by an average of 4.1% per year in the most recent decade, while costs increased by an annual average of 4.2%, driven by higher resource utilisation and medical costs. The NHI began experiencing financial deficits as early as 1998 and this has forced policymakers to pursue both cost-containment measures and occasional hikes in insurance premium rates (in September 2002 and April 2010) to help ensure that revenues keep pace with rising healthcare costs, and to bolster the NHI’s dwindling reserves.

Financial reforms implemented in 2013, including the introduction of new supplementary premiums, helped to stabilise the NHI’s finances. However, the reduction of both the basic and supplementary rates at the beginning of 2016 has contributed to a drop in revenues and eroded the NHI’s budget surplus. With deficits recorded in 2017 and 2018, a hike in health insurance premium rates is likely at some point in the next few years, though more fundamental structural reforms will be required to ensure the NHI system’s long-term sustainability.
**Cost-containment strategies**

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

**Global budget payment system**

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

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

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

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

- **MOHW**
  - Propose general parameters for the global budget (January - April)
  - Estimate budget based on actual spending
  - 1. Target sector growth rates
  - 2. Details of budget increases
  - 3. Revise relevant formulas
  - 4. Consult NHI committee

- **Executive Yuan**
  - Approve the global budget parameters (May - June)
  - Review by National Development Council
  - 1. Payers’ willingness to pay
  - 2. Financial considerations

- **NHI Committee**
  - Negotiate and allocate global budget (August - December)
  - Allocate expenditure based on approved budget

Source: National Health Insurance Administration.
Alternative reimbursement mechanisms

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

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

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

Annual drug price adjustments

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

Taiwan currently uses a drug expenditure target (DET) system to adjust pharmaceutical prices on an annual basis. It was implemented in 2013 and replaced the previous system of biennial reviews using drug price and volume surveys. Under the DET mechanism, the NHIA sets a target for NHI drug spending for a year, and should expenditure exceed the amount allocated, price adjustments will be subsequently made. In the latest review, the prices of 7,470 drug products were cut by an average of 3.5%, from 1 April 2019, which will help generate costs savings of NT$5.8bn (US$194m).

Besides costs savings, the drug price cuts are also aimed at reducing the gap between procurement and reimbursement prices from which hospitals profit. Most hospitals in Taiwan operate in-house pharmacies and are allowed to buy medicines at discounted rates, whilst charging for dispensing them at the NHI reimbursement prices, which are often significantly higher. Recent estimates show that hospitals together make a profit of NT$25bn (US$830m) from this so-called ‘drug price black-hole’ every year, and pharmaceutical companies claim this artificially inflates the NHI’s drug costs.

Table 3: Drug price adjustments under DET system, 2013-2019

<table>
<thead>
<tr>
<th>Year</th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<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>
<td>3.212</td>
</tr>
<tr>
<td>Target expenditure (NT$bn)</td>
<td>138.0</td>
<td>142.6</td>
<td>147.5</td>
<td>154.8</td>
<td>151.1</td>
<td>156.0</td>
</tr>
<tr>
<td>Overspend amount (NT$bn)</td>
<td>5.7</td>
<td>8.2</td>
<td>3.2</td>
<td>5.7</td>
<td>7.4</td>
<td>5.8</td>
</tr>
<tr>
<td>Effective date of price cut</td>
<td>1 May 2014</td>
<td>1 July 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>
<td>3.5</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>
<td>7,470</td>
</tr>
</tbody>
</table>

Note: The announcement of the 2020 DET price adjustment has been postponed to 1 October 2020 due to the COVID-19 pandemic.
Source: National Health Insurance Administration.
Tackling waste and fraud

The NHIA is also been taking aim at the wastage of medical resources, notably prescription drugs. Reports indicate patients in Taiwan dump some 70 tonnes of drugs each year, mostly medication for chronic diseases. To reduce such waste, the NHIA has expanded use of its medical information sharing system, NHI MediCloud, to more closely monitor the drug usage of patients and doctors’ prescribing practices. It’s also considering to stop reimbursement of duplicate prescriptions, raising the current NT$200 (US$6.9) ceiling for drug co-pays, and switching more drugs to OTC status.

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

Private health insurance

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

Even so, private health insurance is expanding in Taiwan, having grown at a CAGR of 5.2% in the 2010-2019 period, and accounting for NT$389bn (US$13bn), or 10.7%, of total insurance industry premiums in 2019. Property and casualty insurers have marketed yearly renewable insurance plans since 2008, and these have posted strong growth. Individual health insurance products with a fixed payment scheme dominate the Taiwan market. Reimbursement-based health insurance products have only been rolled out in more recent years.

Notwithstanding universal access to subsidised provision through the NHI, households currently foot 33% of overall healthcare expenditure on an out-of-pocket basis, up from 22% in 1995. This increasing share of rising healthcare costs amid cost-shifting to patients, as an ageing population puts the NHI under strain, will impose a growing financial burden on households. This, together with higher insurance awareness resulting from the COVID-19 crisis, could lead to more demand for private insurance to protect patients against downside risks and to drive better care decisions.
## Biomedical industry

<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Taiwan’s biomedical industry</td>
<td>26</td>
</tr>
<tr>
<td>Biotechnology sector</td>
<td>29</td>
</tr>
<tr>
<td>• Regulatory environment</td>
<td>30</td>
</tr>
<tr>
<td>• Conducting clinical trials</td>
<td>31</td>
</tr>
<tr>
<td>• Business environment</td>
<td>34</td>
</tr>
<tr>
<td>Pharmaceutical sector</td>
<td>35</td>
</tr>
<tr>
<td>• Regulatory environment</td>
<td>36</td>
</tr>
<tr>
<td>• Registration and approval</td>
<td>37</td>
</tr>
<tr>
<td>• Reimbursement and pricing</td>
<td>39</td>
</tr>
<tr>
<td>• Business environment</td>
<td>41</td>
</tr>
<tr>
<td>Medical device sector</td>
<td>43</td>
</tr>
<tr>
<td>• Regulatory environment</td>
<td>44</td>
</tr>
<tr>
<td>• Registration and approval</td>
<td>45</td>
</tr>
<tr>
<td>• Reimbursement and pricing</td>
<td>46</td>
</tr>
<tr>
<td>• Business environment</td>
<td>47</td>
</tr>
</tbody>
</table>
Taiwan’s biomedical industry

The biomedical industry—encompassing applied biotechnology, pharmaceuticals, medical devices and general healthcare—has been designated a key sector for priority development, as part of the government’s “5+2 Innovative Industries Plan” to accelerate the transformation of Taiwan’s industrial base. A long period of investment has produced a solid foundation, with an ecosystem that spans the entire value chain of the biomedical industry, from pre-clinical and clinical research in drug discovery and development to manufacturing and marketing.

In 2016, the Taiwan government launched a policy initiative called the Biomedical Industry Innovation Programme (BIIP), which aims to enhance health and wellness for citizens, and promote Taiwan as an Asia-Pacific hub for biomedical R&D. The BIIP comprises four action plans which are focused on creating local, global and future links in order to achieve the programme’s goals of developing 20 new drugs, bringing 80 high-value medical devices to global markets, and building biomedicine into a trillion-Taiwan-dollar (US$33bn) industry by 2025.

Another goal of the BIIP is to establish at least 10 biotechnology and health-related flagship brands, by encouraging Taiwanese enterprises to acquire or establish strategic alliances with high-potential international biomedical companies (such as small and medium-sized pharmaceutical developers and manufacturers, medical suppliers, distributors and service providers), as well as to expand into global markets. Taiwan’s state-run National Development Fund has established an industrial innovation and transformation fund to support expansion activity.

As momentum continues to build in the biomedical industry, investors are taking note of the potential opportunities. According to government statistics, the total market revenue of the burgeoning industry (excluding the general healthcare sector) grew at a 10-year CAGR of 4.9% to NT$495bn (US$16bn) in 2019. The pharmaceutical sector accounted for the largest share of the market at NT$223bn (45%), followed by the medical device sector NT$154bn (31%) and biotechnology NT$119bn (24%). These three sectors will now be analysed in more detail.

