www.pwc.tw

Taiwan health industries outlook

Prospects and challenges

A concise guide to Taiwan's healthcare, biotech, pharma and medical device industries.

January 2015

pwc

資誠

Foreword

Across Asia, a convergence of shifting economic and demographic trends, the implementation of health reform policies and greater public awareness of healthcare issues has created an environment that is poised for dramatic growth and change.

The opportunities for organisations and businesses across Asia's health industries are vast as countries throughout the region search for the best way to finance, organise and deliver healthcare services with the right balance of quality, cost and access.

Taiwan boasts one of the most progressive health systems in Asia, but it currently faces a number of pressing healthcare policy challenges, including the impact of one of the most rapidly ageing populations in the world as well as rising healthcare costs.

Healthcare providers and biotechnology, pharmaceutical and medical device companies also face a dynamic and challenging operating environment in Taiwan, but one which also offers many opportunities for growth potential across the health spectrum.

This updated paper, first published in July 2012 as *"Checking up on Taiwan healthcare,"* provides an introductory overview of Taiwan's health industries and examines the future prospects, opportunities and challenges for market participants.

PwC's health industries practice focuses on the healthcare, pharmaceutical and life sciences sectors, and our people bring industry experience as it pertains to audit and assurance, tax and advisory services. We help build the value you're looking for.

To have a deeper conversation about Taiwan's health industries market, please contact our dedicated team (see page 34) who can help tailor solutions that meet your needs.

Lily Wong
PwC Taiwan
Health Industries Leader

Contents

This report is complied by Damian Gilhawley and is based on a combination of industry interviews and secondary research. It has been prepared for general guidance on matters of interest only, and does not constitute professional advice. Please read the legal disclaimer on the back cover for more information.

Executive summary

Taiwan healthcare services industry

Healthcare demand

- Taiwan demand for healthcare services continues to steadily grow, as reflected by increases in inpatient- and outpatient-related indicators, which rank relatively high among advanced healthcare systems.
- The uptrend has been driven by several factors, including no gatekeeper or strict referral system, a greying population and increasing prevalence of chronic diseases, and a lack of long-term care facilities.
- Taiwan has a fast ageing population that will increase demand and opportunities for long-term care and related services in the future, but also present significant challenges for public healthcare policy.
- Another important driver of demand for healthcare services is the government's promotion of Taiwan as a medical tourism destination, with a focus on attracting visitors from China for healthcare-related purposes.

Healthcare provision

- Taiwan had 495 hospitals and 21,218 clinics in 2013, the vast majority of which are privately owned. The number of hospitals has gradually fallen in recent years, but the number of clinics has grown.
- Cost pressures from reduced reimbursements have caused a number of small private hospitals to exit the market, while the surviving institutions have grown significantly in size as they look to increase revenue.
- Doctor availability in Taiwan is below average OECD levels, with 2.1 doctors per 1,000 people in 2013. Also, medical staff shortages have become a pressing issue in recent years.

Expenditure and funding

- Taiwan spends about 6-7% of GDP on healthcare, the sixth highest level in Asia-Pacific but lower than the OECD average of 9.3%. Expenditure is majority funded through the universal National Health Insurance (NHI) system.
- Taiwan's NHI is a public-run, single-payer health insurance scheme, which provides mandatory health coverage for almost all Taiwanese citizens and offers freedom of choice of healthcare provider.
- With the government seeking to tighten healthcare and pharmaceutical expenditure, cost-containment policies will continue to put downward price pressures on healthcare providers and drugmakers.
- A second-generation NHI was implemented in 2013 to help shore up the system's finances, but the NHI will continue to face financial strains resulting from an ageing population and rising healthcare costs.

Regulatory and policy

- The restructuring of Taiwan's Department of Health as the Ministry of Health and Welfare (MOHW) was completed in 2013, with the integration of welfare responsibilities being the major changes made.
- The MOHW administers the national healthcare system and is charged with fostering a healthy population and erecting a complete social safety net—an increasingly important role given Taiwan's ageing demographics.
- A key priority is to establish a comprehensive care and support system for the elderly. New legislation is being developed to soon pave the way for a national system.

Biotech, pharma and medical device industries

Demand trends

- Taiwan's biotech market is relatively small in size, worth about USD$3.3 billion in 2013, but its growth momentum is strong, due to government policy support and the maturation of companies' drug pipelines.
- The increasing trend of cross-Strait regulatory harmonisation for new drug development offers significant opportunities for Taiwan's biotech sector, as its R&D programmes are highly relevant to the Chinese market.
- Taiwan demand for pharmaceuticals totalled about US$5.4 billion in 2013, underpinned by high volume consumption of prescription drugs per capita, while the medical device market was worth about US$4.3 billion.
- The increasing elderly population and subsequent rise in demand for healthcare products and services will drive growth in Taiwan's pharma and medical device markets in the coming years.

Supply trends

- With Taiwan's biotech industry in the late incubation stage and attracting investor interest, there has been a marked jump in the number of domestic companies going public to raise funds for R&D and growth opportunities.
- Most new and patented drugs are imported by pharma multinationals, but their market share is under pressure from government policies promoting the use of cheaper locally-made generic drugs.
- Taiwan depends on imports for high-end medical devices and equipment used in hospitals, as domestic medical device manufacturers mainly produce mid- and low-level products designed for homecare and consumer use.
- Taiwan's lengthy registration process for pharmaceuticals and medical devices, and an additional time-consuming review for NHI reimbursement approval, slows market entry for new innovative products.

Pricing issues

- Drug and medical-device makers have been critical of Taiwan's pricing and reimbursement policies, arguing low prices may delay launches of new drugs or advanced devices in Taiwan.
- To control pharmaceutical spending, the NHI has conducted frequent price volume surveys (PVS) since 2000 to cut reimbursement prices, which have resulted in some of the lowest drug prices in the developed world.
- Successive price reductions have not resolved the drug price gap between reimbursement and market prices, due to the incomplete separation of prescribing and dispensing in hospitals.
- The NHI implemented a trial run of a new drug expenditure target system in 2013-14 as an alternative to biennial price cuts, which it is hoped will offer greater predictability and stability than the PVS system.

Growth strategies

- Taiwan's biotech and pharma companies generally look to form alliances with contract research organisations and pharma multinationals, develop high-end drugs, and expand into China, Asia and the rest of the world, either through distribution partnerships, strategic relationships or acquisitions.
- China presents a big opportunity. Its lower production costs and large market size are attractive to Taiwanese manufacturers, though there are concerns around IP protection.
- Taiwan is also well positioned to act as a bridge to China for multinationals, while domestic firms also look to collaborate with Chinese counterparts to take advantage of China's healthcare system reforms.

Taiwan healthcare services industry

Taiwan has a modern, efficient healthcare system that enjoys very high rates of public satisfaction, largely due to its affordable universal coverage and equal access to quality healthcare. However, Taiwan currently faces a number of pressing healthcare policy challenges, including an ageing population and rising healthcare costs, which will add further financial pressures on its National Health Insurance (NHI) programme.

Figure 1: Key features and challenges for Taiwan's healthcare services industry.

Key features

- Healthcare providers are a mixture of public and private, almost all of which are contracted with the NHI.
- Government-run, single-payer health insurance system which centralises the disbursement of healthcare funds.
- Compulsory health coverage for almost all Taiwanese citizens and freedom of choice of healthcare providers.
- Good accessibility, low out-of-pocket costs, short waiting times and high-quality medical personnel.
- Positive health outcomes and consistently high rates of public satisfaction with Taiwan's healthcare system.

Challenges

- Universal access with no formal gatekeeper system or restrictive referral regulations.
- Overuse of healthcare services, facilitated by ease of access to medical treatment and facilities.
- Cost-containment policies putting downward pricing pressures on healthcare providers and drugmakers.
- Fast ageing population increasing demand pressures on the provision of healthcare and long-term care.
- Uncertainty over the long-term sustainability of the NHI due to ageing demographics and rising healthcare costs.

Source: PwC Taiwan.

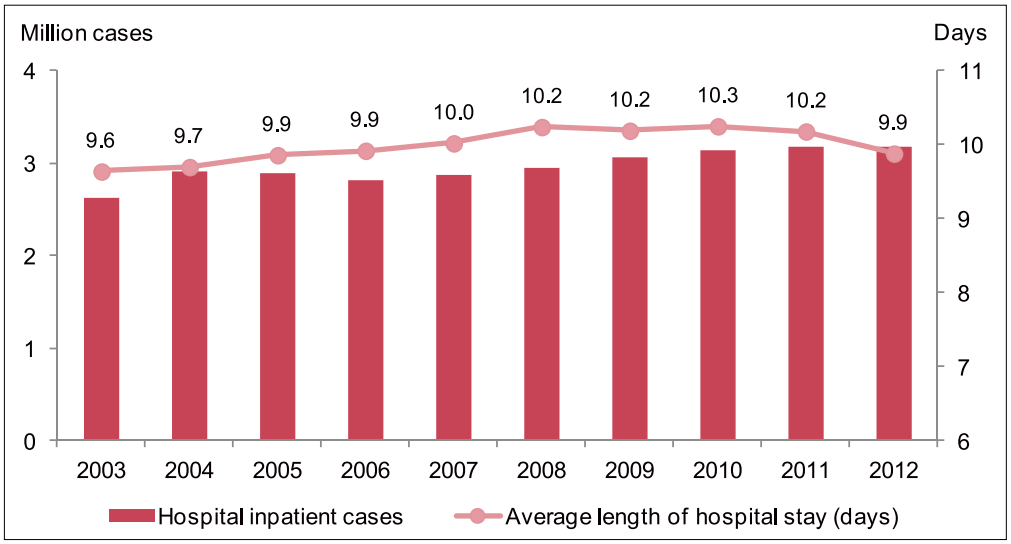
The performance of Taiwan's healthcare system depends upon the interaction of several, interdependent factors, each of which will be addressed in the following pages.

Healthcare demand

Taiwan demand for healthcare services continues to steadily grow, as reflected by increases in inpatient- and outpatient-related indicators, which rank relatively high among advanced healthcare systems. A rapidly ageing population will increase demand and opportunities for long-term care and related services, but also present significant challenges for public healthcare policy. Medical tourism is another growth driver.

Hospital inpatient volume grew from 2.6 million cases in 2003 to 3.2 million cases in 2012, growing at a compound average growth rate (CAGR) of 2.2%. The average length of stay rose from 9.6 to 9.9 days over the same period, which is the second highest level in Asia-Pacific after Japan (see Appendix). The uptrend has been driven by several factors, including no gatekeeper or strict referral system, a greying population and increasing prevalence of chronic diseases, and a lack of long-term care facilities.

