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HEALTH TECHNOLOGY INDUSTRY

IN AUSTRALIA

FLANDERS INVESTMENT & TRADE MARKET SURVEY

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HEALTH TECHNOLOGY INDUSTRY

IN AUSTRALIA (2019)

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1. FOREWORD

The aim of this paper is to provide an overview of the health system and the health-related technologies in Australia, outline the key factors and assess business opportunities for Belgian companies in approaching the Australian market.

This paper attempts not to provide a comprehensive coverage of all areas of health technology, but to briefly examine some of the more significant developments within the industry, focusing on three major areas: biotechnology, medical devices and digital health.

With technological progress resulting from research in materials, information technology and biotechnology, the healthcare system will continue to improve.

The information included in this document were collected by Ms Sara Khancheh Zar, during her internship at FIT Melbourne (July – September 2019). The contents were structured in a way to provide an easy-to-read and brief overview.

Mr Luca Bottallo, Head of Post, thanks Ms Khancheh Zar and congratulate her on her ability and commitment.

If not specified \$ stands for Australian dollar.



- a quality of life that is rated the seventh highest in the world.

Accordingly to the latest official data, Australia spent nearly \$181 billion on health in 2016–17:

- 41% by the Australian government
- 27% by State (5) and Territory (2) governments
- 17% by individuals (for products and services that aren't fully subsidised or reimbursed)
- 9% by private health insurers
- 6% by non-government organisations

Health spending is about 10% of gross domestic product. This means \$1 in every \$10 spent in Australia was related to health.

2.2 DEMOGRAPHIC FACTORS

The Australian population counts 25.2 million people with a clear growing trend (in 2017 the Australian population grew by 1.6% partially due to immigration, with the State of Victoria and its capital city Melbourne presenting the highest rate).

DECEMBER KEY FIGURES

PRELIMINARY DATA	Population at end Dec qtr 2018 '000	Change over previous year '000	Change over previous year %
New South Wales	8 046.1	123.8	1.6
Victoria	6 526.4	139.4	2.2
Queensland	5 052.8	89.9	1.8
South Australia	1 742.7	14.6	0.8
Western Australia	2 606.3	24.0	0.9
Tasmania	531.5	6.5	1.2
Northern Territory	245.9	-1.0	-0.4
Australian Capital Territory	423.8	7.6	1.8
Australia(a)	25 180.2	404.8	1.6

(a) Includes Other Territories comprising Jervis Bay Territory, Christmas Island, the Cocos (Keeling) Islands and Norfolk Island.

Even if Australia is a vast geographical area, it is important to notice that 85% of Australian population lives in urban areas, with 70% living in capital cities. This demographic factor is of importance since people living in remote locations may encounter difficulties when in search for medical treatment.

In 2040 significant ageing of the population is expected as consequence of two simple factors: a) Australian families are, on average, having less children, b) longer life expectations. An older population implies a higher demand of appropriate health care which can be facilitated by innovation in health technology.

Although Australians are living longer, they are also increasingly suffering from chronic disease. 50% of Australians are estimated to have at least 1 of 8 selected common chronic disease conditions: cancer, cardiovascular disease, mental health conditions, arthritis, back pain and problems, chronic obstructive pulmonary disease, asthma and diabetes.

3. CURRENT STATUS OF HEALTH TECHNOLOGY IN AUSTRALIA

Health technology is defined by the World Health Organization as the "application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of lives". Note that in this paper, the term 'technology' includes specific tools (e.g. a syringe, a drug, a diagnostic reagent), methods for collecting and processing information (e.g. health informatics), methods for creating knowledge (e.g. clinical trials, systematic reviews of evidence), machinery (e.g. X-ray machine, syringe driver) and assemblages of machinery and expertise (e.g. cardiac catheter lab, hospital).

According to "The 2018 Fact Book Medical Technology", published by the MTAA (Medical Technology Association of Australia), in the last 20 years Australia has seen a 25% decline in annual mortality, 25% decline in disability rates, 56% reduction in hospital bed days and an increase in life expectancy by 4.6 years, which can be partly attributed to health technology.

Sectors like biotechnology, medical technology and digital health have all made significant contributions to improving the health of Australians.