**Figure 16: Scope of Taiwan’s biomedical industry**

- **Applied biotechnology**: Agriculture, food, environment, new biopharmaceuticals, contract services
- **Pharmaceutical manufacturing**: Small molecule drugs, biologics, active pharmaceutical ingredients, traditional Chinese medicine
- **Medical devices**: Diagnosis and monitoring, surgery and treatment, in vitro diagnostics, assistance and compensatory, other miscellaneous devices
- **Healthcare services**: Healthcare services, healthcare promotion, wellness services

Note: Healthcare was included in the scope of Taiwan’s biomedical industry from 2018.
Source: Biotechnology and Pharmaceutical Industries Promotion Office.
Table 4: Status of Taiwan’s biomedical industry, 2010-2019

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>7.2</td>
<td>8.2</td>
<td>8.9</td>
<td>9.3</td>
<td>9.5</td>
<td>9.4</td>
<td>9.7</td>
<td>10.7</td>
<td>11.4</td>
<td>11.8</td>
</tr>
<tr>
<td>No. of companies</td>
<td>1,355</td>
<td>1,428</td>
<td>1,505</td>
<td>1,601</td>
<td>1,631</td>
<td>1,871</td>
<td>1,918</td>
<td>2,004</td>
<td>2,082</td>
<td>2,143</td>
</tr>
<tr>
<td>Personnel</td>
<td>54,550</td>
<td>65,362</td>
<td>69,470</td>
<td>71,580</td>
<td>72,769</td>
<td>76,159</td>
<td>78,019</td>
<td>80,732</td>
<td>85,623</td>
<td>89,907</td>
</tr>
<tr>
<td>Export value</td>
<td>2.6</td>
<td>2.9</td>
<td>3.2</td>
<td>4.0</td>
<td>4.1</td>
<td>4.4</td>
<td>4.8</td>
<td>5.2</td>
<td>5.7</td>
<td>6.0</td>
</tr>
<tr>
<td>Import value</td>
<td>5.1</td>
<td>6.3</td>
<td>6.9</td>
<td>7.1</td>
<td>7.1</td>
<td>7.1</td>
<td>7.9</td>
<td>8.9</td>
<td>9.5</td>
<td>10.2</td>
</tr>
<tr>
<td>Import:Export</td>
<td>64:36</td>
<td>65:35</td>
<td>64:35</td>
<td>64:35</td>
<td>64:35</td>
<td>61:39</td>
<td>59:41</td>
<td>52:48</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Domestic market size</td>
<td>9.7</td>
<td>11.6</td>
<td>12.6</td>
<td>12.4</td>
<td>12.5</td>
<td>12.0</td>
<td>12.8</td>
<td>14.4</td>
<td>15.2</td>
<td>16.0</td>
</tr>
</tbody>
</table>

Note: This table excludes the general healthcare sector.

Figure 17: Market size of Taiwan’s biomedical industry, 2010-2019

Note: This chart excludes the general healthcare sector.
Biotechnology sector

Biotechnology, or biotech for short, encompasses a broad variety of techniques that involve the use and manipulation of living organisms to develop or make commercial products and services, mainly for use in agriculture, food science and medicine. In Taiwan, the applied biotechnology sector covers five main areas: agriculture, food and environment biotechnology, as well as new biopharmaceuticals and contract services. The 2009 national plan for biotech development helped kick-start the sector, which has since doubled in revenue size to reach NT$118.6bn (US$3.8bn) in 2019. The main focus is on the development of new drugs and biologics.

Strong government commitment has helped drive the expansion of the biotechnology sector. In 2007, the Act for the Development of Biotech and New Pharmaceuticals Industry was enacted to lay the foundation for future 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 policy initiative, renamed as the Biotech Industrialisation Take-off Action Plan, focused on augmenting the capabilities of the biotechnology value chain. More recently, in 2016, biomedicine was designated as a key innovative industry for priority development.

The Biomedical Industry Innovation Programme was subsequently launched with an overall goal of making Taiwan a regional hub for biomedical R&D. It has four strategic aims—establishing an effective industry ecosystem, integrating existing innovation clusters, connecting with international markets, and driving growth areas. A number of additional priorities, including focuses on digital healthcare solutions and regenerative medicine, were incorporated into the industry plan in 2018. Supporting measures include, among other items, a tax incentive scheme for new biomedical start-ups, and the relaxation of investment regulations.

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

### Table 5: Status of Taiwan’s biotechnology sector, 2010-2019

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>2.0</td>
<td>2.3</td>
<td>2.5</td>
<td>2.6</td>
<td>2.7</td>
<td>2.8</td>
<td>2.9</td>
<td>3.2</td>
<td>3.5</td>
<td>3.6</td>
</tr>
<tr>
<td>No. of companies</td>
<td>405</td>
<td>402</td>
<td>450</td>
<td>490</td>
<td>500</td>
<td>510</td>
<td>525</td>
<td>557</td>
<td>596</td>
<td>626</td>
</tr>
<tr>
<td>Personnel</td>
<td>10,250</td>
<td>15,780</td>
<td>16,770</td>
<td>17,540</td>
<td>18,340</td>
<td>19,259</td>
<td>20,219</td>
<td>21,432</td>
<td>22,718</td>
<td>23,854</td>
</tr>
<tr>
<td>Export value</td>
<td>0.8</td>
<td>0.9</td>
<td>1.0</td>
<td>1.0</td>
<td>1.0</td>
<td>1.1</td>
<td>1.2</td>
<td>1.4</td>
<td>1.5</td>
<td>1.6</td>
</tr>
<tr>
<td>Import value</td>
<td>0.9</td>
<td>1.5</td>
<td>1.6</td>
<td>1.7</td>
<td>1.6</td>
<td>1.6</td>
<td>1.7</td>
<td>1.8</td>
<td>1.9</td>
<td>1.9</td>
</tr>
<tr>
<td>Domestic market size</td>
<td>2.0</td>
<td>2.8</td>
<td>3.2</td>
<td>3.3</td>
<td>3.3</td>
<td>3.3</td>
<td>3.4</td>
<td>3.7</td>
<td>3.8</td>
<td>3.8</td>
</tr>
</tbody>
</table>

Regulatory environment

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

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

Successive governments have all provided strong regulatory support for biotech sector development. The primary governing law is the 2007 Act for the Development of Biotech and New Pharmaceuticals Industry, which provides for tax incentives, special rules that encourage investment in start-ups, and state-sponsored funding. The Act also mandated the establishment of the Nangang Biotechnology Research Park (which opened in 2018), Hsinchu Biomedical Science Park (in operation since 2011), and a medical device zone (for dentistry and orthopaedics) within the Southern Taiwan Science Park.

Taiwan’s biotech statute was amended in 2017 to expand the R&D tax breaks available to qualified biopharmaceutical companies for investments in emerging biomedical technologies, which include precision medicine and cell-gene therapies. The government is particularly keen to accelerate R&D activities in precision and regenerative medicine, as these are seen as key growth areas. In addition, the Fundamental Science and Technology Act was similarly revised in 2017 to facilitate biotech talent flows between the academic and private sectors.

**Figure 18: Product life cycle management framework for medicinal products**

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Step 2</th>
<th>Step 3</th>
<th>Step 4</th>
<th>Step 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
<td>Preclinical</td>
<td>Clinical</td>
<td>Pre-market</td>
<td>Marketing</td>
</tr>
<tr>
<td>development</td>
<td>validation</td>
<td>trial</td>
<td>application</td>
<td></td>
</tr>
</tbody>
</table>

GLP: Good Laboratory Practice  
GCP: Good Clinical Practice  
TFDA / IRB: Institutional Review Board  
GTP: Good Tissue Practice  
ADR: Adverse Drug/Device Reaction  
GPvP: Good Pharmacovigilance Practice  
GDP: Good Distribution Practice  
GPP: Good Pharmacy Practice  

Source: Taiwan Food and Drug Administration.
Conducting clinical trials

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

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

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

Research and clinical trials infrastructure

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

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

This institutional support infrastructure for clinical research is integral to Taiwan’s attractiveness as a site for clinical trials. Another positive factor is the availability of high quality, GCP-compliant clinical trial centres. At present, 146 medical centres and hospitals are qualified to conduct clinical trials in Taiwan. Also, centres of excellence for clinical trials have been set up at leading research hospitals to enhance Taiwan’s capacity to conduct early-stage clinical trials. Additionally, the MOHW has funded new clinical trial centres at some hospitals under its Clinical Trial Development Promotion Project.
Clinical trials of biomedical interventions typically proceed through four phases, and all require prior approvals from both the TFDA and the relevant IRB (Institutional Review Board). Taiwan has a central IRB system consisting of seven main IRB and 35 collaborative IRBs, which are formally designated to review and monitor clinical trials involving human subjects. In practice, a clinical trial application for TFDA approval is usually made by the sponsor or contract research organisation (CRO), and the IRB one is filed in the name of the principal investigator.