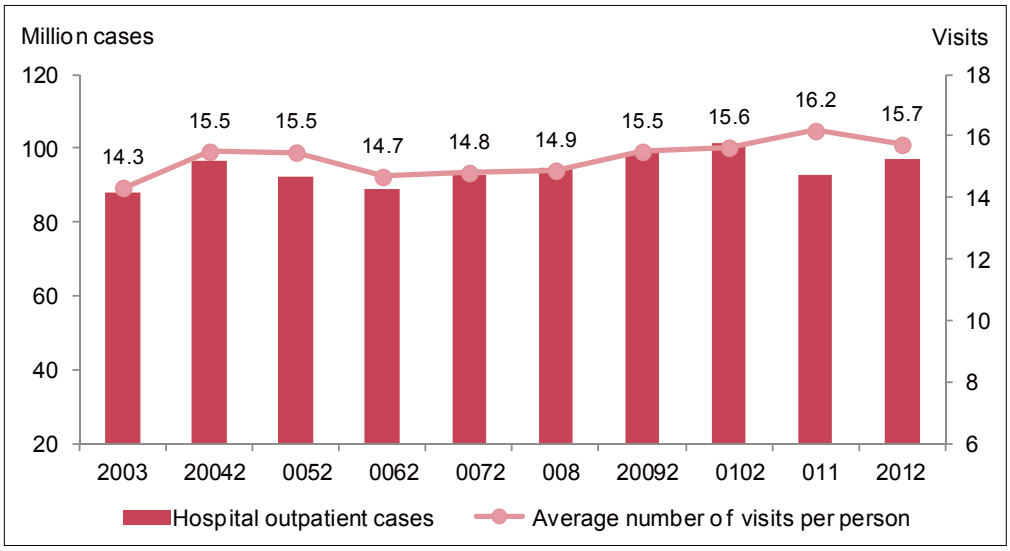
Figure 2: Taiwan inpatient volume and average length of hospital stay, 2003-2012.



Source: Ministry of Health and Welfare, Taiwan.

Hospital outpatient volume grew from 88.1 million visits in 2003 to 97.1 million visits in 2012, increasing at a CAGR of 1.1%. The average annual number of outpatient visits per person rose from 14.3 to 15.7 over the same period, higher than the OECD average of six to seven doctor consultations per person, which is largely due to Taiwan's easy access to medical treatment, low out-of-pocket costs and ageing demographics.

Figure 3: Taiwan outpatient volume and average number of visits per person, 2003-2012.



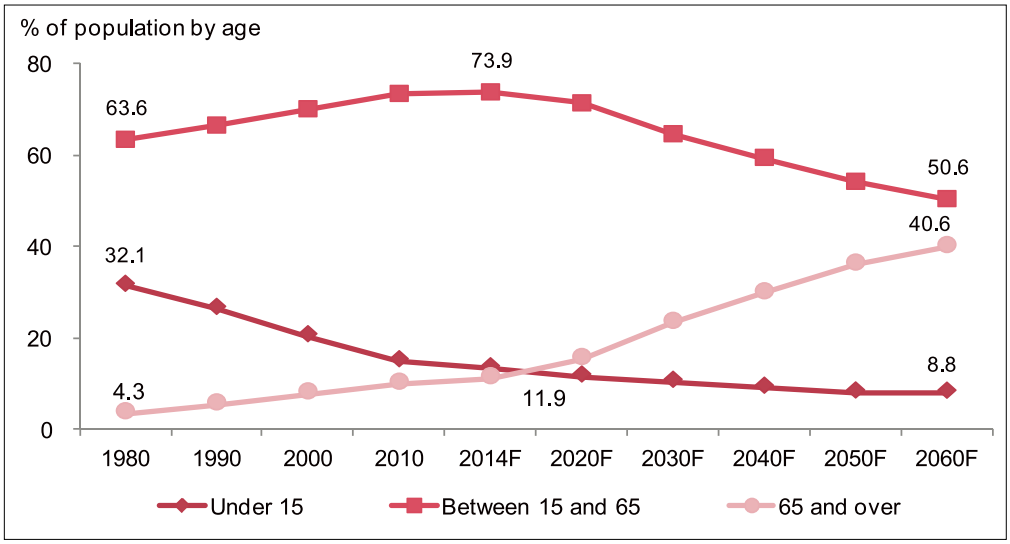
Source: Ministry of Health and Welfare, Taiwan.

Ageing population spurring demand for long-term care

Taiwan's population is slowing and ageing, due to a very low fertility rate and longer life expectancy (see Appendix). The population grew by an average of 1.4% a year in the 1980s, by 0.9% annually in the 1990s and by 0.5% a year in the 2000s. Growth dwindled to 0.2% in 2013, and the slowing trend is expected to persist in the coming years. The government estimates Taiwan's population will peak at around 23.6 million within the next 12 years (versus 23.4 million currently) and then decline significantly.

Taiwan became an ageing society—in which people 65 or older account for at least 7% of the population—in 1993. The proportion of elderly has since increased to 11.5% in 2013. According to the national population estimate for 2014-2060, released in August 2014, Taiwan will become an aged society (14%) in 2018 and a super-aged society (20%) in 2025, and senior citizens will account for around 41% of society in 2060.

Figure 4: Taiwan demographic structure, 1980-2060.



Source: Population Projections for Taiwan: 2014-2060, National Development Council, Taiwan.

These projections put pressure on the government to strengthen Taiwan's long-term care system. In 2008, it launched a Ten-year Long-term Care Plan, under which only senior citizens who have difficulties performing activities for daily living qualify for care. Since then, centres for long-term care management have been established by local authorities to offer various service options, including home and community-based care, respite care, transportation and meal services, as well as institutional care.

The government is planning to establish a more comprehensive care and support system. A draft Long-term Care Services Act, which would regulate the provision of care professionals and the establishment and management of long-term care institutions, is currently under legislative review. It also plans to transform institutions providing related services into social enterprises and launch a new long-term care insurance system, as well as encourage more private investment in the long-term care sector.

Medical tourism also offers growth opportunities

Another important driver of demand for healthcare services is the promotional development of Taiwan as a medical tourism destination, with a focus on attracting visitors from China. In recent years, the government has launched several initiatives to penetrate the medical tourism sector, as increasing numbers of people travel abroad to access healthcare. Taiwan is hoping to become a regional major player in this field.

Medical care in Taiwan is on a par with more developed countries but service fees are lower. Its other key competitive advantages include the availability of highly qualified personnel and state-of-the-art facilities and procedures. Also, several Taiwanese healthcare providers have received international accreditation from the US-based Joint Commission International, which is considered the gold standard in global healthcare.

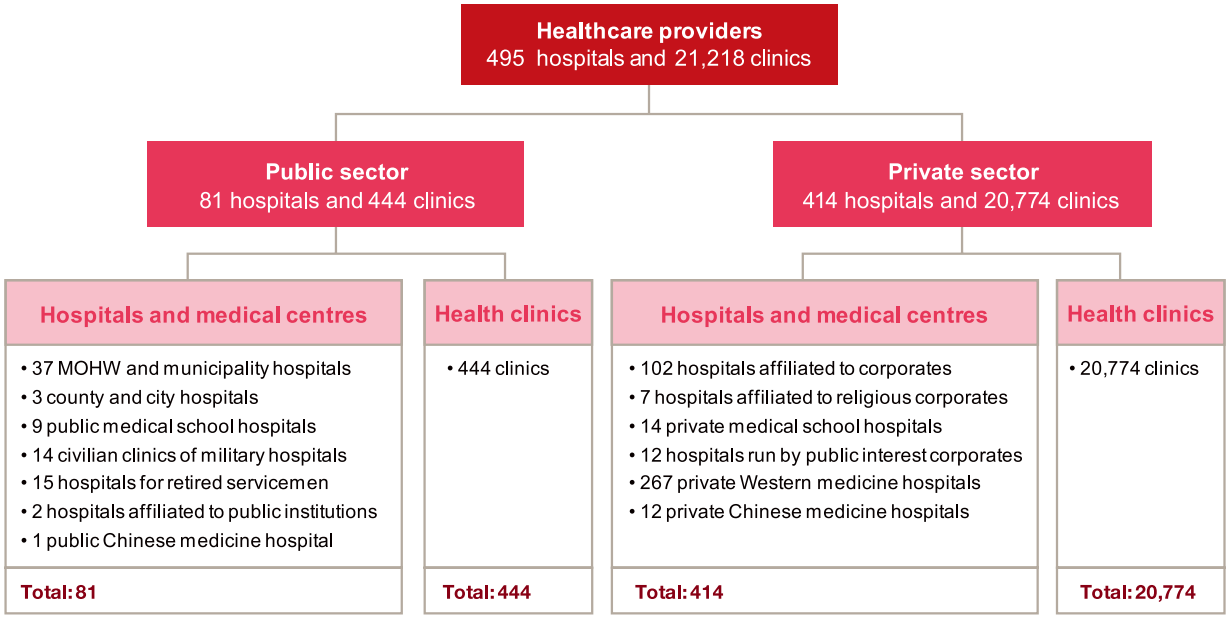
To help accelerate growth in the medical tourism sector, the government has recently established medical service centres at Taiwan's major airports to cater to inbound visitors, and also eased restrictions on allowing Chinese tourists to visit Taiwan for treatment. Such measures should help boost Taiwan's healthcare industry and bring opportunities for investors looking to provide premium services for affluent patients.

Long-term care and medical tourism to drive demand growth

Healthcare provision

Taiwan had 495 hospitals and 21,218 clinics in 2013, the vast majority of which are privately owned (84% of hospitals and 98% of clinics). The number of hospitals has fallen by 16% over the past decade, mainly due to smaller private hospitals exiting the market, while the number of clinics has grown by 14% over the same period.

Figure 5: Taiwan healthcare service infrastructure (2013).