3.1 LOCAL MARKET

3.1.1 Size

The Australian healthcare sector is not short of innovation. In a single year, around 10,000 digital health apps are added to the app store, almost as many pharmaceutical research papers are published by academic journals, and the Australian medical technology industry is expected to gross over ten billion dollars.

Commercial activity across the sector has seen solid growth across most metrics since 2016 (growth in number of current companies, capital raised, and market capitalisation of listed companies).

Since 2018, the sector added \$4.9 billion in Gross Value Added (GVA) to the Australian economy, the same contribution as in 2016. The sector also supported a total of 70,000 industry and research jobs in 2018 (8,000 added jobs since 2016; the broader life sciences sector employs more than 243,000 people). There has been a 2% per annum (p.a.) increase in the total number of medical technologies, biotechnology and pharmaceutical (MTP) companies since 2016, and a 34% increase in the ASX - Australian Securities Exchange market capitalisation (\$129 billion in November 2018) of listed MTP companies (135 in November 2018) from 2017 to 2018. Manufacturing exports is valued at \$6.5 billion in 2018 (from \$5.2 billion in 2016), now the 9th most valuable export sector for Australia.

According to MTPConnect, underlying R&D activity across the health technology sector has seen strong growth. Total publications have grown by 4% p.a. since 2016, with the share of publications involving industry collaborations remaining steady at 3%. The estimated number of companies undertaking

Following table provides insight in how Australia compares to other markets like the UK and Japan.

	AUSTRALIA	UNITED KINGDOM	JAPAN
Total healthcare spending	\$137 billion	\$252 billion	\$469 billion
Healthcare expenditures total (% of GDP)	9.4%	9.1%	10.2%
Healthcare expenditures per capita	\$6031 (USD)	\$3935 (USD)	\$3703 (USD)
Expenditures on healthcare	Government: 67% Private: 33%	Government: 83% Private: 17%	Government: 84% Private: 16%
Number of hospital beds	3.9 per 1000 people	2.9 per 1000 people	13.7 per 1000 people
Age distribution	0-14 years: 18% 15-64 years: 67% 65 years and over: 15%	0-14 years: 17% 15-64 years: 65% 65 years and over: 18%	0-14 years: 13% 15-64 years: 60% 65 years and over: 27%

3.1.2 Megatrends in the Australian health technology sector

These megatrends are the overarching social, economic, environmental, technological and geopolitical forces that will change existing business models and present opportunities and challenges for organizations.

Megatrends can be divided into seven categories:

1. Digital evolution

There will be a significant shift in how we exchange and process the significant amounts of data generated daily. Standardisation of data sharing will accelerate the development of new technologies and treatments that target individuals and the wider health system, particularly as artificial intelligence-based solutions become increasingly sophisticated. The upside will be improved efficiency for everything from R&D to patient-care coordination. Cybersecurity will be a growing challenge that will need to be addressed as more data is exchanged.

Data standardisation, AI and cybersecurity need to be central concerns for the health technology sector if it is to take full advantage of the digital world. There is an opportunity for agile countries to gain global advantage by setting and adopting global best practice standards around the rapid development and validation of digitally enabled health technologies and by developing the use of de-identified health datasets in healthcare research and practice. Fully integrated systems will allow continuous improvement in the health technology sector and in healthcare services more broadly, and ensure Australia keeps pace with the global digital frontier.

2. Consumer control

Technology and information access are empowering patients to manage their healthcare more actively. Consumers are also increasingly aware of issues that impact their general wellbeing, such as sleep, mental health and nutrition, etc. As such, there will be growing demand for products and services that focus on prevention and enable the consumer to be more actively involved in the management of their health.

Patients will be able to track their health status via personal health records, wearable sensors and in-home monitors, gathering information that allows them to contribute more actively to healthcare decisions that concern them.

This trend will see a change from the historical model of healthcare provision, based on consultation with medical specialists, to one where medical technology is part of a consumer-driven, consumer-focused, digitally enabled ecosystem. Opportunities exist for Australia to build advanced clinical product development systems that support consumer-driven decisions and consumer-responsive products and services.