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

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

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

Figure 19: Standard review process for clinical trial (IND) applications
Figure 20: IND applications in Taiwan by clinical trial type, 2010-2019

![IND applications by clinical trial type](chart)

- Taiwan single centre
- Taiwan multiple centre
- Multi-regional multi-centre


Figure 21: IND applications in Taiwan by study phases, 2010-2019

![IND applications by study phases](chart)

- Phase I
- Phase II
- Phase III
- Phase IV/Others

Source: Taiwan Food and Drug Administration.
Business environment

Taiwan’s applied biotechnology sector is small in scale and has a fragmented structure. Almost 600 enterprises, mostly small and medium sized, are classified as biotechnology companies, and their combined revenues were NT$110.6bn (US$3.6bn) in 2019. Major biotechnology clusters are located in science parks in Taipei and Hsinchu in northern Taiwan, Taichung in the central area, and Tainan and Kaohsiung in the southern region. Because of the small domestic market, local drug developers often work with CROs and pharma multinationals to develop high-end drugs and expand overseas.

As funding is a primary challenge for both biotech start-ups and development-stage companies, the government has encouraged the creation of small and medium biotechnology venture capital funds. Furthermore, the state-run National Development Fund also provides significant funding support to the sector. As of the end of 2019, it had invested an aggregate total of NT$13.3bn (US$430m) in 15 biotech companies and 26 biotech venture capital firms. Also, initial public offering (IPO) rules have been relaxed to make it easier for biotech firms to raise funds through local stock exchange listings.

Given the prevalence of small-sized biotech firms in Taiwan, many opt to manage the costs and risks associated with drug development by adopting the acquire-develop-transfer model of doing business. This involves the acquisition or the in-licensing of an early-stage drug candidate, performing research to add value and then out-licensing the compound to a larger company. A number of Taiwanese firms are at the forefront of breakthrough drugs, delivery systems and diagnostics. In particular, Taiwan has established a niche in the area of oncology, with several companies developing new cancer drugs.

As a result, the number of biotech companies going public on Taiwan’s stock market has risen steadily in recent years, from 48 in 2010 to 124 by the end of 2019. In addition, a further 58 biotech start-ups were listed on the Emerging Stock Board, and 21 on the Go Incubation Board. With Taiwan’s biotech sector in the late incubation stage, the maturation of companies’ drug pipelines is attracting investor attention and given a boost to biotech stocks. The sector’s stock market capitalisation has increased considerably over the past decade, from US$6.9bn in 2010 to around US$23.9bn at the end of 2019.

Figure 22: Market value of listed biotech stocks in Taiwan, 2010-2019

![Market value of listed biotech stocks in Taiwan, 2010-2019](image)

*Biotech market capitalisation  Number of listed biotech companies

Pharmaceutical sector

Taiwan’s pharmaceutical sector encompasses a broad range of related products, including small molecule drugs, biologics, active pharmaceutical ingredients (APIs) and Chinese herbal medicine. The total domestic market (including imports) for pharmaceuticals was worth NT$222.5bn (US$7.2bn) in 2019, having grown at a CAGR of 5.0% since 2010. Sales of chemical drugs and APIs account for the majority of the market, with 30% of demand fulfilled by local drugmakers, mostly for APIs and finished drug formulations, and the rest supplied by large and growing imports of innovative drugs.

Market growth has been, and will continue to be, supported by the accelerated ageing of Taiwan’s population and high demand for chronic disease treatments and new innovative drugs. A key factor weighing on this growth remains cost containment, since Taiwan’s drug reimbursement system uses price controls to strictly regulate public spending on patented medicines. Research company Fitch Solutions forecasts total drug sales in Taiwan will grow at a five-year CAGR of 3.1% to NT$232.8bn (US$7.7bn) by 2024, and at a ten-year compound rate of 3.3% to NT$276bn (US$9.1bn) by 2029.

Taiwan’s advanced healthcare infrastructure also favours the sale of pharmaceuticals, with a large network of hospitals and medical clinics serving as the primary access points for medicines. The lack of proper drug prescribing and dispensing, which allows hospitals to operate their own pharmacies for profit and encourages over-prescribing, is also beneficial to pharma suppliers. Prescription drugs dominate the Taiwan market, accounting for 93% of total pharmaceutical sales in 2018—the bulk of which (about 70%) came from patented drugs, and the balance from locally-produced generic drugs.

The over-the-counter (OTC) medicine segment is under-developed, representing less than 8% (and falling) of the overall pharmaceutical market. This is largely due to the comprehensive nature of the NHI’s prescription drug reimbursement schedule, which lists more than 17,000 items. Nevertheless, as reimbursed price cuts are stifling growth in the prescription drugs sector, pharma companies may look to the OTC sector for opportunities. As part of cost containment efforts, the authorities are taking a more proactive approach to Rx-OTC switching and promoting self-medication for minor ailments.

<table>
<thead>
<tr>
<th>Table 6: Status of Taiwan’s pharmaceutical sector, 2010-2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
</tr>
<tr>
<td>No. of companies</td>
</tr>
<tr>
<td>Personnel</td>
</tr>
<tr>
<td>Export value</td>
</tr>
<tr>
<td>Import value</td>
</tr>
<tr>
<td>Domestic market size</td>
</tr>
</tbody>
</table>

Regulatory environment

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

The Pharmaceutical Affairs Act (PAA) provides the basic structure for the regulation of medicines, and the MOHW has issued more than 100 subordinate regulations, guidelines and standards to clarify the implementation of the PAA. A new Medical Devices Act was promulgated in January 2020 in order to separate the market regulation of medical devices from pharmaceutical drugs (see page 44 for more details). The PAA divides pharmaceuticals into raw materials (APIs) and finished formulation products, with the latter category further split into new drugs, biological agents, generic drugs and orphan drugs.

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

Pharmaceutical IP protections

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

The patent linkage system will help to ensure that new generics are not launched in Taiwan while the original patent is still valid, as it now makes potential patent infringement a mandatory consideration and an examination basis during the review process for generic drug applications. The TFDA must check such an application against a list of patented drugs with therapeutic equivalence, akin to the US Orange Book. The new mechanism is likely to benefit large pharma multinationals at the expense of domestic generics makers, which will face longer approval periods because of extra validation requirements.

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

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

The TFDA and CDE review teams examine all of the submitted data related to the application and make a decision to approve it or not. The approval timeline for a NDA differs according to each pathway (Figure 24), ranging from six months (ANDA) to one year (standard NDA). In recent years, the TFDA has developed several expedited pathways to accelerate the approval process for drugs that treat rare or serious conditions. In 2017, the TFDA introduced a refuse-to-file mechanism to reduce unnecessary reviews and incomplete applications.

Notwithstanding recent improvements to expedite the drug review and approval process in Taiwan, the actual review timeline is still relatively lengthy. According to the latest TFDA statistics, the median review time for NCE and biologics applications was 357 days in 2019 (Figure 25), with 50%-60% of the cases meeting the review-time target of 360 days. The revamp of the CDE is expected to help speed up the drug review process, with the percentage of reviews completed for NCE applications within 360 days projected to rise from 50% currently to 90%.

Continued improvements to the current approval process will reduce the time required to launch a pharmaceutical drug product in Taiwan, and help support the expansion of the local patented drug market. In 2019, the TFDA approved a total of 100 new drugs, including 37 NCEs, 22 biologics and 41 non-NCEs. Of the approved applications, 15 were for new drugs developed domestically and 85 for imported drugs. The top therapeutic areas of the new approved drugs were cancer (25%), neurological disorders (15%) and infection diseases (8%).

Figure 23: Review process for new drug applications

Consult with AC Experts If needed

Source: Center for Drug Evaluation.
Figure 24: Review pathways for new drug applications

Figure 25: New drugs approved in Taiwan, 2011-2019

Source: Taiwan Food and Drug Administration.
Reimbursement and pricing

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

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

Reimbursement listing approval

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

According to the NHIA, the time from submission to listing for a new drug was 11.7 months on average in 2018, and 10.6 months in the 2013-2018 period. International pharmaceutical companies have long advocated the need for greater transparency and efficiency in the reimbursement approval process. They point to the lack of set time limits between key review milestones, and also that the scientific data a pharmaceutical company submits to the TFDA and NHIA for their registration and reimbursement processes is reviewed sequentially, creating delays.

Reimbursement price setting

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

To further control pharmaceutical expenditure, the cost of most new drugs is reviewed on an annual basis under the Drug Expenditure Target system introduced in 2013. Under this scheme, the NHIA sets a target for NHI drug spending for a year, and should actual expenditure exceed this figure, price adjustments will subsequently be made. This has resulted in several price reductions in recent years (see page 23). Low drug reimbursement prices and annual price cuts are a contentious issue for Big Pharma and may affect companies’ willingness to bring new and innovative medicines into Taiwan.