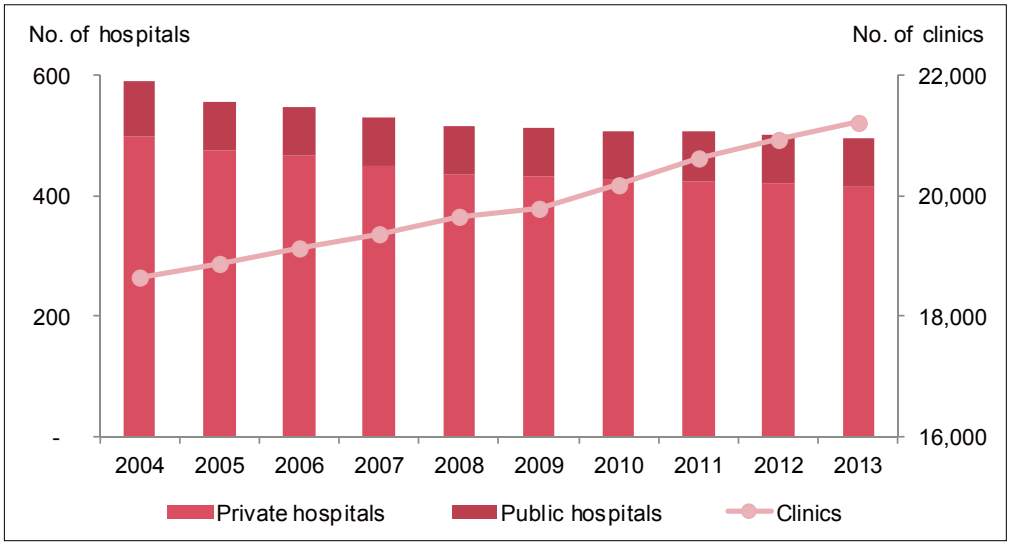
Source: Ministry of Health and Welfare, Taiwan.

The number of hospitals in Taiwan has gradually fallen in recent years, from an aggregate total of 590 (90 public and 500 private) in 2004 to 495 (81 public and 414 private) in 2013. Cost pressures from reduced NHI reimbursements have caused a number of small private hospitals to increasingly exit the market, while the surviving institutions have grown significantly in size as they look to increase revenues.

Besides Taiwan, local hospitals have also been actively exploring the huge market potential in China, as the government there opens up its healthcare sector to attract funds and reduce the burden on public hospitals. Many Taiwanese enterprises have already established joint-venture and fully-owned hospitals in China, having gained preferential access to its private hospital sector under the Economic Cooperation Framework Agreement signed between Taiwan and China in June 2010.

The number of clinics in Taiwan has grown from 18,650 (481 public and 18,169 private) in 2004 to 21,218 (444 public and 20,774 private) in 2013. Within the overall increase, there has been a marked rise in the number of cosmetic and aesthetic medicine clinics, driven by the out-of-pocket paying segment. The development of self-paid services has received growing attention by clinics as possible revenue drivers.

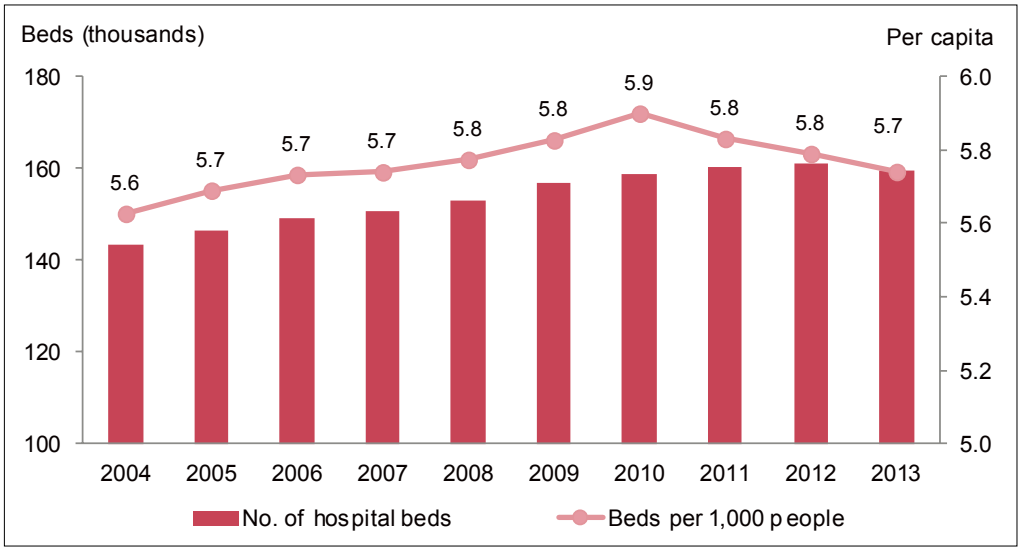
Figure 6: Taiwan hospitals and clinics, 2004-2013.



Source: Ministry of Health and Welfare, Taiwan.

The number of hospital beds in Taiwan grew by 11% from 143,343 in 2004 to 159,422 in 2013, and the number per thousand people rose from 5.6 to 5.7 over the same period. The number of beds in private hospitals is around twice that in public hospitals. Also, Taiwan's current per capita supply of beds is above the OECD average of 4.8 and higher than other Asia-Pacific economies except for Japan and Korea (see Appendix).

Figure 7: Taiwan hospital bed capacity, 2004-2013.

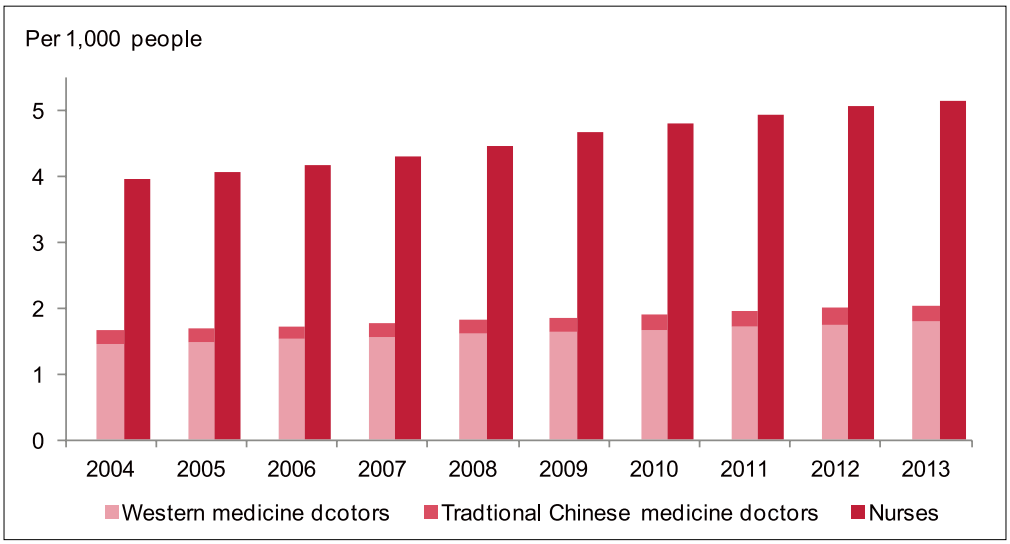


Source: Ministry of Health and Welfare, Taiwan.

Taiwan had 2.1 doctors (1.8 for Western medicine and 0.3 for traditional Chinese medicine) and 5.1 nurses per thousand people in 2013, which are lower than the respective OECD averages of 3.2 physicians and 8.8 nurses (see Appendix). Due to the lack of a gatekeeper system and low reimbursement rates per consultation, doctors in Taiwan attend to more patients than their counterparts in Western countries.

Medical personnel shortages have become a pressing issue in recent years. Many doctors have chosen to work in private clinics or to leave Taiwan and take up higher-paying positions overseas, leaving shortages in key hospital departments. While the overall number of registered nurses is increasing, it is still not enough to meet the growing healthcare demands of an ageing population, especially in rural and remote regions. The government is working to address hospital staffing shortages and improve retention.

Figure 8: Taiwan doctors and nurses, 2004-2013.



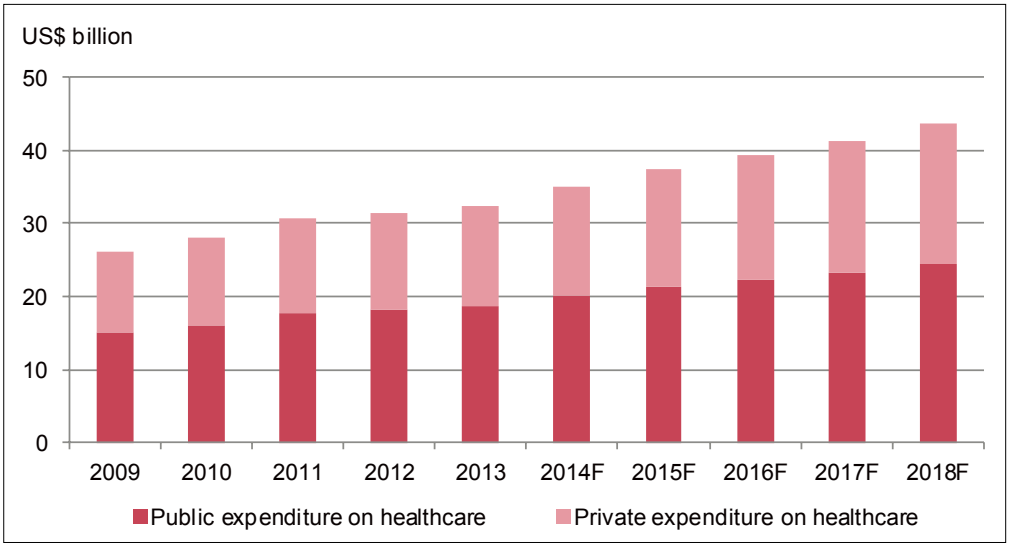
Source: Ministry of Health and Welfare, Taiwan.

Expenditure and funding

Healthcare expenditure in Taiwan has grown from US$14.4 billion (5.3% of gross domestic product) in 1995, when the NHI was introduced, to US$32.4 billion (6.6%) in 2013. The current share of GDP is similar to regional levels but lower than the OECD average of 9.3% (see Appendix). A key reason for the low spend is that the 2-3% cost of administering Taiwan's NHI system is among the least expensive in the world.

Research firm Business Monitor International (BMI) forecasts Taiwan healthcare expenditure will rise by a CAGR of 6.1% (in US dollar terms) between 2013 and 2018, up from 4.5% in the preceding five years, and as a proportion of GDP to remain between 6% and 7% of GDP in the forecast period. Although growth in private out-of-pocket spending is expected to be higher in 2013-18 than for public sector expenditure, the latter will still account for about 57% of total healthcare spending in Taiwan.

Figure 9: Taiwan healthcare expenditure, 2009-2018.



Source: Ministry of Health and Welfare, Taiwan; Business Monitor International.