3. Healthy ageing

Focus on “healthy ageing centres” to maintain good health for as long as possible and increase the healthy lifespan. The WHO recently implemented an extension code for ageing-related diseases, an acknowledgement that ageing is a disease and hence can be treated. There is often assumption that ageing will lead to increased cost burden, but economic modelling by Deloitte Access Economics has shown that the health, societal and economic benefits of therapeutic interventions in an ageing population are significant, even greater than those of eliminating an entire disease.

This megatrend presents opportunities for new products and services that target healthy living and the prevention of diseases, rather than just treatment. It is closely related to the chronic burden and consumer control megatrends. Solutions for healthy ageing will include digital devices, sensors, and novel therapies, and will require companies to understand and respond to consumer needs effectively. Developing solutions will also require greater input from the social sciences and anthropology.

4. The chronic burden

Between 2015 and 2030, the proportion of the population aged 60 or over is projected to grow by 56%. Modern medical and pharmaceutical technology allows us to manage chronic disease and live longer than ever before but comes at an ever-increasing cost to the public health system. Globally, health systems face the challenge of finding cost-effective models to cope with longer lifespans and maximise health and wellbeing at all ages.

In recent years, mental health conditions such as depression and anxiety are becoming increasingly prevalent. Mental health conditions impact Australians of all ages, and it is estimated that nearly half of all Australians will experience a mental health condition at some point in their lifetime. The management of mental health will require a consumer-centric approach, and a focus on prevention as well as treatment.

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This trend places significant pressure on the health technology sector. The public may demand new technologies, but access will be determined by governments' and healthcare providers' judgements about the economic sustainability of those technologies. Sector participants need to work with governments and healthcare providers to make sure research priorities and new technologies improve population health outcomes in a more cost-effective manner.

5. Precision healthcare

Advances in science and technology are enabling more precise healthcare solutions. Targeted pharmaceuticals, biologicals and personalised medical technologies will be delivered that provide improved outcomes for cohorts of patients. The technologies advancing this trend include genomics, synthetic biology, gene- editing technologies, cell therapies, computational biology, medical imaging, 3D printing, data mining, and artificial intelligence.

Biosensors are already providing clinicians and patients with real-time personalised data, regardless of location. In 2014, health wellness monitoring applications accounted for 66.3% of biosensor revenue globally.

The growing trend for precision healthcare solutions will impact on the sector's supply chain, with an increasing focus on point-of-care optimisation. Real-time measurement and assessment of individual health will create demand for product and service providers that can offer integrated precision solutions, rather than single best-in-class products. A key implication for Australian developments is navigating the regulatory process in such a way that reimbursement for products is achieved. There will be a need for an innovation-oriented regulatory environment (adaptive regulation) and the development of novel business models.

6. Value-based health care

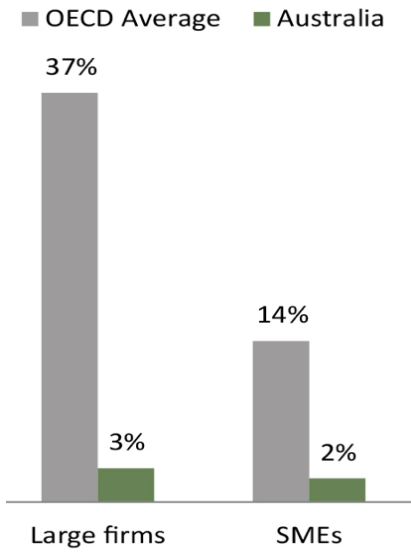
The concept of value-based healthcare, where patients' health outcomes drive the choice, delivery and reimbursement of therapies, has been around for almost a decade. The rise of precision medicine combined with the rising cost of traditional fee-for-service approach to healthcare is driving a paradigm shift towards this new patient-centric model.

This megatrend has enormous implications across multiple parts of the healthcare value chain. For example, the regulatory process for approving and reimbursing drugs and devices will need to adapt from the current volume-based approach to an outcome-based approach. There will need to be greater coordination among sector participants in the delivery of care and more efficient capturing of value delivered.

7. Integrated care models

Models for the delivery of healthcare are evolving to better address the context and specific needs of the patient. These integrated models reflect the whole of a patient's care needs, from prevention through to





Australia shares these challenges with countries around the world. According to the 2019 Global health care sector outlook, a study by Deloitte Australia, global health care sector issues include the creation of financial sustainability, improving access and affordability, adapting to changing consumer needs, cyber security, and investing in digital innovation.