Although NHIA has used price-volume agreements with drug manufacturers to a limited extent as part of its reimbursement model, it is just beginning to adopt risk-sharing agreements—also known as managed entry agreements (MEAs)—which are a way of accommodating innovative but often costly new medications without causing budgets to soar out of control. In 2018, the NHIA set out guidelines for entering into MEA schemes, which may take a variety of forms, some based on assessing the outcome of the drug treatment and some geared to the financial impact. The use of MEAs will allow NHIA and pharma firms more room to negotiate the price and budget, and to allocate risks more reasonably.
Figure 26: Pharmaceutical listing and pricing flowchart

- Manufacturer / Importer
  - Submission of application
  - NHIA Administrative review
  - PBRS Joint Meeting
    - Composed of stakeholders
    - Reach consensus
  - Drug Listed and reimbursed
  - MOHW
    - Decision making
  - CDE HTA report if needed
  - Advisory Meeting
    - External clinical consultants

Source: National Health Insurance Administration.

Figure 27: Drug reimbursement pricing process

- Category 1: demonstrates clear therapeutic improvements from existing treatments
  - Median prices of reference countries
  - Multiple possible pricing methods:
    - lowest price among reference countries
    - price of originator country
    - international price ratio
    - Combination drug is priced at 70% the sum of each ingredient’s price

- Category 2a: demonstrates modest improvements from best existing treatment
  - Drug mark-ups
    - local clinical trials (10%) + local pharmacoeconomic study (up to 10%) + better therapeutic effects / safety / convenience (up to 15% each)

- Category 2b: demonstrates clinical benefits close to existing treatments

- Yes: Branded drug pricing
- No: Generic drug pricing

Source: National Health Insurance Administration.
Business environment

Taiwan is the seventh largest pharmaceutical drug market in the Asia-Pacific region and a net importer of pharmaceuticals. Its attraction to multinational drugmakers is underpinned by high drug spending per capita, reflecting a large and growing demand for chronic disease treatment as the population ages rapidly. A well-developed healthcare system also serves to support the sale of patented drugs. Posing downside risks to companies looking to launch innovative medicines in the market is the increasing policy focus on cost containment and use of price controls to curb healthcare spending.

The patented drug market remains dominated by pharma multinationals, but Taiwanese firms have started to invest more heavily in researching and developing new drugs. Most of the leading foreign drugmakers are active in Taiwan, mainly focusing on sales and marketing, and they generally use a local pharmaceutical products distributor. Around 360 domestic companies are currently engaged in pharmaceutical manufacturing, largely production of APIs, finished generics or both. Recent phased-in compliance with global PIC/S GMP standards has helped sharpen their export competitiveness.

Research and development

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

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

Pharmaceutical retail sector

The principal sales channels for pharmaceuticals in Taiwan are hospitals, clinics and pharmacies. Out of some 35,000 pharmacists in Taiwan, about 50% work in pharmacies located within hospitals and clinics. The remainder work in almost 8,000 community pharmacies, of which around 6,000 are contracted with the NHIA and allowed to dispense reimbursed prescription drugs. However, only 10% of all prescriptions are dispensed in community pharmacies, reflecting the reluctance of hospitals and clinics to forfeit profits made on the purchase and sale of medicines by their in-house pharmacies.

As a result, community pharmacies must rely on the sale of OTC medicines, which may be sold in licensed premises without a doctor’s prescription, and consumer health products. The market share of OTC drugs in Taiwan is low at 8%, yet pharma companies see potential growth opportunities, as the NHIA continues to cut the prices of prescription drugs and is more proactive toward the transfer of prescription drugs (Rx) to OTC status. Changing consumer behaviours, such as higher awareness of personal health issues and a greater willingness to self-medicate, will be another influential factor.
Medical device sector

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

The total domestic market (including imports) for medical devices was worth NT$153.7bn (US$5bn) in 2019, having grown at a CAGR of 3.8% since 2010. Due to the limited size of the market, local medical-device makers rely on exports for around 60% of their revenues, mostly for mid-to-low-end medical equipment and contracted manufacturing for multinationals. Nonetheless, Taiwan is highly dependent on imports for some 60% of domestic demand, mostly for high-end surgical, therapeutic, and medical imaging devices used in hospitals and supplied from the United States, Europe and Japan.

Further steady growth in the sector is expected in the coming years on account of Taiwan’s growing elderly population and related higher demand for healthcare products and services, as well as the government’s policy support for more higher-value medical device manufacturing. Research company Fitch Solutions forecasts the market will increase at a CAGR of 7.4% in the 2019-2024 period. The major constraint on growth will be the authorities’ continued reliance on cost containment to control public healthcare expenditure, which will increase pricing pressures for medical device companies.

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

Table 7: Status of Taiwan’s medical device sector, 2010-2019

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</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>
<td>4.8</td>
<td>5.3</td>
<td>5.5</td>
</tr>
<tr>
<td>No. of companies</td>
<td>580</td>
<td>626</td>
<td>705</td>
<td>761</td>
<td>781</td>
<td>1,041</td>
<td>1,073</td>
<td>1,090</td>
<td>1,128</td>
<td>1,157</td>
</tr>
<tr>
<td>Personnel</td>
<td>25,800</td>
<td>30,250</td>
<td>34,200</td>
<td>35,040</td>
<td>35,429</td>
<td>38,400</td>
<td>39,300</td>
<td>40,300</td>
<td>43,850</td>
<td>46,953</td>
</tr>
<tr>
<td>Export value</td>
<td>1.3</td>
<td>1.4</td>
<td>1.6</td>
<td>2.3</td>
<td>2.4</td>
<td>2.5</td>
<td>2.7</td>
<td>2.9</td>
<td>3.2</td>
<td>3.4</td>
</tr>
<tr>
<td>Import value</td>
<td>1.7</td>
<td>1.9</td>
<td>1.9</td>
<td>2.1</td>
<td>2.2</td>
<td>2.3</td>
<td>2.3</td>
<td>2.5</td>
<td>2.6</td>
<td>2.9</td>
</tr>
<tr>
<td>Domestic market size</td>
<td>3.4</td>
<td>3.8</td>
<td>4.1</td>
<td>3.7</td>
<td>3.8</td>
<td>3.9</td>
<td>4.0</td>
<td>4.4</td>
<td>4.7</td>
<td>5.0</td>
</tr>
</tbody>
</table>

Regulatory environment

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

The regulations for medical device management in Taiwan were originally set in the Pharmaceutical Affairs Act. Owing to the different characteristics of pharmaceutical drugs and medical devices, the new Medical Devices Act was promulgated in January 2020 to establish a separate, dedicated legal framework for medical devices. Although its implementation date has yet to be determined, the government is expected to complete the related implementation rules in a timely manner, since the new law is integral to the government’s efforts to promote development of the medical device sector.

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

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

Figure 28: Medical device management framework

<table>
<thead>
<tr>
<th>Medical Needs/Fundamental researches</th>
<th>Product Design/Prototype Development</th>
<th>Preclinical Validation</th>
<th>Clinical study</th>
<th>Premarket Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>General/Advanced Consultation</td>
<td>Laboratory Practices (GLP/GTP)</td>
<td>Clinical Trial Inspection (GCP)</td>
<td>Clinical Study Protocol Review (TFDA/IRB)</td>
<td>Registration (Approval/Listing)</td>
</tr>
<tr>
<td>Product Designation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Quality System Control</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDs: Medical Devices</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GLP: Good Laboratory Practice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GTP: Good Tissue Practice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GCP: Good Clinical Practice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRB: Institutional Review Board</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GMP: Good Manufacturing Practice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QSD: Quality System Document</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ADR: Adverse Drug/Device Reaction</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GVP: Good Vigilance Practice</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Manufacturer’s Quality System Audit (GMP/QSD)

ADR & Product Defect Reporting
Safety Surveillance & Alert Collection (GVP)
Consumer Health Education Promotion
Good Distribution Practice (GDP)
Postmarket Control

Source: Taiwan Food and Drug Administration.
Registration and approval

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

The applicant must be a registered legal entity in Taiwan and also have a pharmaceutical company licence. Therefore, international pharmaceutical firms usually set up a subsidiary or branch office in Taiwan or appoint an agent to comply with the requirements. Registration of Class I devices just involves a simple paper review, but that of Classes II and III devices, as well as new medical devices, requires the submission of detailed documents. In addition, most medical device manufacturers must submit quality system documentation that meets Taiwan’s GMP requirements for medical devices.