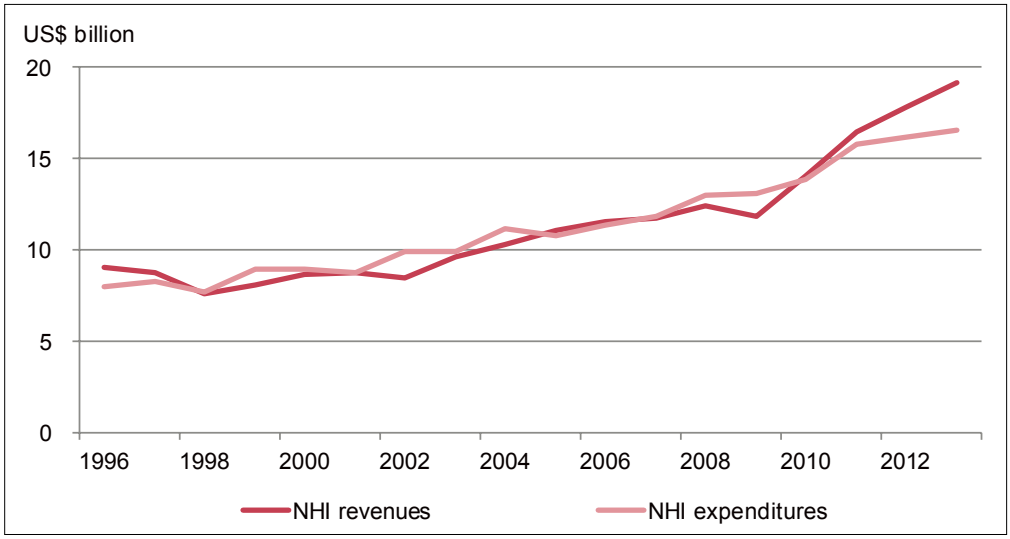
Taiwan's healthcare expenditure is majority funded by public sources, primarily through the NHI, and the rest from private out-of-pocket spending, mostly co-payments for hospitalisations and doctor visits. The NHI system is managed by the National Health Insurance Administration (NHIA) of the Ministry of Health and Welfare, and funded primarily through premiums jointly paid by the insured, employers and the government. Co-payment fees are required for both outpatient and inpatient care.

Taiwan's compulsory NHI scheme offers a comprehensive benefits package to 99.6% of Taiwanese citizens (plus foreign residents), including outpatient and inpatient care, preventative care, dental services, traditional Chinese medicine services and prescription drugs. The insured have freedom of choice among recognised healthcare providers—over 90% of all medical facilities in Taiwan are contracted with the NHI.

Reimbursement is generally on a fee-for-service basis. As this encourages the overuse of resources, the NHIA has adopted other reimbursement methods in recent years to improve the quality and efficiency of care, as well as to keep spending down. These include pay-for-performance programmes, diagnosis-related group-type payment systems, an integrated outpatient services programme and capitation payment.

Taiwan has also been making increased use of Health Technology Assessments (HTAs) to evaluate the cost effectiveness, budget impact, and ethical, legal and social implications of new (and often more costly) technologies entering the pipeline. Taiwan introduced HTA in 2007 as part of the decision-making process for new drug approvals, and extended the practice to medical devices in 2011 and to medical services in 2014.

Figure 10: NHI revenues and expenditures, 1996-2013.



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

The NHI system has constantly been threatened by financial deficits due to underfunding, as overall contributions are not enough to provide the quality of care that many of the population would like to receive. To control rising healthcare and pharmaceutical expenditures, the government has sought to cut reimbursement rates, putting downward price pressures on hospital providers and drugmakers.

A second-generation NHI was implemented in 2013 to expand the premium base and put the scheme's finances on a sounder footing. While the increase in premium collection has helped boost its sustainability, the NHI still runs the risk of returning to deficit, as it's difficult to assess the actual medical demand for the ageing population. With this in mind, the government plans to launch a long-term care insurance system, similar to the NHI scheme, though the draft bill has yet to finalised or approved.

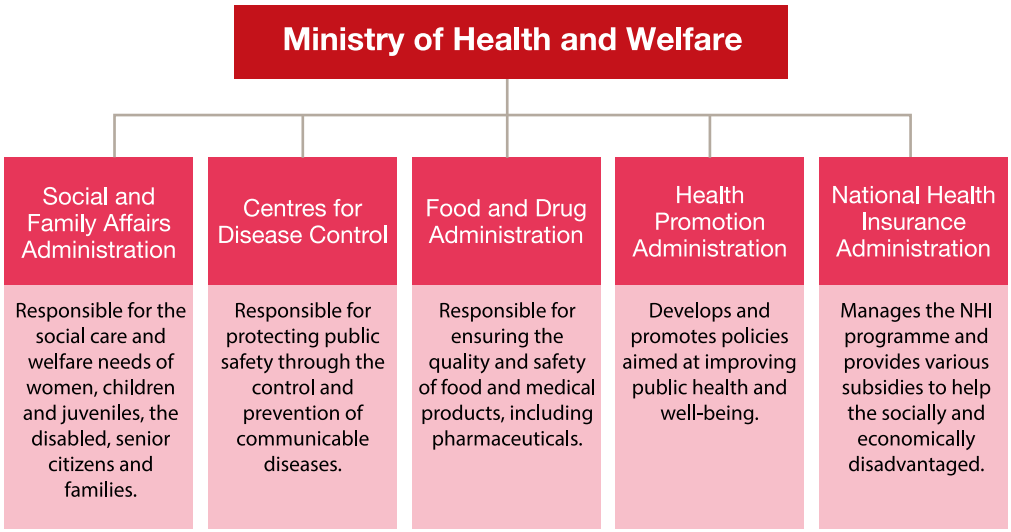
Despite universal coverage through the NHI, it is also possible to purchase supplementary private health insurance in Taiwan. But it's limited to very specific disease based plans or linked with life insurance schemes. The high quality of the public healthcare system has constrained demand for private insurance, but concerns about the NHI's finances may encourage greater levels of take-up in the future.

Healthcare regulatory and policy

Taiwan's Department of Health (DOH) was upgraded in July 2013 to become the Ministry of Health and Welfare (MOHW), with the integration of certain welfare responsibilities being the major changes made. It administers Taiwan's healthcare system and is charged with fostering a healthy population and erecting a complete social safety net–an increasingly important role given a rapidly ageing population.

As illustrated below, the MOHW now has five first-tier agencies: the Social and Family Affairs Administration, Centre for Disease Control, Food and Drug Administration, Health Promotion Administration and the NHIA. Also under its auspices are 26 public hospitals originally run by the DOH and 13 social-welfare institutions that used to be under the purview of the Ministry of the Interior. In addition, the MOHW oversees the national health insurance system as well as the national pension programme.

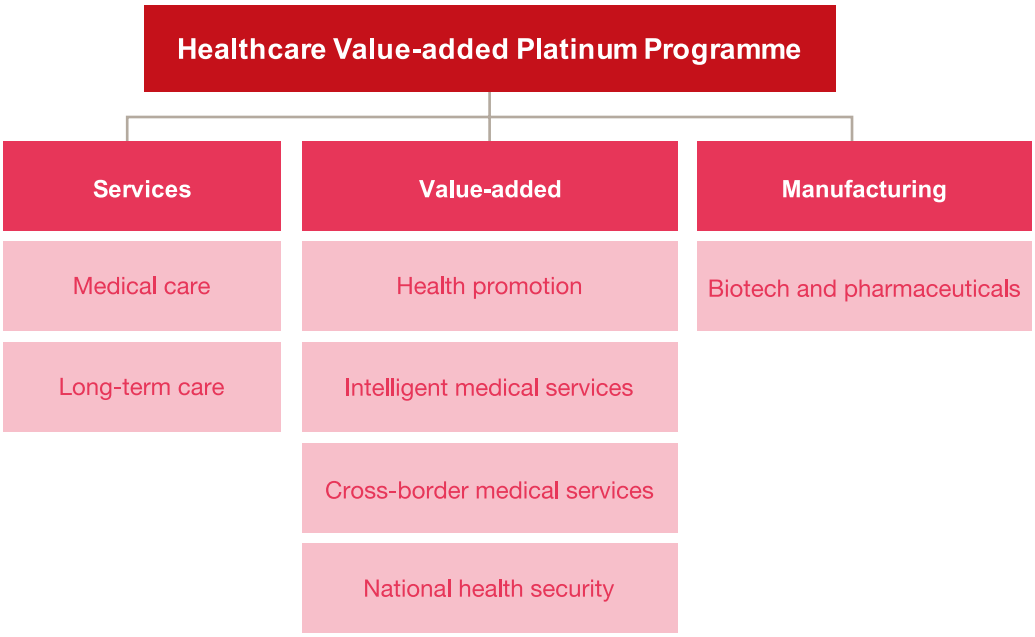
Figure 11: Taiwan's healthcare regulatory structure.



Source: Ministry of Health and Welfare, Taiwan.

Healthcare is one of Taiwan's six emerging industries that are expected to shape the future of the country's industrial landscape. In 2009, the government launched a Healthcare Value-added Platinum Programme (HVPP), with the aim of promoting and strengthening the healthcare industry's development in three key areas, as below. The HVPP has also played an integral role in the growth development of medical tourism.

Figure 12: Taiwan's Healthcare Value-added Platinum Programme.



Source: Department of Investment Services, Ministry of Economic Affairs, Taiwan.

A key policy priority for the MOHW is the establishment of a comprehensive care and support system for the elderly. Several new pieces of legislation are being developed. A draft Long-term Care Services Act is currently under legislative review, which when passed is expected to pave the way for implementation of a national system in 2015. The MOHW is drafting another bill to create a long-term care insurance system, but this has yet to be finalised and it is uncertain when it would be implemented.