<https://www2.deloitte.com/au/en/pages/life-sciences-and-healthcare/articles/global-health-care-sector-outlook.html>

4. SECTOR PARTICIPANTS

4.1 GOVERNMENT

Prevention of illness is a high priority of the Australian government, with several programs such as vaccination, public health warnings about smoking and AIDS, public education campaigns on nutrition and exercise, and public awareness campaigns regarding heavy drinking and illicit drugs. The Australian government usually funds most of the spending for medical services and subsidised medicines.

For a comprehensive overview of the healthcare system, please click the following weblink:

<https://www.health.gov.au/about-us/the-australian-health-system>

Since healthcare was faring well in a number of state budgets in 2018, the Federal Budget announced that billions of dollars will be injected into designing, developing and modernising healthcare nation-wide. With the government set to deliver [more than \\$30 billion in additional public hospital funding](#) under a five-year National Health Agreement, Australia is set to see a boom in hospital infrastructure development with funding increasing for every state and territory.

To meet previously mentioned challenges, the Australian government is investing in multiple initiative and organisations.

Medical research and technological innovation through the [Medical Research Future Fund](#) (MRFF) will see more innovations developed, tested and made available for Australians in all areas of health care. [MRFF priorities \(2018-2020\)](#) focus on consumer driven research, innovation in public health technologies, translational research infrastructure, and clinical researcher capacity. These priorities are addressed by providing research grants and extensive investment.

The Department of Health aims to improve health services, treatments and products, with a great focus on health records. Australia has a secure online health record system called [My Health Record](#): having a My Health Record account means that important health information including allergies, medical conditions and treatments, medicine details and scan reports can be accessed through one system. This technology also helps doctors and patients in regional, rural and remote areas.

The Department of Health supports the following initiatives with regard to health technology:

- The [Australian Digital Health Agency](#) is responsible for national digital health services and systems, with a focus on engagement, innovation and clinical quality and safety. They focus on putting data and technology safely to work for patients, consumers and the healthcare professionals who look after them.
- The Practice Incentives Program eHealth Incentive (ePIP) program encourages general practices to use the latest developments in digital health technology. This helps improve the administration processes and patient care.

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4.3 LABS & MEDICAL RESEARCH INSTITUTES

In Australia medical researchers are investigating a wide range of areas affecting human health outcomes, including public health, genomics, bionics and biomaterials, cancer, cardiovascular disease, mental health, indigenous health, stem cells and tissue engineering.

Australia’s Medical Research Institutes are well placed to achieve high level of research impact as their research is focused on improving health outcomes and are closely linked with clinical and health services. Primarily based on hospital campuses, Medical Research Institutes have a distinct and vital role in the health and medical research sector, providing a direct interface between laboratory-based research and clinical practice.

With a combined annual turnover of over \$1 billion, as non-profit organisations, Medical Research Institutes receive a large proportion of their research funding through competitive grants for research projects—primarily through the federal government’s National Health and Medical Research Council (NHMRC).

The [Association of Australian Medical Research Institutes](#) (AAMRI) is the peak body, with 52 member organisations working on a broad spectrum of human health issues such as preventive health, chronic disease, mental health, immunology and Indigenous health. Their research ranges from fundamental biomedical discovery through to clinical research and the translation of research findings from bench to bedside.

4.4 CSIRO

As an independent Australian federal government agency responsible for scientific research, the [Commonwealth Scientific and Industrial Research Organisation](#) (CSIRO) runs more than 50 sites across Australia and in France, Chile and the United States, employing about 5,500 people. Its research focuses also on health sciences, with research initiatives including drug discovery and development, diagnostics, therapeutic delivery, functional foods, bioinformatics, and biomaterials and tissue engineering. The CSIRO has identified commercial opportunities in each of these areas and conducts multiple research projects. It often undertakes research in partnership with industry players and universities, with the view to increase acceleration and improve commercialization in the health technology sector.

4.5 AUSBIOTECH

[AusBiotech](#) is a leading Australia’s life sciences organisation, working on behalf of members for more than 30 years to provide representation and services to promote the global growth of the Australian life sciences industry. AusBiotech is a network of over 3,000 members in the life sciences, including therapeutics, biotechnology, medical technology (devices and diagnostics), digital health, food technology and agricultural sectors.