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

In response to industry calls to reduce pre-market registration times, the TFDA has sought to simplify documentation requirements as well as shorten the registration process for medical devices. In 2017, it launched a pilot scheme for the online review and submission of application documents through an electronic platform known as ExPRESS, which has attracted a rising number of e-submission cases every year. Also, in 2017, the TFDA introduced a priority review programme for medical devices, which seeks to expedite the approval process for innovative devices and devices in urgent demand.

Figure 29: Medical device registration process

Source: Taiwan Food and Drug Administration.
Reimbursement and pricing

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

Medical devices are paid for either under a fee-for-service or a diagnosis related group-based scheme. Reimbursement is based mainly on the product’s functionality, with all medical devices performing the same function reimbursed at the same price. Industry players argue this does not differentiate between lower-cost devices and more advanced, higher quality products, and may thus discourage the introduction of innovative devices into Taiwan. Also, the NHIA typically sets reimbursement prices low for new medical devices, compared with similar products currently on the market, as with drugs. Because of the expenditure caps imposed by the NHI’s global budget and DRG systems, hospitals bargain to obtain transaction prices lower than the reimbursement prices for medical devices in order to make up for shrinking payments for patient care. To ensure reimbursement rates reflect the actual prices that hospitals are paying vendors, the NHIA makes periodic price adjustments to reimbursable medical devices using price-volume surveys. As products may undergo several rounds of surveys and price cuts, this could cause newly marketed devices to lose price competitiveness over time.

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

Figure 30: Reimbursement listing process for new medical devices

Source: National Health Insurance Administration.
Business environment

Taiwan’s medical device manufacturing sector is dominated by small to medium enterprises, which mostly produce and export mid-to-low-end medical equipment, and conduct contract manufacturing for multinationals. Even so, the sector is growing in sophistication and expanding into new and high-value product areas, backed by strong government support. In a sign of progress, in 2018, 49 locally-developed medical devices received the US FDA’s 510(k) clearance, mostly high-value items such as dental, ophthalmological and orthopaedic materials, as well as those for minimally invasive surgeries.

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

Also, in 2017, the government announced that it would invest NT$2bn (US$66.7m) in the medical sector over four years, with the aim of increasing its output value to NT$200bn (US$6.7bn) by 2020. It identified three key focus areas for development, including advanced medical imaging equipment, intensive therapy equipment and aesthetic medical devices. Also, the government is encouraging the development of 3D printed medical devices, which have a growing presence in a number of product areas, and it has established a medical 3D printing cluster within the Southern Taiwan Science Park.

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

Figure 31: Development status of Taiwan’s medical device sector

Key industry topics

Digital health
Digital health is rapidly being realised as the future of healthcare, and Taiwan is well-placed to lead the development of digital health innovations, thanks to its strengths in technology and manufacturing, as well as a world-class health-care system. This focus section looks at how the digital health trend is playing out in Taiwan, including policy support initiatives and cross-sector collaboration. Page 51

Long-term care
Taiwan’s population is ageing rapidly and is currently projected to reach the level of a super-aged society by 2025, which is driving increased demand for long-term care facilities, products and services. This focus section examines the government’s efforts to establish a comprehensive long-term care system in Taiwan, and also looks at the related business opportunities in the sector. Page 55

Precision medicine
With its potential to improve clinical outcomes, precision medicine is a growing area of interest for health systems. In Taiwan, the government has prioritised the development of precision medicine as part of its broader goal to transform the island into a regional biomedical R&D hub. This focus section reviews the current status of the local precision medicine market and its growth prospects. Page 59

International collaboration
As momentum accelerates in Taiwan’s biomedical industry, global biopharma companies are showing growing interest in potential strategic collaboration and investment opportunities across the industry’s value chain. This focus section examines the current status of international collaboration in Taiwan’s biomedical R&D ecosystem, as well as recent M&A developments in its health industries. Page 63
Digital health

Digital health is an innovative, ever-changing area in healthcare, encompassing a wide range of digital tools that can improve healthcare, enable lifestyle change and create operational efficiencies. These include everything from ingestible sensors to wearable gadgets, from AI to mobile healthcare apps, from electronic records to robotic caregivers. With the potential to ease the demand on overstretched health systems across the world, while enabling patients to control their own disease management, digital health offers an opportunity to improve care for patients and help doctors to be more efficient.

The World Health Organisation (WHO) is leading the development of a global digital health strategy, urging member states to prioritise the development and greater use of digital solutions in healthcare as a means of promoting universal health coverage and advancing the UN’s sustainable development goals. As a result, more and more countries are adopting digital tools to help reform and modernise their health systems and health service delivery. According to the WHO, 58% of its member states have a digital health strategy in place, and 87% have one or more national digital health initiatives.

The growing, widespread adoption of digital health tools and solutions, together with increasing policy support, will help boost growth in the global digital health market in the coming years. The COVID-19 pandemic has also catalysed the uptake of digital health solutions. Research firm Frost and Sullivan predicts the global digital health market will grow at a CAGR of 12% from an estimated US$133.0bn in 2018 to reach US$234.5bn in 2023. Key drivers will include AI, data analytics, care coordination cybersecurity, digital therapeutics, remote patient monitoring and telemedicine, among other areas.

In Taiwan, the digital health trend is attracting the growing attention of businesses and new start-ups operating at the intersection of technology and medical science. A growing number of the island’s renowned hi-tech companies are diversifying into the biomedical industry, with the aim to transform not only Taiwan’s own healthcare system, but also the world’s. The focus is on integrating advanced technologies with the latest medical applications to enable connected and smart healthcare. This development is expected to have a synergistic impact on Taiwan’s emerging biomedical industry.

Figure 32: Projected growth of global digital health market, 2018-2023

Supportive infrastructure and policies

Digital information is the bedrock of high-quality patient healthcare, and Taiwan has long developed a comprehensive health information technology system, which is used to improve and monitor the financing and delivery of healthcare services. The government initiated implementation of a National Health Information Network as early as 1988, and twenty years later it launched the National Health Informatics Project to promote the transition to an electronic medical records system. More recently, the NHIA has expanded its use of cloud-based systems to improve data integration and sharing.

Since its inception in 1995, the NHI has tracked the healthcare data for Taiwan’s entire population of 23.6m people, including patients’ medical records, drug information, medical images and laboratory test results, creating a vast database matched by few other countries. The NHI data has so far been available to academic and research organisations mostly, but businesses are starting to get access too. In 2019, the NHIA launched a pilot project to allow data access to biotech and health companies to promote development of AI and big data apps for precision medicine and cloud-based medical care.

The government also supports the development of telemedicine (medical services via the Internet) to provide long-distance healthcare support to those living in rural and remote areas, which suffer from a shortage of medical personnel, and the elderly community. In 2018, the MOHW established a process for medical diagnosis and treatment by telecommunications, which laid the foundation for the expansion of telemedicine services in Taiwan. It further expanded the scope of coverage during the COVID-19 pandemic to people in isolation as part of Taiwan’s coronavirus response measures.

Taiwan’s FDA is responsible for the enforcement of laws and regulations related to digital health, and the issuance of licenses, permits and approvals. Digital health technologies include both hardware and software solutions and services. Where hardware, such as an IoT device, meets the criteria of a medical device, it is subject to the Regulations for Governing the Management of Medical Device. The TFDA has also issued guidance for software-based medical devices, including Guidance for Medical Software Classification in 2015 and Guidance for Software-based Medical Device Validation in 2017.

Figure 33: Policy support for digital health development in Taiwan

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Health IT infrastructure development</strong></td>
<td><strong>Cloudification of healthcare data-sharing systems</strong></td>
<td><strong>AI and big data innovation in healthcare</strong></td>
</tr>
<tr>
<td>Health Information Network, 1988</td>
<td>National Health Informatics Projects, 2008</td>
<td>AI innovation: Grand strategy for a small country, 2017</td>
</tr>
<tr>
<td>Health Information Network 2.0, 1988</td>
<td>Smart Healthcare Service Plan, 2009</td>
<td>AI Taiwan Action Plan, 2018</td>
</tr>
</tbody>
</table>

Source: PwC analysis.
Business investment environment

Digital health is rapidly being realised as the future of healthcare, thanks to transformative innovations in the areas of AI and data analytics, telemedicine and connected devices, among others. Because of Taiwan’s established strengths in information and communication technology and manufacturing, as well as having one of the best healthcare systems and the largest medical databases in the world, it is uniquely well-equipped to lead the development of innovative products and solutions across the whole digital-health ecosystem, as illustrated by the various cross-industry collaborations below.