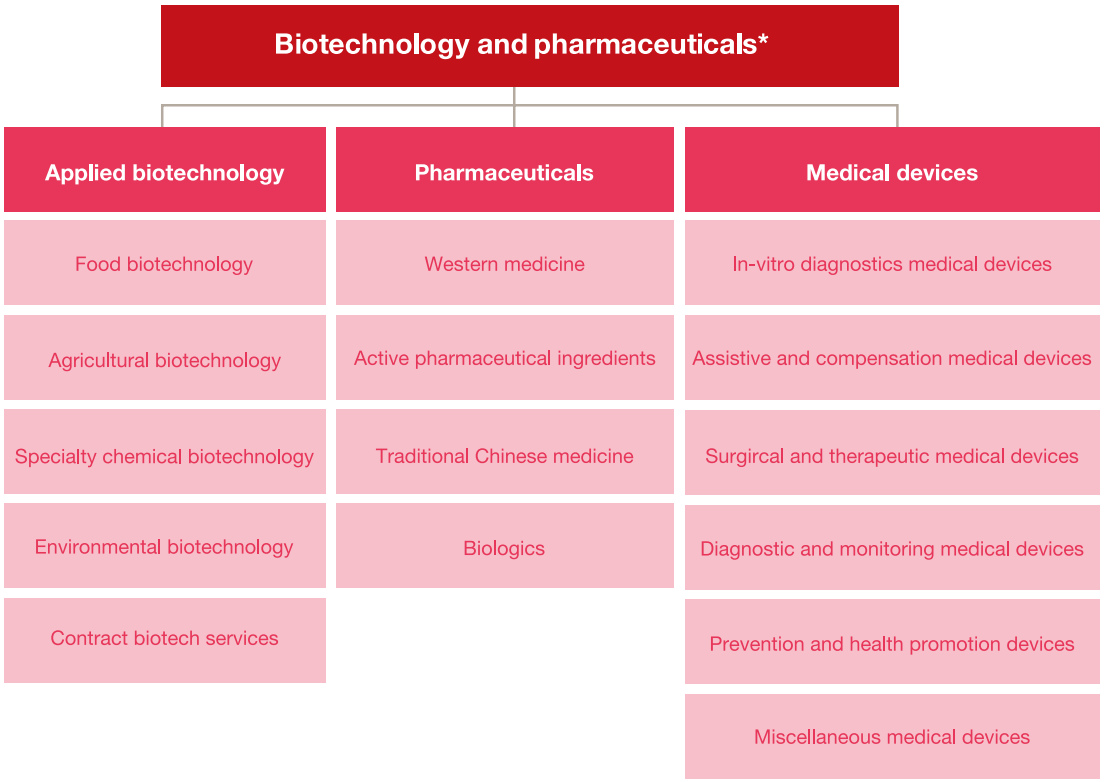
The MOHW is also active in adopting cloud computing to enhance patient-centred care. In 2013, it launched a cloud medication record system, known as "NHI PharmaCloud," which allows doctors and pharmacists to check patients' medication records online and so avoid duplicate prescriptions and potential health risks incurred by patient drug overuse. The MOHW is also developing an electronic health record database called "My Health Bank," which will allow people to download their medical records online.

Taiwan biotech, pharma and medical device industries

Taiwan has created a favourable environment for development of its biotech, pharma and medical device industries. Already in place is a highly-regarded clinical research infrastructure, a high-quality, low cost R&D and manufacturing environment, an abundant talent pool with capabilities in both fundamental and applied research as well as product development, and an industry culture that respects intellectual property.

The government has enacted several policies and laws to position biotech, pharma and medical devices as key priority industries for Taiwan in the 21st century. The Taiwan Diamond Action Plan for Biotech Take-off was launched in 2009 to strengthen the basic industrial structure. The second phase of the plan, renamed the Taiwan Biotech Industrialization Take-off Action Plan in 2013, promotes the development of new drugs, advanced medical devices and healthcare management services.

Figure 13: Scope of Taiwan's biotechnology and pharmaceutical industries.



** Taiwan uses the broad term 'biotechnology and pharmaceuticals' to describe the biotech, pharma and medical device sectors.*

Source: Biotechnology and Pharmaceutical Industries Promotion Office, Ministry of Economic Affairs, Taiwan.

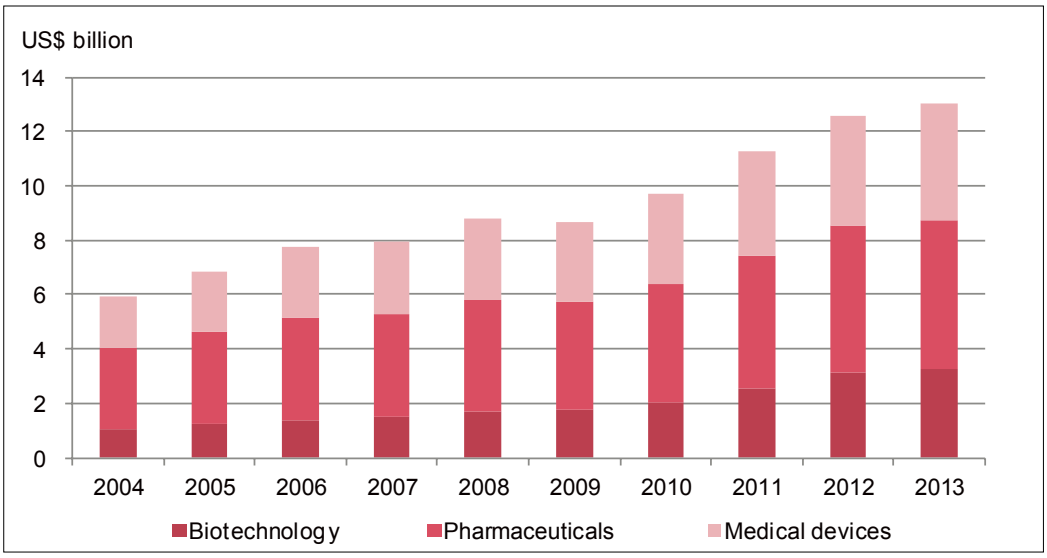
The table below highlights the current market status of Taiwan's biotech, pharma and medical device industries. Their combined domestic market demand totalled US$13.0 billion in 2013, of which the pharma industry represented the largest share at US$5.4 billion (41.7%), medical devices US$4.3bn (33.1%) and biotech US$3.3 billion (25.2%). Each of these industry sectors will be analysed in the following pages.

Figure 14: Current status of Taiwan's biotech, pharma and medical device industries.

Unit: US$ billion	Biotechnology		Pharmaceuticals		Medical Devices		Total	
	2012	2013	2012	2013	2012	2013	2012	2013
Revenue	2.5	2.6	2.7	2.8	3.7	3.9	8.9	9.3
No. of companies	450	490	350	350	705	761	1,505	1,601
Personnel	16,770	17,540	18,500	19,000	34,200	35,040	69,470	71,580
Export value	1.0	1.0	0.7	0.7	1.6	1.6	3.2	3.3
Import value	1.6	1.7	3.3	3.3	1.9	2.0	6.9	7.0
Import-export ratio	62:38	62:38	76:24	76:24	58:42	58:42	64:36	65:35
Domestic market demand	3.2	3.3	5.4	5.4	4.1	4.3	12.6	13.0

Source: 2014 Taiwan Biotechnology Industry White Paper, Ministry of Economic Affairs, Taiwan.

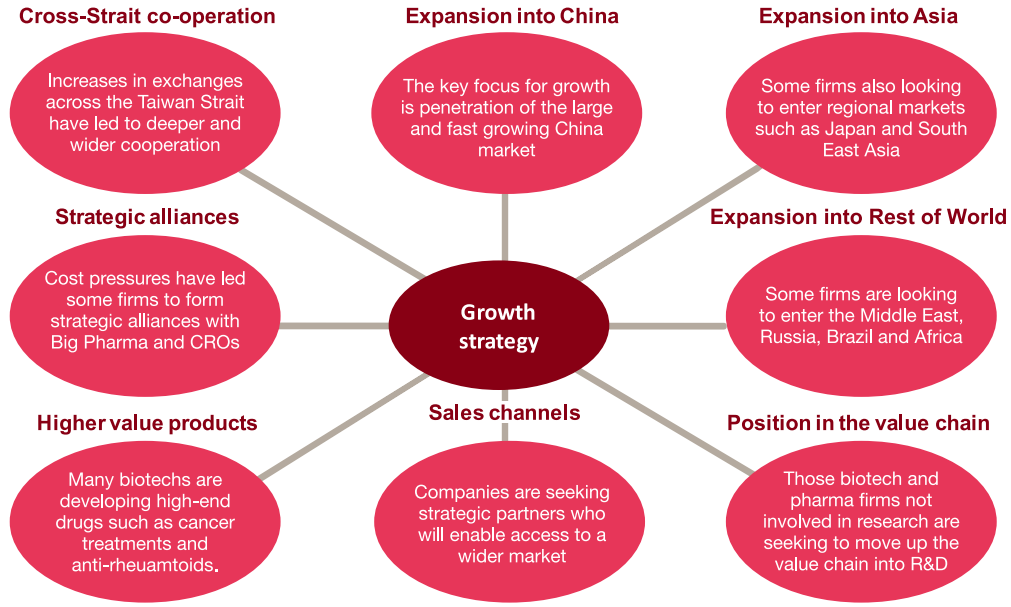
Figure 15: Market size of Taiwan's biotech, pharma and medical device industries, 2004-2013.



Source: Taiwan Biotechnology Industry White Papers 2005-2014, Ministry of Economic Affairs, Taiwan.

Because of a limited domestic market, Taiwanese companies generally look to form alliances with contract research organisations and pharma multinationals, develop high-end drugs, and expand into China, Asia and elsewhere, either through distribution partnerships, strategic relationships or acquisitions. Drug and medical-device makers are also taking advantage of the opportunities created by healthcare reforms around the world to expand overseas and increase the proportion of their export sales.

Figure 16: Growth strategies of Taiwan's biotechnology and pharmaceutical companies.



Source: PwC Taiwan.

China presents a big opportunity. Its production costs and large market size are attractive to Taiwanese manufacturers, though there are concerns around intellectual property protection. Taiwan is also well positioned to act as a bridge to China for foreign multinationals, while domestic firms look to also form collaborations with Chinese counterparts to take advantage of China's healthcare system reforms.

China has become Taiwan's biggest trading partner because of its geographic proximity, cultural similarities and common language. The relationship has deepened following their signing of an Economic Cooperation Framework Agreement in 2010, which gives Taiwanese enterprises preferential access to China's service market, including its private hospital sector. The two sides also signed a medical and healthcare cooperation agreement in 2010, which has led to increased collaboration on drug R&D.

Biotechnology

Taiwan's biotech industry is expanding steadily, supported by strong government commitment and private sector interest. The 2009 national plan for biotechnology development helped kick-start the domestic market, which almost doubled in size over the next five years to reach USD$3.3 billion in sales in 2013. The key areas of focus are food biotech, medical diagnostics, specialty biochemicals and agricultural biotech.