Commonwealth legislation and guidelines. NHMRC invests across the four pillars of health and medical research: biomedical, clinical, public health and health services. [Research grants](#) administered by the National Health and Medical Research Council (NHMRC) are the second largest area of spending for the Australian Government in science and research.

The following table indicates the amount of funding that NHMRC received from the MRFF from 2014 until 2018.

Program	2014–15 (\$M)	2016 (\$M)	2017 (\$M)	2018 (\$M)
NHMRC Research Grants	855.8	834.4	832.3	842.9

Australian Research Council (ARC) grant funding, received from MRFF.

Program	2014–15 (\$M)	2016 (\$M)	2017 (\$M)	2018 (\$M)
ARC Discovery	549.9	488.8	515.2	517.5
ARC Linkage	325.8	262.4	268.4	274.8

6. TAXATION & REIMBURSEMENT

The [R&D Tax Incentive](#) (R&DTI) provides a tax offset for some of a company's cost of doing eligible research and development activities by reducing a company's income tax liability. The R&DTI offers increased access also for international companies.

Tax offsets of 43.5% or 38.5% are available for costs incurred on eligible activities depending on a company's annual aggregated turnover.

The R&DTI has been one of the most significant policies for the Australian health technology ecosystem, offering eligible companies accelerated growth and supporting the commercialisation of medical research. It helps to advance the industry and attract clinical trials, which benefits Australian patients and the domestic healthcare system as well as generating clear economic activity in science-based jobs. It provides additionality by retaining R&D activity in Australia that may otherwise have migrated to other countries with competitive tax regimes, and by attracting R&D activity into Australia from other countries. It also enables clinical trials to be fast tracked.

Industry firms require access to funding for R&D from private and public entities to commercialize their activities. Any cuts to R&D funding sources may threaten the industry. Concerns relating to the long-term future of the \$3 billion R&D tax incentive remain, following proposed measures in the 2018-19 Budget to cap cash refunds for research activities at \$4 million as part of a series of measures designed to save the government \$2.4 billion over 2018-19 to 2020-21. However, private research and development expenditure is expected to increase over 2018-19.

The proposed R&D changes include refocusing the R&DTI on larger companies to provide greater assistance for those that invest a higher proportion of their spending on R&D, while also placing a \$4 million annual cap on companies with annual revenue of less than \$20 million. As the industry depends on a stable and supportive operating environment, any ongoing R&D limitations will likely constrain the industry's performance.

7. BIOTECHNOLOGY

7.1 DEFINITION

The common definition biotechnology might include any commercial exploitation of biological processes. However, in this market research biotechnology refers to research and development of the newer aspects of biology such as genetic engineering. The best-known products of biotechnology are new drugs, vaccines, genetically engineered crops or animals.

7.2 MARKET OVERVIEW



The Biotechnology industry generated revenue of \$7.7 billion in 2018-19, with an increase of 2.4% over the current year. New funding sources, including the new \$500 million Biomedical Translation Fund, have also driven industry growth. The industry is likely to benefit from measures in the Federal Budget designed to boost Australia's competitive advantage in clinical trials.

However, ongoing uncertainty due to changing government policies has dampened the industry's performance over the past five years, particularly regarding changes to the R&D tax incentive. Proposed changes outlined in the 2018-19 Federal Budget include the \$4 million cap on annual cash refunds for research activities, new intensity tests and tighter compliance and enforcement measures. Widespread concerns exist in the industry that such measures would curb industry research and force companies to move their operations offshore.

A larger proportion of industry firms are expected to generate sales revenue and shift towards profitability over the next five years. An ageing population will likely drive demand for new, targeted biotech products that focus on unmet needs. The need for sustainable and environmentally friendly bioenergy is projected to encourage advances in industrial and environmental biotechnology. Industry revenue is forecast to grow at an annualised 3.2% over the five years through 2023-24, to \$9 billion.