Taiwan also provides certain incentives to facilitate the development of new digital health products and services. The Act for the Development of Biotech and New Pharmaceuticals Industry provides R&D tax breaks to qualified companies for investments in high-risk medical devices. AmCad BioMed was the first digital health company to obtain eligibility approval under the Act in relation to its innovative computer-aided detection and diagnosis devices. In addition, the Ministry of Economic Affairs offers investment subsidies to start-ups to encourage the development of cutting-edge medical AI solutions.

Figure 34: Examples of digital health collaborations in Taiwan

CMUH hospital group embraces medical AI applications
Since 2016, Taiwan’s China Medical University Hospital (CMUH) has collaborated with EverFortune.AI, a local medical AI start-up, to develop a variety of medical AI-assisted applications, including bone age analysis, breast cancer identification, liver fibrosis assessment and atrial fibrillation detection. These have been implemented in CMUH’s AI outpatient service to provide more efficient medical diagnosis.

New AI-based system makes brain tumour diagnosis more efficient
In 2018, Taiwan AI Labs, a privately funded research organisation, collaborated with Taipei Veterans General Hospital to develop Deepmets, an AI-based automatic brain tumour diagnostic system that leverages medical imaging, for use in clinical practice. The new technology has helped to significantly reduce the time required for brain tumour diagnosis, from more than 30 minutes to around 30 seconds.

New smart tool enables early diabetic retinopathy screening
In 2019, Taiwan’s Industrial Technology Research Institute, a government-sponsored R&D organisation, collaborated with three major hospitals to develop an AI-based diagnosis system for the early detection of diabetic retinopathy, a condition that can cause blindness if left untreated. The technology is installed in a smart funduscope to allow ophthalmologists and doctors to earlier diagnose the disease condition.

Wistron Medical aims to improve hospital systems
In 2019, Wistron Medical Technology, a subsidiary of contract electronics manufacturer Wistron, said it was cooperating with En Chu Kong Hospital in New Taipei City to develop “smart hospital architecture” and establish an intelligent healthcare ecosystem by using the Internet of Things, big data analysis and artificial intelligence. It also launched a series of smart solutions that improve haemodialysis treatment.

Taiwan uses advanced technology to effectively control COVID-19
Taiwan’s digital capabilities played an important role in combating the COVID-19 pandemic, with the government and private sector working together to leverage advanced technology for case identification, containment and resource allocation to protect public health. For instance, the government integrated data from the NHI, immigration and customs systems to trace potential cases and contain the outbreak.

Source: Publicly available information.
Long-term care

Taiwan’s population structure is ageing rapidly due to the combination of a shrinking birth rate and increasing longevity. In 2018, Taiwan crossed the threshold for an aged society, with more than 14% of the population older than 65, and is on course to become a super-aged society by 2025 when 20% of the population, or one out of every five people, will be senior citizens. While the government has tried to boost births through various policies, those efforts have largely been fruitless. Taiwan’s fertility rate was 1.1 children per woman in 2018, which is one of the lowest worldwide, down from 1.7 in 2000.

The growing number of elderly people and the low birth replacement rate—which means fewer young people to help look after aged family members—has increased the urgency to establish a long-term care system to meet the needs of Taiwan’s ageing population. The Long-Term Care Services Act was enacted in 2015 as the legal basis for developing comprehensive long-term care services in Taiwan. Two years later the government launched its ten-year Long-term Care Plan 2.0 (see next section), followed by a new subsidy schedule in 2018 to support the contract-based service provider system. Also, as part of the government’s long-term care plan, the Income Tax Act was amended in 2019 to provide an annual tax deduction of NT$120,000 (US$4,000) for each person in need of long-term care services, benefiting low- and middle-income families caring for members with physical and/or mental disabilities. In addition, to address future labour shortages due to population ageing, a new law was enacted in 2019 to promote employment of older middle-aged workers and senior citizens, increasing the flexibility of existing work regulations that set Taiwan’s mandatory retirement age at 65.

Besides improving the supporting legal framework for long-term care, the government has increased the number of care facilities and expanded funding for care, which is based on budget appropriations supported by tax revenue. However, adequate and stable funding for long-term care remains a thorny issue. With demand for long-term care in Taiwan expected to rapidly rise in the coming years, and given public spending constraints, the expansion of the long-term care system will offer opportunities for private investment in facilities and services to address the needs of Taiwan’s greying population.

Figure 35: Projection of long-term care needs in Taiwan, 2017-2026

Source: Ministry of Health and Welfare.
Long-term Care Plan 2.0

Taiwan is currently in the second stage of a two-decade long-term care programme. The first part, from 2007 to 2016—referred to as Long-term Care Plan 1.0—established state-subsidised care for the elderly and disabled, covering home nursing, meals and transportation, as well as rehabilitation and respite care services. Implemented in 2017, the Long-term Care Plan 2.0 added community-based services, including preventive care, dementia care and family caregiver services. Also, coverage was extended to about 738,000 care recipients under the new policy, compared with 511,000 previously.

The 2.0 Plan aims to establish a comprehensive community care system that promotes “ageing in place” and integrates social care, medical care and preventive health resources. The system has three tiers: community-based integrated service centres (Tier A); combined day-care service centres (Tier B); and long-term care stations in alleys and lanes (Tier C). Local governments are encouraged to work with private service providers to increase the types of care available. Subsidies are now paid according to services provided, not hours worked, in order to increase the efficiency of care delivery.

The government seeks to make long-term care services accessible to more people under the 2.0 Plan, but the expansion is placing heavy demands on funding and the care workforce, with the MOHW anticipating shortages over the next decade as the number of long-term care recipients rises steadily. The government’s annual budget for long-term care has expanded from less than NT$5bn (US$155m) in 2016 to NT$33.8bn (US$1.1bn) in 2019, and the MOHW has estimated long-term care costs could reach NT$73.6bn (US$2.5bn) by 2026, indicating that funding the system will be a major challenge.

Aside from government budget allocations, the long-term care plan relies on supplementary tax revenues—including inheritance, gift and cigarette taxes—but these are not a stable source of funds. The previous KMT administration had considered funding long-term care through a public insurance scheme, similar to how Taiwan’s NHI programme is financed, but a bill along these lines failed to win legislative support. The current ruling DPP opted for a tax-based scheme to fund the 2.0 Plan, but it will likely have to consider other funding options as long-term care expenditure rises further over time.

Figure 36: Missions and goals of the Long-Term Care Plan 2.0

**Goals**

1. “Ageing in place” as policy goal
2. Establish an accessible, affordable, universal long-term care service system with good quality.
3. Upstream prevention to delay disability
4. Downstream preparedness to provide discharge plan, home-based medical care.

Source: Ministry of Health and Welfare.
Business investment environment

Taiwan’s fast-ageing population is driving higher demand for long-term care products and services, as well as infrastructure investment. This presents potential opportunities for private companies and investors, particularly in the areas of digital health and construction and management of long-term care facilities. Given Taiwan’s emphasis on ageing in place as the policy goal for managing its elderly population, demand for digital-health products and services—such as mobile diagnostics, wearables, remote monitoring and internet-connected medical devices—will grow as the number of seniors rises.

Taiwan’s cultural norms around family care of the elderly, combined with the government directing resources and funds towards community ageing in place, mean that demand for institutional long-term care facilities is low at present. Nevertheless, people are becoming more aware of the needs for long-term assistance, and increasingly accepting of using long-term care services. With demand for long-term care institutions expected to expand in the years and decades to come, the government is seeking to encourage private investment in the long-term care sector and facilities management.

The establishment and management of long-term care facilities in Taiwan is governed by the Long-term Care Services Act as well as the Institutional Long-term Care Juridical Entities Act, which were enacted in 2015 and 2018 respectively. These laws permit foreign nationals and companies to invest in a long-term care institution in Taiwan. Basically, foreign entities can enter the domestic market as a long-term care facility operator, but may only be minority owners in a local joint venture company (owning up to 49%), and may hold only up to one-third of the board of director seats of this entity. Long-term care institutions in Taiwan are divided into five different categories based on the scope of their long-term care services provided: home services; community-based services; institutional residential services; integrated services, and other services designated by the MOHW. Institutional residential service providers are required by law to be established as corporate bodies or juridical associations (hence referred to as “institutional long-term care juridical entities”). The figure below depicts the range of services, including healthcare, provided under Taiwan’s Long-term Care Plan 2.0.