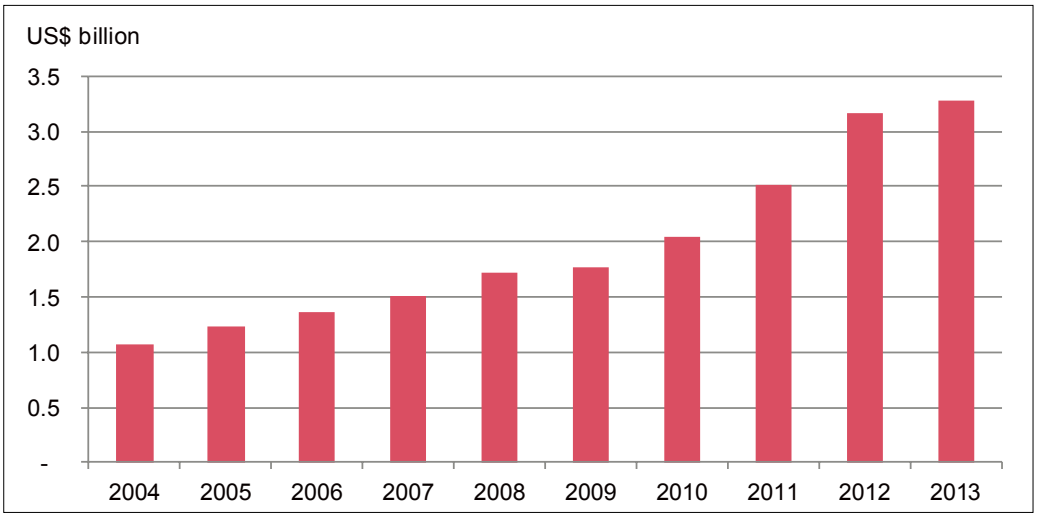
Although Taiwan's market size is relatively small, its growth momentum is strong. Key drivers for future growth include the government's continuing strong policy support, closer collaboration with China on new drug development, and the maturation of company pipelines and service offerings. Also, many of the more mature companies have begun to enter the public capital markets to raise funds for growth opportunities.

Figure 17: Status of Taiwan's biotechnology industry, 2004-2013.

Unit: US$ billion	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Revenue	1.0	1.2	1.3	1.5	1.7	1.8	2.0	2.3	2.5	2.6
No. of companies	240	253	268	294	320	380	405	402	450	490
Personnel	7,650	8,090	8,570	9,320	9,600	9,750	10,250	15,780	16,770	17,540
Export value	0.4	0.5	0.5	0.6	0.7	0.7	0.8	0.9	1.0	1.0
Import value	0.4	0.5	0.6	0.6	0.7	0.7	0.9	1.2	1.6	1.7
Import-export ratio	60:40	60:40	60:40	60:40	60:40	59:41	58:42	60:40	62:38	62:38
Domestic market demand	1.1	1.2	1.4	1.5	1.7	1.8	2.0	2.5	3.2	3.3

Source: Taiwan Biotechnology Industry White Papers 2005-2014, Ministry of Economic Affairs, Taiwan.

Figure 18: Taiwan biotechnology market by sales revenue, 2004-2013.



Source: Taiwan Biotechnology Industry White Papers 2005-2014, Ministry of Economic Affairs, Taiwan.

Market characteristics and trends

Taiwan has many of the conditions essential for building a successful biotechnology hub. These include the availability of a large talent pool, good medical and research infrastructures, and ample clinical trial experience focusing on Asia-prevalent diseases.

Other key draws for investors are a relatively transparent regulatory environment, strong government support, as well as an industry culture that respects intellectual property rights. Moreover, Taiwan's strategic location on the Pacific Rim and its strengthening ties with China make it an ideal biotech hub for the Asia region, as well as a springboard for companies looking to enter the large Chinese pharma market.

The increasing trend of cross-Strait regulatory harmonisation for new drug development offers significant benefits for Taiwan's biotech sector. It was announced in September 2014 that Taiwan and China had reached a consensus on cooperation in clinical tests of drugs, recognition of clinical data and data using for reference in drug inspection and registration. This will help accelerate the market clearance process for certain drugs and enable Taiwanese companies to gain faster entry into China.

The government is also pushing to make Taiwan a gateway and stepping stone for international partners to enter China. Its biotech R&D programmes are highly relevant to the Chinese market, focusing on diseases common in ethnic Chinese populations in China and elsewhere. As Taiwan has a solid reputation for well-run clinical trials, more multinationals may choose to conduct trials there if such trial data is recognised by China in future. This could in turn lead to greater clinical investment into Taiwan.

Among the biggest challenges for Taiwan's biotech industry is its fragmented infrastructure. Most domestic companies typically step in, or 'in-license,' at a certain stage of a drug's development, apply research to add value to the treatment, and then 'out-license' the resulting compound as early as possible to a pharma multinational, hopefully for a handsome profit. Instead of such R&D in bits and pieces, the government is encouraging the idea of 'translational' drug development, with the goal that the whole process from drug discovery to regulatory approval takes place in Taiwan.

Strong government support

Government policy support has been a key contributor to the growth of Taiwan's biotech industry. In 2007, Taiwan enacted the Biotech and New Pharmaceutical Development Act to provide various tax breaks and incentives to promote development. Two years later, the government launched its Diamond Action Plan for Biotech Take-off to strengthen the industry's basic structure. It has since established several biotech-focused science parks around Taiwan to give a further boost to the industry.

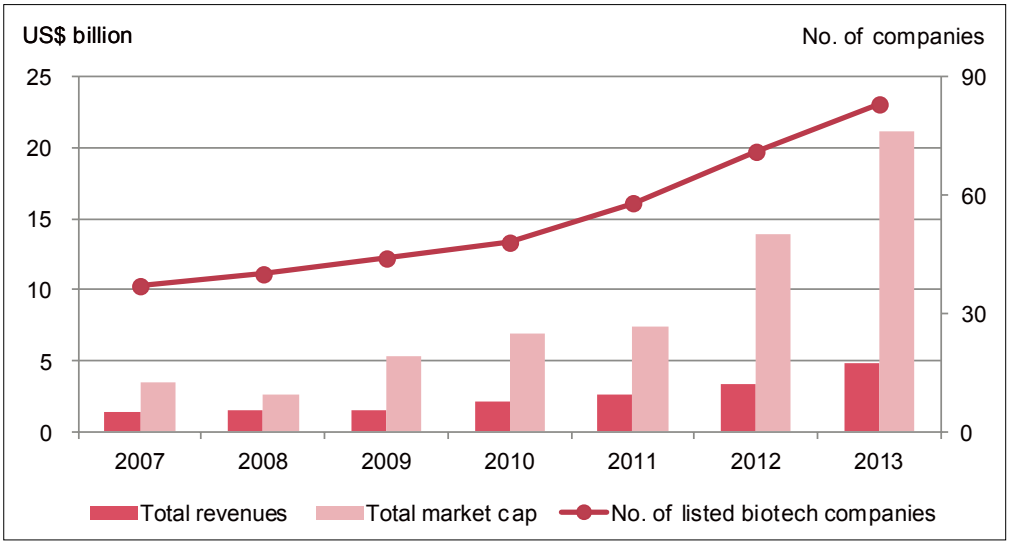
The government is now focused on building the capability of the biotech value chain in Taiwan. Its plan to create a National Biotechnology Research Park, to be completed in 2016, aims to facilitate translation of drug discovery results to clinical trials. Drug candidates that pass pre-clinical studies in the research park will be transferred to medical centres and other institutions for clinical trials. This is expected to induce a clustering effect and help accelerate the development of Taiwan's biotech industry.

Biotech funding issues

Because it can be difficult to find private funding for biotech firms in Taiwan, government financial support takes on special importance. The 2013 revised action plan for the biotech industry encourages the formation of small and medium biotech venture capital funds. The government's National Development Fund (NDF) also plays a support role and invests in individual projects directly. At the end of 2013, the NDF had invested a total of NT$12.4 billion (about US$400 million) in the biotech industry.

The government has also relaxed initial public offering rules to make it easier for biotech companies to raise funds through listing on Taiwan's stock exchanges. With the industry in the late incubation stage, the maturation of company pipelines is attracting investors looking for "the next big thing." The number of biotech firms listed in Taiwan increased from 37 in 2007 to 83 at the end of 2013, and their combined market capitalisation grew from US$3.5 billion to US$21.1 billion over the same period.

Figure 19: Taiwan biotechnology industry market capitalisation, 2007-2013.



Source: Taiwan Biotechnology Industry White Papers 2008-2014, Ministry of Economic Affairs, Taiwan.

Strong growth momentum in the biotech sector

Pharmaceuticals

Taiwan's pharmaceutical market was worth about US$5.4 billion in 2013 in terms of sales value. Prescription drugs (including patented and generic) for both outpatient and inpatient care, primarily delivered through hospitals, account for over 90% of the total pharma market. Due to widespread NHI reimbursement, the over-the-counter (OTC) segment is under-developed and represents less than 10% of the overall market.

Patented drugs account for about 70% of total prescription spending in Taiwan, but this share is set to decline slightly, under pressure from government policies promoting the use of cheaper generic products, as well as pending patent expirations. Some are manufactured locally, but the majority are imported from Europe, the US and Japan. Domestic firms mostly focus on generic drugs (30% of prescription spending), but are increasingly engaging in original R&D to move up the pharma value chain.

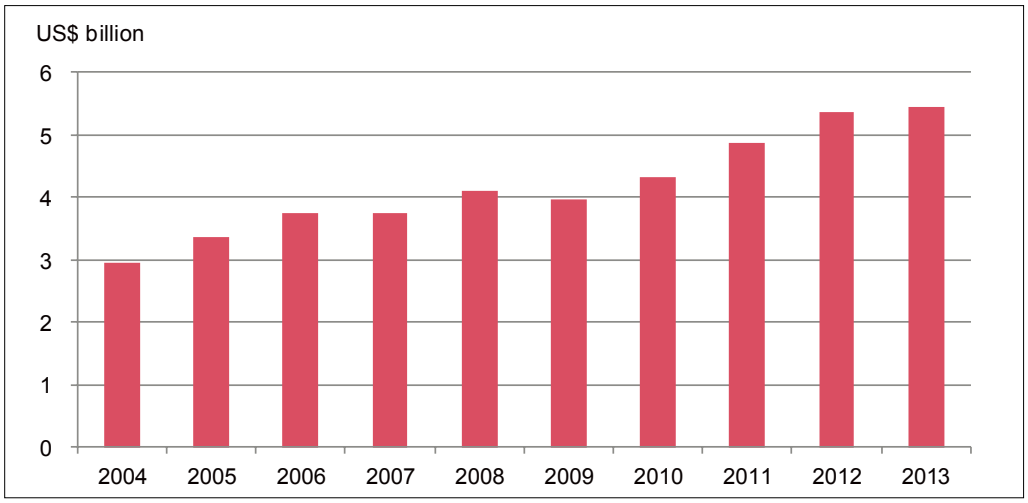
BMI forecasts pharmaceutical sales in Taiwan will grow at a CAGR of 6.2% (in US dollar terms) between 2013 and 2018, up from a 5.8% increase in the preceding five-year period. Taiwan's rapidly ageing population and the subsequent increased consumption of advanced and high-value medicine for the treatment of long-term chronic illnesses will result in higher demand for prescription drugs in the forecast period.

Figure 20: Status of Taiwan's pharmaceutical industry, 2004-2013.