7.3 COMPANIES

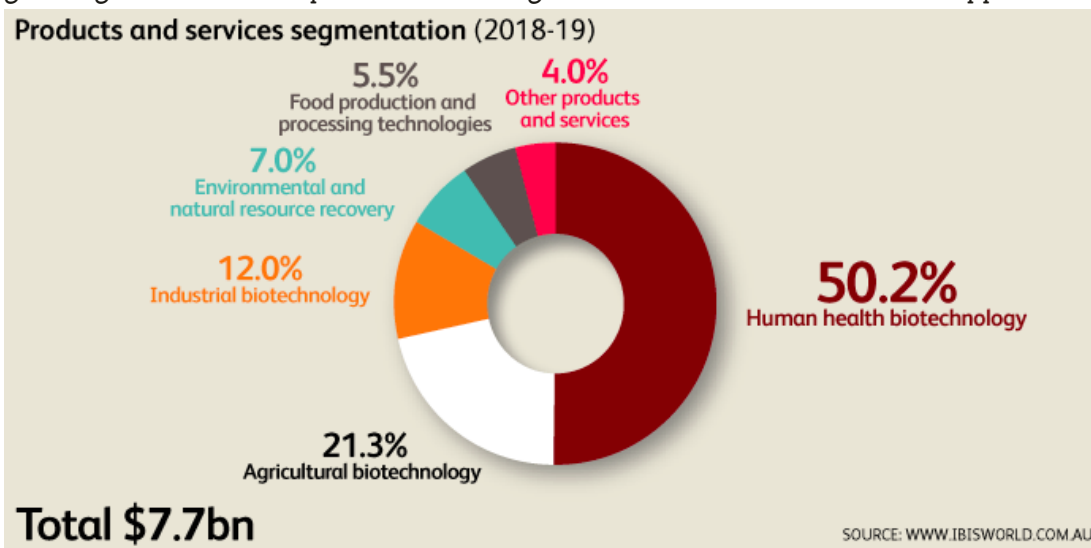
Most publicly listed Australian biotechnology companies are biomedical, and key players include CSL, Mesoblast, Acrux and Bionomics.

CSL Limited is Australia’s largest biotechnology company with a market capitalisation in excess of \$50 billion. The company develops, markets and manufactures pharmaceutical products of biological origin for healthcare industries. CSL is a global specialty biopharmaceutical company with 22,000 employees, eight major manufacturing facilities and operations in Australia, the Asia-Pacific, the United States and Europe. CSL is one of Australia’s largest investors in biopharmaceutical research, and the company was expected to spend approximately \$900 million on research and development across its global operations in 2018-19.

7.4 AREAS IN BIOTECH

The Australian biotechnology industry mainly focuses on human health, and the healthcare sector’s reliance on biotechnology is forecast to increase over the next five years. Key human therapeutics biotechnology categories are likely to include biologics and biosimilars, personalised medicine and genomics. Issues regarding sustainability are projected to become more prominent over the period, causing the industry to focus more on agriculture, climate change and water scarcity.

Most biotechnology companies are small- to medium-size enterprises that focus on a small number of product lines. Nearly all of these companies seek to develop products, although only a few operate in the marketplace and sell these products to consumers. Many biotech companies license their products to other companies that have a market presence, including larger multinational players. Most industry companies research and develop new therapeutic or diagnostic products that target human diseases, although a growing number of companies focus on agricultural and industrial biotech applications.



8. MEDICAL DEVICES

8.1 DEFINITION

A medical device is any device intended to be used for medical purpose. Which implicates that the difference between a medical device and an everyday device is its intended use since medical devices benefit patients by helping health care providers diagnose and treat patients, improving their quality of life.

https://en.wikipedia.org/wiki/Medical_device

https://www.who.int/medical_devices/full_definition/en/

8.2 MARKET OVERVIEW

Australia represents about 2% of the global medical device market, with a significant demand for sophisticated medical equipment and a positive tendency to adopt new technology.

However, the Australia medical device market is one of the slowest-growing markets in the South Pacific region in coming years. The market was valued at US \$4 billion in 2016, down from US\$5 billion in 2014. Market recovery will be slow through 2019 due to Australia's depreciating currency. However, Australia's aging population, Federal Budget initiatives, and willingness to adopt new technologies should stabilize the market despite its modest growth. The domestic manufacturing industry is controlled by subsidiaries of large, global corporations.

Approximately 80% of domestic demand for medical devices and diagnostics is met by imports, while nearly all medical technology products manufactured in Australia are exported. The three major suppliers of medical imports are the United States, the European Union and China (over half of all imports originate from the United States and Germany).