Figure 37: Services of the Long-term Care Plan 2.0

<table>
<thead>
<tr>
<th>Health</th>
<th>Sub-health</th>
<th>Frailty</th>
<th>Dementia/Disability</th>
<th>Serious illness</th>
<th>End of life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Community Senior Centers</td>
<td>Home care</td>
<td>Transportation</td>
<td>Home nursing care</td>
<td>Reablement</td>
<td>Day care</td>
</tr>
<tr>
<td>Programs for prevent or delay disability and dementia</td>
<td></td>
<td></td>
<td></td>
<td>Institutional care</td>
<td></td>
</tr>
</tbody>
</table>

Support service centers for family caregivers

| Health Promotion | Discharge plan | Home-based medical care | Chronic diseases management | Palliative Care |

Source: Ministry of Health and Welfare.
A guide to Taiwan's health industries
**Precision medicine**

Around the world, rising pressures to decrease healthcare costs, the emergence of value-based reimbursement models and healthcare digitisation trends are transitioning medical treatment models from a one-size-fits-all type of clinical approach to stratified and outcome-based targeted therapies. Precision medicine, in particular, is a growing area of interest for health systems, as it has the potential to substantially improve patient care by tailoring treatments that consider individual variability in genes, environment and lifestyle for each person; it has become increasingly important in oncology.

In Taiwan, the government has listed biomedicine as a priority industry, and one of the action plans of its Biomedical Industry Innovation Programme targets the development of high-potential specialty therapies, including precision medicine and other new areas such as regenerative medicine and cell-based therapies. Taiwan’s participation in the US-led Cancer Breakthroughs 2020 programme since 2016 is a good example of such efforts, as it helps promote the sharing of new biomedical advances among countries and links Taiwan into the global medical research and development supply chain.

In late 2019, the MOHW announced a roadmap for a precision healthcare system by 2030, with tasks to include the establishment of a gene bank, the promotion of new-born genomic sequencing, and the development of new NHI reimbursement strategies for precision medicine. A national-level flagship programme, coordinated by the National Health Research Institute (NHRI), aims to embed whole genome and exome sequencing in the health system by 2025. The institute is also tasked with creating an integrated platform combining data and specimens from 31 biobanks to speed up drug R&D.

The NHRI is set to launch Taiwan’s first precision medicine pilot project in 2021, which will focus on cancer therapies. Collaborating with major medical centres and biotech companies, the project aims to collect gene data from 10,000 specific cancer patients in five years, and establish a gene bank. Such developments are expected to boost growth in Taiwan’s precision medicine market, which was valued at US$900m as at 2017 and is projected to expand at a CAGR of 7.6% to reach US$1.3bn by 2022, according to a 2018 joint study by PwC and Taiwan’s Development Center of Biotechnology.

![Figure 38: Projected growth of Taiwan’s precision medicine market, 2017-2022](image-url)
Regulatory support for precision medicine

Taiwan has improved its regulatory environment in recent years to encourage the development of precision medicine initiatives. The key law covering biomedical innovation, the Act for the Development of Biotech and New Pharmaceuticals Industry, was amended in 2017 to broaden the definition of high-risk medical devices and extend R&D tax breaks to new emerging biomedical technologies, including precision medicine. Quark Biosciences was the first precision medicine company to receive eligibility approval under the statute in relation to its novel testing platform for cancer and other therapeutics.

To keep up with the fast-paced development of precision medicine, in 2018, TFDA established a laboratory management system (based on ISO 15189) for precision medicine molecular testing, in addition to existing in-vitro diagnostics (IVDs). It set guidelines to ensure the quality of laboratory developed tests and services (LDTS), with local laboratories required to register with the TFDA. At present, laboratories follow various accreditation standards (like ISO, CLIA and CAP), but, in April 2020, the MOHW proposed new rules requiring that all LDTS providers be TFDA-certified by 2026.

Figure 39: Taiwan’s regulatory framework for IVDs and LDTS

<table>
<thead>
<tr>
<th>Products/services</th>
<th>In vitro diagnostics (IVDs)</th>
<th>Laboratory developed test and services (LDTS)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery process</td>
<td>R&amp;D / Import</td>
<td>Development of test</td>
</tr>
<tr>
<td></td>
<td>TFDA Approval</td>
<td>Lab register at TFDA</td>
</tr>
<tr>
<td></td>
<td>Manufacturing</td>
<td>Request by physician</td>
</tr>
<tr>
<td></td>
<td>Sales channel</td>
<td>Patient sample collected at health facilities</td>
</tr>
<tr>
<td></td>
<td>Health facilities</td>
<td>Test and analyze at lab</td>
</tr>
<tr>
<td></td>
<td>Patients</td>
<td>Interpret by physician</td>
</tr>
<tr>
<td>Patients</td>
<td>Patients</td>
<td>Patients</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quality standards</th>
<th>ISO 13485 Medical Devices</th>
<th>ISO 15189 Medical Laboratories</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-market approval (Class I, II, III)</td>
<td>CLIA certification, CAP certification (optional)</td>
</tr>
<tr>
<td></td>
<td>Good manufacturing practice</td>
<td>TFDA certification (mandatory from 2026)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory body</th>
<th>TFDA (Market approval)</th>
<th>TFDA (Lab registration)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IDB (Manufacturing)</td>
<td></td>
<td>IDB (Medical practice)</td>
</tr>
<tr>
<td>NHI (Insurance coverage)</td>
<td></td>
<td>NHI (Insurance coverage)</td>
</tr>
</tbody>
</table>

Source: Taiwan Food and Drug Administration; PwC analysis.
Business investment environment

Taiwan’s comprehensive national health insurance scheme, with its massive medical database, and strong background in R&D make it an ideal place for development of precision medicine applications. Taiwan’s ICT and medical sectors are converging to produce personalised solutions and treatments through the use of high-speed DNA sequencing, smart wearables and AI-assisted data analytics. In a sign of progress, in 2018, 14 locally-developed IVD products received US FDA 510(k) clearance, and PlexBio received the European CE Mark to market its lung-cancer diagnostic panel in Europe.

Taiwan’s efforts to develop its precision medicine offerings are also attracting international attention, as reflected by a growing number of collaborative arrangements. For example, US company Insilico Medicine, which specialises in AI-assisted drug discovery, announced in 2018 the establishment of a R&D base in Nankang Software Park. It has also teamed up with the Development Center for Biotechnology, the Medical and Pharmaceutical Industrial Technology Development Center and Taipei Medical University for novel drug discovery research using AI, deep learning and genomics.

The COVID-19 crisis presents an opportunity for precision medicine to play an expanded role in healthcare treatment. In Taiwan, the government marshalled national resources for development of technologies such as potential vaccines or drugs against the coronavirus. Local research institutes have produced prototypes of rapid test kits and identified several candidate vaccines for clinical evaluation, among other response actions. Thanks to Taiwan’s effective management of COVID-19, many nations and international organisations have actively sought out cooperation on related matters.

These collaborations allow international partners to gain access to Taiwan’s well-established R&D and manufacturing capabilities to help speed the battle against the virus at home. Several Taiwan precision diagnostic companies are developing new rapid coronavirus antibody testing kits for international markets short of testing supplies. Also, local biopharma company Medigen Vaccine Biologics is currently working with the US-based National Institutes of Health to develop a vaccine against COVID-19, having signed a global license agreement in May 2020 for a vaccine candidate.
International collaboration

As momentum accelerates in Taiwan’s biomedical industry, global biopharma companies are showing growing interest in potential strategic collaboration and investment opportunities across the industry’s value chain. Likewise, local research institutes and companies are eager to enter collaborations with counterpart institutes overseas and Big Pharma on ground-breaking R&D projects and other activities to boost biomedical innovation. This focus section examines the status of international collaboration in Taiwan’s biomedical R&D ecosystem, as well as recent M&A developments in its health industries.

Taiwan’s attractive biomedical environment

Taiwan’s biomedical industry has been designated a key sector for development in the government’s 5+2 Innovative Industries Plan, which aims to move the island up the innovation value chain and add new momentum to economic growth. A long period of investment has produced a solid foundation for future industry growth, supported by a strong pool of scientific talent, excellent research and medical infrastructures, a treasure trove of medical data (from the National Health Insurance system), rich clinical-trial experience, cost-competitive R&D and manufacturing and a robust IP protection regime.

To facilitate the industry’s development, in 2016, the government launched its Biomedical Industry Innovation Programme, which seeks to establish Taiwan as a hub for biomedical R&D in the Asia-Pacific region. Efforts are being directed into four action plans to create links locally, globally and to the future in order to achieve the initiative’s 2025 goals of developing and launching 20 new drugs, bringing 80 new medical devices to international markets, cultivating at least 10 biotechnology and health-related flagship brands, and building bio-medicine in Taiwan into a NT-trillion-dollar industry.