Unit: US$ billion	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Revenue	1.8	1.9	2.0	2.1	2.2	2.1	2.3	2.5	2.7	2.8
No. of companies	414	419	368	321	320	367	370	400	350	350
Personnel	2,931	14,995	12,224	11,274	11,250	18,000	18,500	19,332	18,500	19,000
Export value	0.1	0.4	0.4	0.5	0.4	0.4	0.5	0.5	0.7	0.7
Import value	1.3	1.8	2.1	2.2	2.3	2.3	2.5	2.9	3.3	3.3
Import-export ratio	92:08	82:18	79:21	77:23	80:20	79:21	79:21	78:22	76:24	76:24
Domestic market demand	3.0	3.4	3.8	3.8	4.1	4.0	4.3	4.9	5.4	5.4

Source: Taiwan Biotechnology Industry White Papers 2005-2014, Ministry of Economic Affairs, Taiwan.

Figure 21: Taiwan pharmaceutical market by sales revenue, 2004-2013.



Source: Taiwan Biotechnology Industry White Papers 2005-2014, Ministry of Economic Affairs, Taiwan.

Market characteristics and trends

Healthcare and pharmaceutical needs also continue to rise in Taiwan as a result of universal access to and overuse of medical care services. People in Taiwan visit a doctor 15.7 times a year on average, higher than the OECD average of 5.9 times per year, and typically seek medical treatment in hospitals. In addition, the prescribing and dispensing functions are not separated in most hospitals and clinics in Taiwan, which therefore gives doctors both the incentive and ability to over-prescribe drugs.

Pharmaceutical drugs have accounted for around 25% of all medical costs in Taiwan since the introduction of the NHI, higher than the OECD average of 16%. To control drug spending, the government has conducted frequent price volume surveys, followed by substantial price cuts for both imported and domestically produced drugs. This has led to low drug prices and attracted much criticism from industry stakeholders.

To further control drug costs, the government encourages the use of generics in preference to their more expensive originals, which has advantaged local drugmakers. It also actively assists the domestic pharmaceutical industry to upgrade its manufacturing facilities. Moves to bring Taiwanese producers in line with the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) standards by end-2014 should help improve the quality of locally produced medicines.

Although Taiwan's market is relatively small and reliant on imports for high-end drugs, most pharma multinationals have a presence on the island. The majority of them only focus on sales and marketing, as they are discouraged from establishing manufacturing operations in Taiwan due to concerns about the government's drug pricing and reimbursement policies and intellectual property rights (IPR) protection. These issues are frequently raised in the annual lobbying papers of the American and European chambers of commerce in Taiwan, as well as by the Pharmaceutical Research and Manufacturers of America (PhRMA) in its Special 301 submission reports.

Industry concerns remain surrounding pharmaceutical patent protection in Taiwan. In particular, the lack of a patent linkage mechanism has resulted in several cases of generics reaching the domestic market while the original drug is still under patent. In response, in April 2014, the government established a task force to take steps to develop a system of patent linkage, similar to the U.S. Orange Book, for marketing approval of pharmaceuticals. At the same time, it agreed to study the extension of its data exclusivity provisions to cover new indications, new uses and biologic drugs.

Pricing and reimbursement

The NHIA controls drug pricing and reimbursement in Taiwan. It typically acts to reduce the price it is willing to reimburse for drugs that are to be distributed under the NHI scheme. Although prices are supposed to be fixed with reference to those for A10 countries (a basket of ten benchmarked developed markets), the price is usually set at the lower end of the scale. According to PhRMA, Taiwan has priced innovative drugs some 60% lower (on average) than in the A10 markets over the past three years.

Prior to implementation of the second-generation NHI, the NHIA adjusted drug prices on a biennial basis through price volume surveys. The last one was conducted in December 2011 and led to price cuts totalling about US$500 million for 6,800 drugs. Following the introduction of revised NHI legislation in 2013, drug prices are to be adjusted annually using an alternative Drug Expenditure Target (DET) system.

The NHIA is currently running a two-year trial of the DET system, under which it will negotiate with industry to set an annual target for pharmaceutical expenditure using the previous year's drug expenses as a baseline and a nominal growth rate to account for increasing costs and demand. If actual spending for the year exceeds the set target, the NHIA will adjust drug prices for the next year so as to control expenditure.

Taiwan's reimbursement system further complicates matters by allowing healthcare providers to claim full-price reimbursements on medicines and medical items sold to them at discount. This provides additional income for hospitals and encourages them to demand significant discounts from drugmakers. Generic drugmakers may offer discounts as high as 50%, whereas brand manufacturers typically offer a 5-10% discount. Also, the price gap between generic and originator drugs has steadily narrowed.

Regulatory and policy developments

Taiwan has a robust pharmaceutical regulatory regime. The Taiwan Food and Drug Administration (TFDA) handles the development of drug production standards and regulations in line with international norms. The basis for market regulation in Taiwan is the Pharmaceutical Affairs Act. The law has been amended a number of times over the past few years, with most changes taking place to facilitate government policy aimed at encouraging international companies to conduct clinical trials in Taiwan.

The TFDA must approve all drugs imported into Taiwan before they can be marketed. Its registration approval process for new drugs is considered lengthy and slow by multi-nationals compared with other developed countries. In response, the TDFA has been working to simplify and shorten the process in line with international standards. For instance, in 2013, it established a fast-track approval process for certain imported drugs that cuts three to six months off the current approval process for new drugs.

Taiwan became a member of PIC/S in 2013. Membership is regarded as indication of the maturity of a country's pharmaceutical industry, and enables Taiwan and the health authorities of the 45 other member countries (as of December 2014) to mutually recognise the certification of pharmaceuticals. The PIC/S standard will also help boost Taiwan's standing as a pharmaceutical manufacturing hub in the Asia region.

Taiwan is also working closely with China on pharmaceutical issues. In December 2010, they signed a medical and healthcare cooperation agreement, which has ushered in a new era of partnership and cooperation, as they move towards harmonisation of regulations and clinical trials. Under the Cross-Strait Pharmaceuticals R&D Scheme, a joint initiative between the TFDA and its Chinese counterpart, new drug applications can be evaluated and approved simultaneously in both Taiwan and China.

Medical devices

Taiwan's medical device market was worth about US$4.3 billion in terms of sales value in 2013, growing by a CAGR of 7.9% (in US dollar terms) between 2008 and 2013. Further steady growth is expected in the coming years, on account of the increasing elderly population and subsequent rise in demand for healthcare products and services. BMI expects the Taiwan market to rise by a CAGR of 8.6% in the 2013-2018 period.

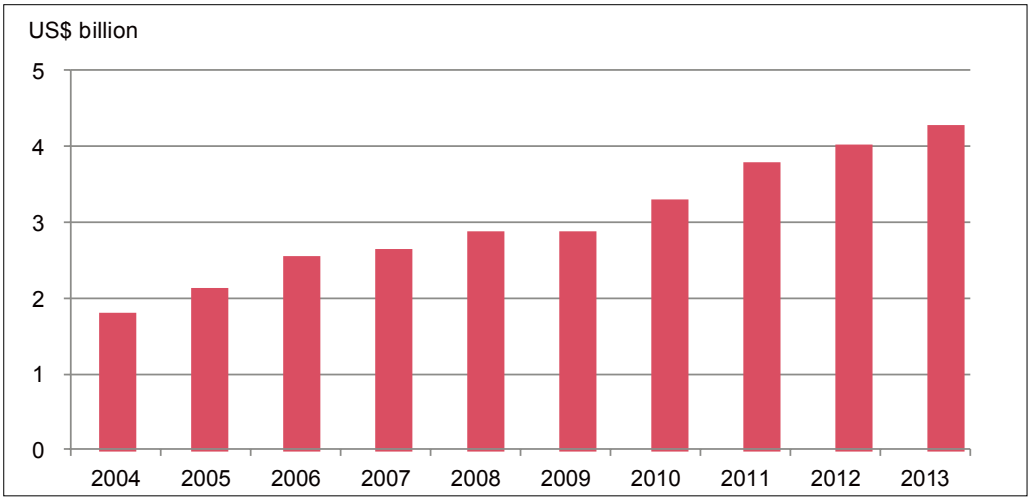
Because of the limited size of Taiwan's market, domestic medical-device makers rely on exports for most (over 60%) of their sales. The top three export items in 2013 were blood glucose meters and strips, mobility aids (including electric wheelchairs and scooters) and contact lenses. At the same time, Taiwan is dependent on imports for some 60% of its requirements, mostly for high-end medical devices and equipment used in hospitals and produced by companies from advanced Western nations and Japan.

Figure 22: Status of Taiwan's medical device industry, 2004-2013.

Unit: US$bn	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
Revenue	1.5	1.8	2.1	2.3	2.5	2.5	2.9	3.4	3.7	3.9
No. of companies	480	484	500	501	544	553	580	626	705	761
Personnel	14,895	15,000	16,350	20,200	21,923	22,900	25,800	30,250	34,200	35,040
Export value	0.7	0.8	0.9	1.0	1.0	1.0	1.3	1.4	1.6	1.6
Import value	1.1	1.2	1.4	1.4	1.5	1.5	1.7	1.9	1.9	2.0
Import-export ratio	52:48	54:46	58:42	58:42	65:35	66:34	57:43	59:41	58:42	58:42
Domestic market demand	1.9	2.2	2.6	2.7	3.0	2.9	3.4	3.8	4.1	4.3

Source: Taiwan Biotechnology Industry White Papers 2005-2014, Ministry of Economic Affairs, Taiwan.

Figure 23: Taiwan medical device market by sales revenue, 2004-2013.



Source: Taiwan Biotechnology Industry White Papers 2005-2014, Ministry of Economic Affairs, Taiwan.

Market characteristics and trends

There are more than 700 medical device-related companies in Taiwan, most of which are small to medium OEM/ODM enterprises. They mainly produce mid- and low-level medical equipment, with 90% of them involved in manufacturing, including contract manufacturing for multinationals. The close collaborative relationship with overseas customers has grown from the supply of components to a level where Taiwan is now a producer of upstream devices and a key link in the global medical device supply chain.

While the global medical device industry mainly specialises in hospital-based diagnosis and treatment products, Taiwan focuses more on homecare and consumer products, which involve a medium to high level of technology and fall within what regulators define as the Class II category. Such devices, though typically directly related to human health, are not subject to strict controls and regulations as applied to Class III, which usually involve more sophisticated technology and are mostly marketed to hospitals.

As for Class I products, these are generally low-value basic medical equipment such as latex gloves and syringes, and are not subject to specific controls or regulations. Taiwan previously specialised in making items in this category until the late 1990s, but production since then has largely moved to China, though a substantial proportion of the production activity there is accounted for by Taiwan-invested companies.