8.3 OPPORTUNITIES

The demand for medical products and healthcare services is expected to grow for all age groups with continuing advances in medical technology, the increasing burden of chronic disease, the aging population, rising incomes and changing consumer expectations. Australians have one of the longest life expectancies in the world (sixth amongst the OECD countries) and demand will continue to increase as Australia's ageing population progressively relies on the health system for care. BMI Research forecasts that the orthopedic and prosthetic market will be the fastest growing sector within the Australian medical device market over the next five years.

There is steady trend in the demand for medical devices intended to treat and manage age-related diseases. In addition, there is growing demand for devices that manage disability and chronic pain and improve recovery times. From a regulatory standpoint, the Australian market is very accessible for devices that already carry CE Marking.

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8.4 CHALLENGES

Despite Australia's sophisticated healthcare system, the medical device market is experiencing slow growth. Medical device companies exporting to Australia will face fierce competition from manufacturers from the US, the UK, and Japan that already have a strong hold on the market. Also, the relatively weak Australian dollar will make it difficult for some companies to remain profitable while meeting the price expectations of Australian buyers.



9. DIGITAL HEALTH

Australia is transitioning towards greater integration of digital technology across the health system and is committed to making effective use of digital technologies and services to improve health. Australia’s expansive geography creates challenges for the cohesion of health and social care provision. To address this, mHealth (mobile health) and telehealth systems are becoming more pervasive, delivering benefits for health-care providers and patients alike.

9.1 DEFINITION

According to the Australian Digital Health Agency, digital health is about electronically connecting up the points of care so that health information can be shared securely. Digital health offers a range of products designed to help deliver safer, quality healthcare using the [My Health Record system](#). The My Health Record system currently provides access to the following types of healthcare documentation:

- Shared Health Summary – a clinically reviewed summary prepared by an individual’s key healthcare provider;
- Event Summary – to capture key information about a key healthcare event relevant to ongoing care;
- Discharge Summary – to support the transfer of a patient from a hospital back to the care of their nominated primary healthcare provider;
- Specialist Letter – to capture key information about specialist visits;
- eReferral – currently from GPs to specialists;
- Prescription and Dispense Records.”

9.2 MY HEALTH RECORD

The Australian Digital Health Agency was established in 2016 by the governments of Australia to lead the development of the National Digital Health Strategy and its implementation. The Strategy builds on Australia’s existing leadership in digital healthcare. The Australian Government announced that every Australian will automatically have a My Health Record which they control – unless they choose not to have one – because of evidence that such a service can improve clinical outcomes.

Australia has made steady inroads in implementing digital health solutions. My Health Record has continued to grow in its capability, usability and integration with clinical information systems across the health sector and now more than 25% of Australian population have a record. Apparently in 2018 Australia had the highest participation rate in a national health record system in the world.

Consumers are already accessing their health information from My Health Record through mobile apps. A number of app developers are providing innovative mobile digital health solutions that address the

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Biotechnology¹, digital health software² and medical devices³ are regulated by the TGA. The Therapeutics Goods Administration regulates these industries and provides an overview of the classification of these products in order to correctly determine the applied regulation.

Australia’s regulatory framework is based on IMDRF guidelines which means that EU and Australian requirements for medical devices are similar. The majority of devices in Australia are supplied under EC certification and European exporters need to appoint an Australian representative/sponsor to obtain regulatory approval from the TGA.

The information in this publication is provided for background information that should enable you to get a picture of the subject treated in this document. It is collected with the greatest care based on all data and documentation available at the moment of publication. Thus this publication was never intended to be the perfect and correct answer to your specific situation. Consequently it can never be considered a legal, financial or other specialized advice. Flanders Investment & Trade (FIT) accepts no liability for any errors, omissions or incompleteness, and no warranty is given or responsibility accepted as to the standing of any individual, firm, company or other organization mentioned.

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¹ TGA regulation of biotechnology: <https://www.tga.gov.au/biologicals-0>

² TGA regulation of digital health: <https://www.tga.gov.au/regulation-software-medical-device>

³ TGA regulation of medical devices: <https://www.tga.gov.au/medical-devices-regulation-basics>