The industry has made significant progress since the BIIP’s launch, backed by strong government support and investment in essential infrastructure. Key developments have included the integration of regional biomedical clusters; the establishment of the National Biotechnology Research Park; the expansion of R&D tax breaks to encourage more investment in emerging biomedical technologies; the relaxation of restrictions on biomedical talent flows between the academic and private sectors; and the establishment of an incubator mechanism (BioHub Taiwan) to support biomedical start-ups.

Collaborations fuelling biomedical progress

Since innovation does not come cheaply or quickly, there is an increasing recognition worldwide of the value and importance of collaboration across the biomedical innovation ecosystem. Multinationals and local companies are increasingly adopting a collaborative, multi-stakeholder approach toward conducting R&D and innovation, partnering with research institutes, healthcare facilities and other stakeholders to tackle scientific and technological challenges, generate greater efficiencies in R&D, and accelerate development and delivery of new and innovative treatments that will benefit patients.

In Taiwan, with the support of the BIIP, there has been increase in collaborations where biomedical multinational companies and local institutions have partnered in new drug development and nurturing of biomedical talent and entrepreneurship. Local firms seek collaborations to speed up development of their innovations and expand their market reach internationally. In return, multinationals can take advantage of the agility of local companies when it comes to identifying market niches with potential for more innovation. All parties therefore benefit from diversified risk and the sharing of R&D costs.

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

- **R&D and manufacturing collaboration**, such as outsourcing to CROs, CMOs, CDMOs, and other co-development partnering arrangements.
- **Licensing agreements**, such as for in- and out-licensing of R&D assets, process development know-how, manufacturing and distribution rights.
- **Direct investments**, subject to the investor’s level of risk tolerance, including equity stakes, joint ventures, and mergers and acquisitions.

Government, academic and industry bodies play a key role in promoting Taiwan’s biomedical industry through conferences, exhibitions and other events—such as the BIO Asia-Taiwan expo, which is one of the largest annual biotech gatherings in Asia—as well as in fostering and facilitating collaborations to help drive industry innovation and future growth. The following figure highlights some recent notable examples of international collaboration between pharma multinationals and local organisations and companies in relation to innovative R&D projects and the cultivation of industry talent and start-ups.
Daiwa SB Investments forms biotech joint venture fund  
In 2014, Taiwan’s state-owned National Development Fund and Japan’s Daiwa SB Investments formed a joint venture-capital fund, named the Taiwan-Japan Biotech Fund, to invest in Taiwanese firms and bring Daiwa’s investment experience and connections in the biotech industry to participating companies.

AstraZeneca establishes collaborative innovation hub  
In 2018, pharmaceutical multinational AstraZeneca established a health innovation hub in Taiwan to support local R&D capacity. It is currently collaborating with the National Biotechnology Research Park and BioHub Taiwan on an accelerator programme to provide start-ups with training and mentorship.

Bayer introduces G4A programme to support healthcare start-ups  
In 2018, global pharmaceutical company Bayer introduced its Grants4Apps (G4A) programme to Taiwan in collaboration with H.Spectrum, Asia’s leading accelerator/incubator focusing on healthcare. G4A is a digital health-focused programme that provides entrepreneurial support and mentorship to start-ups.

Merck collaborates with ITRI to enhance new drug manufacturing  
In 2018, Taiwan’s Industrial Technology Research Institute (ITRI) launched a collaboration programme with German pharma giant Merck to develop a new generation of biopharma products, by combining the R&D resources of ITRI with key technologies and advanced manufacturing processes from Merck.

Amgen and NBRP team up to promote Taiwan’s biomedical talent pool  
In 2019, American biopharmaceutical company Amgen teamed up with the National Biotechnology Research Park to promote the development of Taiwan’s biomedical industry. It established the Amgen Academy to accelerate R&D innovation, cultivate R&D talent and harness the industry’s potential.

Merck launches accelerator programme for biotech start-ups  
In 2019, Merck also collaborated with Taiwan-based start-up platform H.Spectrum to establish a local innovation lab in Taipei. It has launched an incubator programme for biotech start-ups, which supports the development of innovative solutions in the areas of patient experience and precision medicine.

NBPR enhances collaboration with Takeda’s Shonan iPark  
In 2019, the National Biotechnology Research Park signed a MOU with Japan-based Takeda’s Shonan Health Innovation Park to promote a next-generation biomedical research ecosystem. This is expected to increase the success rate of commercialisation, technology transfer and investments in both parks.

Hitachi and MetaTech to establish regenerative medicine joint venture  
In April 2020, Japanese industrial group Hitachi and Taiwanese biomedical company MetaTech agreed to establish a joint venture in the regenerative medicine field. It will combine Hitachi’s technologies and systems/solutions with the strengths of MetaTech to manufacture cells used in regenerative medicine.

Medigen licenses vaccines from US National Institute of Health  
In May 2020, Taiwan’s Medigen Vaccine Biologics (MVC) signed an agreement with the US National Institutes of Health (NIH) to develop a vaccine against COVID-19. It is MVC’s second cooperation with the NIH since 2015, when the two sides first collaborated to develop vaccines against dengue fever.

Academia Sinica teams up with the EU to combat COVID-19  
Taiwan’s top research institute, Academia Sinica, and the European Union agreed in March 2020 to strengthen cooperation on the development of vaccines and rapid tests for COVID-19. For example, BluSense Diagnostics, a joint start-up between Taiwan and Denmark, is developing a rapid test kit.

Source: Publicly available information.
Biomedical M&A activity in Taiwan

A key objective of Taiwan’s biomedical promotion plan is to build domestic biopharmaceutical firms into health-related flagship brands, by encouraging them to make mutual investments, cooperate with venture capital and private equity firms, and initiate merger and acquisition (M&A) activities. The state-run National Development Fund has established an industrial innovation and transformation fund to help finance domestic companies’ acquisitions at home and abroad. This supportive investment policy framework has helped spur M&A activities by Taiwanese drug and medical-device makers.

The M&A trend in Taiwan’s biomedical industry is also being driven by local market consolidation, as well as overseas expansion plans intended to reduce reliance on a small home market. At the same time, Taiwan is attracting more international investor interest in the pharma and life sciences space, thanks to its strong positioning in the Asian clinical trials market, as well as the government’s industry promotion policy and support for related M&A. There have been several notable inbound deals in recent years for acquisitions of domestic pharmaceutical and medical device manufacturers.

Most biomedical companies in Taiwan are small and medium sized, and the average M&A deal size for the industry is relatively small by global deal standards. The biopharmaceutical sector has seen the most M&A activity in recent years, with key deals including the US$400m acquisition of Crown Bioscience by Japan’s JSR in 2017, and the US$240m purchase of Taiwan Tung Yang by Hong Kong-based China Grand Pharmaceutical in 2018. The most significant deal in the medical device sector was Morgan Stanley’s US$300m buy-out of medical-device maker Microlife in 2018.

Biomedical investment flows slowed in 2019 amid rising concerns over geopolitical tensions such as the US-China trade dispute, and M&A activity will be further impacted by the fallout from COVID-19. Notwithstanding the current uncertainty, Taiwan’s burgeoning biomedical industry will continue to be an attractive proposition for domestic and foreign investors, not just existing industry players, but also financial investors like private equity and venture capital firms, as well as new market entrants from the tech world. Government-backed funds will also provide continuing support as key lead investors.

Figure 41: Biomedical M&A activity in Taiwan, 2016-2019

<table>
<thead>
<tr>
<th>Year</th>
<th>Biopharmaceutical</th>
<th>Healthcare Products</th>
<th>Healthcare Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>132</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>2017</td>
<td>400</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>2018</td>
<td>233</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>2019</td>
<td>6</td>
<td>1</td>
<td>2</td>
</tr>
</tbody>
</table>

Source: Bloomberg, publicly available information, PwC analysis.
How PwC can help
PwC’s health industries services

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

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

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

Assurance services

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

Tax and legal services

We deliver practical tax and legal advice and solutions to health industries clients, and provide support 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, and offer support and practical solutions to achieve these objectives. Our service areas include deals, strategy, operations, technology, finance, people and change, risk and forensics. We can assist you with strategic planning and market analysis, as well as with all aspects of the M&A deals process.

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

**Lily Wong**
Advisory Partner
+886-2-2729-6703
lily.wong@pwc.com

**Amenda Lin**
Assurance Partner
+886-3-5780-205
amenda.lin@pwc.com

**Jack Hwang**
Tax Partner
+886-2-2729-6061
jack.hwang@pwc.com

**Ross Yang**
Legal Partner
+886-2-2729-6100
ross.yang@pwc.com