In recent years, the Taiwan government has endeavoured to move the domestic industry up the value-added chain, by offering tax credits and R&D incentives to encourage the development of more advanced products. It has also established a biomedical cluster at the Kaohsiung Science Park in southern Taiwan to focus on the production of medical equipment. And in 2012 it launched an initiative to nurture and promote industry growth in five areas: kidney dialysis care, respiratory care, in vitro diagnostic technology, microsurgery and high-end dental device technology.

Regulatory and pricing developments

Taiwan regulates both medical devices and pharmaceuticals under the same legislation, which differs from most advanced countries. The TFDA plans to establish a separate regulatory framework governing medical devices in the near future. Also, as an active member of the AHWP (Asian Harmonization Working Party), Taiwan has been implementing changes to bring its rules and regulations on medical devices more in line with the IMDRF (International Medical Device Regulators Forum) framework.

The TDFA is the controlling authority in Taiwan for medical devices. Pre-market approval is necessary for all classes of devices. Industry players complain about the length of time it takes to obtain a product license in Taiwan, which is about one to two years, depending on the device and its classification. Acknowledging this, the TFDA is working to simplify documentation requirements and shorten the registration process.

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

Another concern is new guidelines introduced in 2013 on what medical devices may enter the Taiwan market as self-pay items. All medical devices must apply for reimbursement review, which can take up to 18 months to process. While waiting for approval, patients may pay for a device out-of-pocket, but only if the NHIA has assigned a self-pay code, which alone takes some three to 12 months. Any medical devices that fail to obtain a self-pay code are not permitted to be sold in the Taiwan market.

Appendix: Asia-Pacific comparison

Although Taiwan is widely recognised as a leader in universal healthcare access, it is a not a member of the World Health Organisation (WHO), due to its complicated political relationship with China. As the WHO's annual statistics on the health of the world's people excludes Taiwan, this appendix benchmarks a selection of key health data to show where Taiwan stands in comparison to other health systems in Asia-Pacific.

Health status and demographics

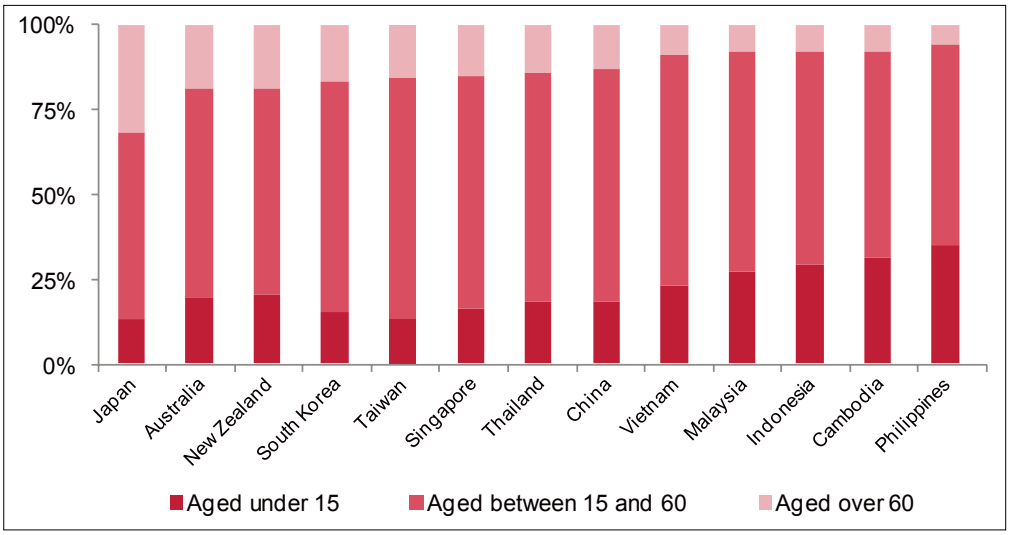
Taiwan's wrinkles are starting to show. It has the lowest fertility rate (1.1 child per woman) in the Asia-Pacific region, as well as the second lowest population growth rate (0.3%) behind Japan (0.1%). In all, Taiwan has the fifth highest population proportion of elderly citizens aged over 60 (16%) among neighbouring Asia-Pacific countries, after South Korea (17%), New Zealand (19%), Australia (19%) and Japan (32%).

Figure 24: Key demographic statistics for Asia-Pacific economies (2012).

Territory	Total population (million)	Population growth (%)	Total fertility rate (per woman)	Infant mortality rate	Healthy life expectancy at birth	Age structure <15	Age structure 15-60	Age structure 60+
Australia	22.3	1.6	1.9	4	83	19	62	19
Cambodia	14.1	1.6	2.9	34	72	31	61	8
China	1,341.3	0.6	1.7	12	75	18	69	13
Indonesia	239.9	1.4	2.4	26	71	29	63	8
Japan	126.5	0.1	1.4	2	84	13	55	32
Malaysia	28.4	1.8	2.0	7	74	27	65	8
New Zealand	4.4	1.2	2.1	5	82	20	61	19
OECD	1,233.7	0.7	1.7	4	80	…	…	22
Philippines	93.3	1.8	3.1	24	69	35	59	6
Singapore	5.1	2.5	1.3	2	83	16	69	15
South Korea	48.2	0.5	1.3	3	81	15	68	17
Taiwan	**23.2**	**0.3**	**1.1**	**4**	**79**	**13**	**71**	**16**
Thailand	69.1	0.5	1.4	11	75	18	68	14
Vietnam	87.8	1.0	1.8	18	76	23	68	9

Source: WHO; OECD; Ministry of Health and Welfare, Taiwan.

Figure 25: Age structure of the population in Asia-Pacific economies (2012).



Source: WHO; Ministry of Health and Welfare, Taiwan.

Healthcare resources

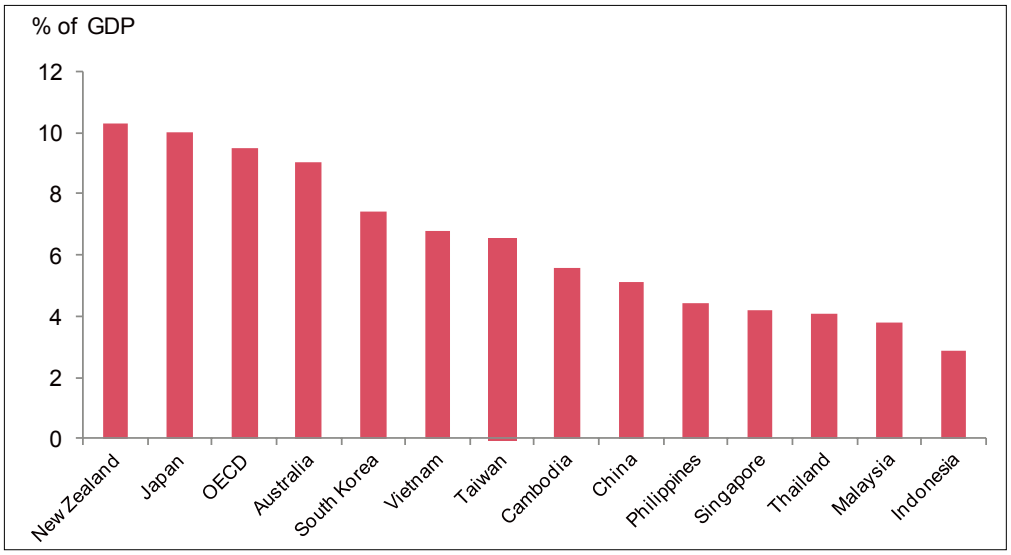
Taiwan's spending on healthcare at 6.5% of GDP is the sixth highest in Asia-Pacific but lower than the OECD average of 9.3%. It has the third largest number of hospital beds per 1,000 population (5.7) after Korea (10.3) and Japan (13.7), and the second highest average length of hospital stay (9.9 days) behind Japan (18.2 days), which are all also above OECD average levels. By contrast, Taiwan's per capita number of doctors and nurses is below OECD levels but on a par with other developed economies in Asia.

Figure 26: Key health resource indicators for Asia-Pacific economies (2012).

Territory	Total health expenditure (% of GDP)	Hospital beds per 1,000 population	Average length of hospital stay (days)	Doctors per 1,000 population	Nurses per 1,000 population
Australia	9.0	3.9	5.1	3.2	10.7
Cambodia	5.6	0.7	5.0	0.2	0.8
China	5.1	3.8	8.6	1.5	1.5
Indonesia	2.9	0.9	4.3	0.2	0.1
Japan	10.0	13.7	18.2	2.3	11.5
Malaysia	3.8	1.9	4.4	1.2	3.3
New Zealand	10.3	2.3	5.5	2.7	10.9
OECD	9.3	4.8	7.2	3.2	8.8
Philippines	4.4	5.0	…	1.1	4.3
Singapore	4.2	2.0	4.7	1.9	6.4
South Korea	7.4	10.3	6.9	2.1	5.0
Taiwan	**6.5**	**5.7**	**9.9**	**2.0**	**5.1**
Thailand	4.1	2.1	4.2	0.4	2.1
Vietnam	6.8	2.0	6.7	1.2	1.1

Source: WHO; OECD; Ministry of Health and Welfare, Taiwan.

Figure 28: Healthcare expenditure for Asia-Pacific economies (2012).



Source: WHO; OECD; Ministry of Health and Welfare, Taiwan.

About PwC

Few industries are as important to society as health; it connects us all.

Health matters to society and it matters to PwC. Imagine the power of 184,000 people in 157 countries worldwide, including 2,700 in Taiwan, with a common purpose—building relationships that create value for you and your business. This is PwC.

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

Assurance services

We provide accounting, auditing and capital market services to a broad range of health-related organisations in Taiwan, including helping emerging and early stage companies prepare for IPOs as well as obtaining private equity or venture funding. Our aim is to deliver services that support your ability to provide stakeholders with accurate and understandable financial and operational information about your business.

Tax services

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

Advisory services

We can assist you in all aspects of the M&A deals process, including buy-sell strategies, due diligence, valuation analysis and negotiating with transaction parties. We can also help your organisation to work smarter and grow faster, through providing IT solutions to drive process improvements, and making sure your human resource operations are delivering the best value for you, in line with your broader business objectives.

To have a deeper conversation about Taiwan's healthcare sector, please contact:

Lily Wong
Health Industries Leader & Advisory Partner
+886-2-2729-6703
lily.wong@tw.pwc.com

Audrey Tseng
Assurance Partner
+886-2-2729-5219
audrey.tseng@tw.pwc.com

Elliot Liao
Tax Partner
+886-2-2729-6217
elliot.liao@tw.pwc.com

Follow PwC Taiwan on Facebook for the latest on our professional insights and events

pwc 資誠